PRIMATE RESEARCH CENTER GRANT **Federal Award Date:** 04/30/2015
Department of Health and Human Services
National Institutes of Health
OFFICE OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH

Grant Number: 5P51OD011133-17
FAIN: P51OD011133

Principal Investigator(s):
ROBERT W GRACY, PHD

Project Title: The Southwest National Primate Research Center

WILLIAM H CASKEY
DIRECTOR, OFC OF SPONSORED PROGRAMS
TEXAS BIOMEDICAL RESEARCH INSTITUTE
7620 NW LOOP 410
SAN ANTONIO, TX 782275301

Award e-mailed to: NIH-NGA@TXBIOMED.ORG

Period Of Performance:
Budget Period: 05/01/2015 – 04/30/2016
Project Period: 06/06/1999 – 04/30/2016

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $7,367,413 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to TEXAS BIOMEDICAL RESEARCH INSTITUTE in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Office Of The Director, National Institutes Of Health of the National Institutes of Health under Award Number P51OD011133. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Gavin Wilkom
Grants Management Officer
OFFICE OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH

Additional information follows

SECTION I – AWARD DATA – 5P51OD011133-17

Award Calculation (U.S. Dollars)

Salaries and Wages	$2,269,321
Fringe Benefits	$642,222
Personnel Costs (Subtotal)	$2,911,543
Travel Costs	$24,772
Other Costs	$1,200,689
Consortium/Contractual Cost	$14,555
Federal Direct Costs	$4,151,559
Federal F&A Costs	$3,215,854
Approved Budget	$7,367,413
Total Amount of Federal Funds Obligated (Federal Share)	$7,367,413
TOTAL FEDERAL AWARD AMOUNT	$7,367,413
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$7,367,413

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
17	$7,367,413	$7,367,413

Fiscal Information:

CFDA Name:	Research Infrastructure Programs
CFDA Number:	93.351
EIN:	1741109630A1
Document Number:	POD011133D
PMS Account Type:	P (Subaccount)
Fiscal Year:	2015

IC	CAN	2015
OD	8014499	$7,367,413

NIH Administrative Data:
PCC: CMP01 / **OC**: 414E / **Released**: eRA Commons User Name 04/29/2015
Award Processed: 03/23/2015 01:36:12 PM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5P51OD011133-17

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – TERMS AND CONDITIONS – 5P51OD011133-17

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the Central Contractor Registration. Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) P51OD011133. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

This award is not subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the eRA Commons (Commons) within 120 days of the expiration date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) quarterly cash transaction data. A final quarterly federal cash transaction report is not required for awards in PMS B subaccounts (i.e., awards to foreign entities and to Federal agencies). NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures or quarterly federal cash transaction reporting. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level. If the grantee submits a final expenditure FFR but does not reconcile any discrepancies between expenditures reported on the final expenditure FFR and the last cash report to PMS, NIH will close the award at the lower amount. This could be considered a debt or result in disallowed costs.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, R13, R25, S10.

Unless an application for competitive renewal is submitted, a final progress report must also be submitted within 120 days of the expiration date. Instructions for preparing a Final Progress Report are at: http://grants.nih.gov/grants/funding/finalprogressreport.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the final progress report. Institute/Centers may accept the progress report contained in competitive renewal (type 2) in lieu of a separate final progress report. Contact the awarding IC for IC-specific policy regarding acceptance of a progress report contained in a competitive renewal application in lieu of a separate final progress report.

NIH strongly encourages electronic submission of the final progress report and the final invention statement through the Closeout feature in the Commons, but will accept an email or hard copy submission as indicated below.

Email: The final progress report and final invention statement may be e-mailed as PDF attachments to: NIHCloseoutCenter@mail.nih.gov.

Hard copy: Paper submissions of the final progress report and the final invention statement may be faxed to the NIH Division of Central Grants Processing, Grants Closeout Center, at 301-480-2304, or mailed to:

National Institutes of Health
Office of Extramural Research
Division of Central Grants Processing
Grants Closeout Center
6705 Rockledge Drive
Suite 5016, MSC 7986
Bethesda, MD 20892-7986 (for regular or U.S. Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express deliveries only)

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final Progress Report is not required. However, a final expenditure FFR is required and should be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Treatment of Program Income:
Additional Costs

SECTION IV – OD Special Terms and Conditions – 5P51OD011133-17

SUBJECT FOA
This award is subject to the conditions set forth in PA/RFA OD-PAR11-136, "Title," which are hereby incorporated by reference as special terms and conditions of this award. Copies of this Funding Opportunity Announcement can be found at the following link: http://grants.nih.gov/grants/guide/pa-files/PAR-11-136.html.

RESTRICTION ON CHIMPANZEE RESEARCH
All NIH-sponsored biomedical and behavioral and social science research involving NIH-owned and -supported chimpanzees must be in accordance with the policies and procedures described in NOT-OD-14-024 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-024.html) and NOT-OD-15-097 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-097.html). Any questions in regard to the NIH policies for the use of chimpanzees in research can be sent to your NIH ORIP Program Director and/or DPCPSI@nih.gov<mailto:DPCPSI@nih.gov>.

ORIP FUNDING PLAN FOR FY2015
This non-competing award reflects the NIH Fiscal Policy for Grant Awards for FY2015 (see NIH Guide Notice NOT-OD-15-050) and the implementation of the ORIP FY2015 grants funding policy: http://dpcpsi.nih.gov/orip/rf/fyg_fp2015

CONSORTIUM

This award includes funds awarded for consortium activity with the The University of Texas Health Science Center at San Antonio. Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at:
http://grants.nih.gov/grants/policy/nihgps_2013/nihgps_ch15.htm.

BREEDING MORATORIUM
The National Academy of Sciences Report on "Chimpanzees in Research: Strategies for their Ethical Care, Management, and Use" (July, 1997) recommended a 5 year moratorium for chimpanzee breeding activities. This is consistent with the NCRR recommendation made in 1995 for the CBRP colonies, and the moratorium has been extended periodically by the ChiMP working group. Currently the moratorium is in effect and will be periodically recalculated. Therefore, as a condition of this award, a moratorium on breeding activities within the NIH supported CBRP colonies will remain in effect for the duration of the Project Period, unless notified in writing by OD staff.

Any additional animals, above the current census, will be the sole responsibility of the grantee institution or owner(s) of the animals, unless notified in writing by the NIH/Office of the Director staff.

SALARY CAP
None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the current salary cap. Therefore, this award and/or future years are adjusted accordingly, if applicable.

Current salary cap levels can be found at the following URL:
http://grants.nih.gov/grants/policy/salcap_summary.htm.

KEY PERSONNEL
In addition to the PI, the following individuals are named as key personnel (individuals who have effort that ORIP staff is tracking):

Excluded by Requester

Written prior approval is required if any of the individual(s) named above withdraws from the project entirely, is absent from the project during any continuous period of 3 months or more, or reduces time devoted to the project by 25 percent or more from the level that was approved at the time of award.

DIRECT CHARGES OF F&A-TYPE COSTS
Funds requested for general office, administrative office supplies, computers and computer supplies. Therefore, the allowability of direct cost charges to this project for this/these purposes is predicated on the awardees compliance with the provisions of applicable OMB Circulars. Regarding allowability of selected items of cost, attention is called to the NIH Grants Policy Statement (2013). The Selected Items of Cost section is found at
http://grants.nih.gov/grants/policy/nihgps_2013/nihgps_ch7.htm#selected_cost_items

PRIOR APPROVAL REQUEST
Any prior approval request (e.g., changes to key personnel as noted on the award, changes in human and animal subjects requiring prior approval, carryover requests) must be submitted to the assigned Grants Management Specialist and Programmatic Official. Please refer to the NIH Grants Policy Statement for the activities and/or expenditures that require NIH approval at
http://grants.nih.gov/grants/policy/nihgps/nihgps.pdfCOMMUNICATIONS/PRESS RELEASE
If the grantee plans to issue a press release concerning the outcome of ORIP grant-supported research, it should notify Ms. Patricia Newman, ORIP Communications at 301-435-0744, in advance to allow for coordination.

The ORIP WWW home page is at http://dpcpsi.nih.gov/orip/.

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Jean Richelsen
Email: richelsj@mail.nih.gov **Phone**: 301-594-9446 **Fax**: 301-480-3777

Program Official: John D. Harding
Email: hardingj@mail.nih.gov **Phone**: 301-435-0776 **Fax**: 30- 480-3819

SPREADSHEET SUMMARY
GRANT NUMBER: 5P51OD011133-17

INSTITUTION: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Budget	Year 17
Salaries and Wages	$2,269,321
Fringe Benefits	$642,222
Personnel Costs (Subtotal)	$2,911,543
Travel Costs	$24,772
Other Costs	$1,200,689
Consortium/Contractual Cost	$14,555
TOTAL FEDERAL DC	$4,151,559
TOTAL FEDERAL F&A	$3,215,854
TOTAL COST	$7,367,413

Facilities and Administrative Costs	Year 17
F&A Cost Rate 1	78.6%
F&A Cost Base 1	$4,091,417
F&A Costs 1	$3,215,854

PRIMATE RESEARCH CENTER GRANT **Federal Award Date:** 06/18/2015
Department of Health and Human Services
National Institutes of Health
OFFICE OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH

Grant Number: 5P51OD011133-17 REVISED
FAIN: P51OD011133

Principal Investigator(s):
ROBERT W GRACY, PHD

Project Title: The Southwest National Primate Research Center

WILLIAM H CASKEY
DIRECTOR, OFC OF SPONSORED PROGRAMS
TEXAS BIOMEDICAL RESEARCH INSTITUTE
7620 NW LOOP 410
SAN ANTONIO, TX 782275301

Award e-mailed to: nih-nga@txbiomed.org

Period Of Performance:
Budget Period: 05/01/2015 – 04/30/2016
Project Period: 06/06/1999 – 04/30/2016

Dear Business Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to TEXAS BIOMEDICAL RESEARCH INSTITUTE in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Office Of The Director, National Institutes Of Health of the National Institutes of Health under Award Number P51OD011133. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Gavin Wilkom
Grants Management Officer
OFFICE OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH

Additional information follows

SECTION I – AWARD DATA – 5P51OD011133-17 REVISED

Award Calculation (U.S. Dollars)

Salaries and Wages	$2,269,321
Fringe Benefits	$642,222
Personnel Costs (Subtotal)	$2,911,543
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Consortium/Contractual Cost	$14,555
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Approved Budget	$7,367,413
Total Amount of Federal Funds Obligated (Federal Share)	$7,367,413
TOTAL FEDERAL AWARD AMOUNT	$7,367,413
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
17	$7,367,413	$7,367,413

Fiscal Information:

CFDA Name:	Research Infrastructure Programs
CFDA Number:	93.351
EIN:	1741109630A1
Document Number:	POD011133D
PMS Account Type:	P (Subaccount)
Fiscal Year:	2015

IC	CAN	2015
OD	8014499	$5,972,931
OD	8017734	$1,394,482

NIH Administrative Data:
PCC: CMP01 / **OC**: 414E / **Released**: eRA Commons User Name 06/17/2015
Award Processed: 03/23/2015 01:36:12 PM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5P51OD011133-17 REVISED

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SECTION III – TERMS AND CONDITIONS – 5P51OD011133-17 REVISED

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a. The grant program legislation and program regulation cited in this Notice of Award.
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c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
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National Institutes of Health
Office of Extramural Research
Division of Central Grants Processing
Grants Closeout Center
6705 Rockledge Drive
Suite 5016, MSC 7986
Bethesda, MD 20892-7986 (for regular or U.S. Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express deliveries only)

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This award is funded by the following list of institutes. Any papers published under the auspices of this award must cite the funding support of all institutes.

Office Of The Director, National Institutes Of Health (OD)

Treatment of Program Income:
Additional Costs

SECTION IV – OD Special Terms and Conditions – 5P51OD011133-17 REVISED

REVISION #1 : This award is revised to address the following issue:

The purpose of this revision is to amend the previous noted Common Accounting Number (CAN) for internal accounting purposes.

All previous terms and conditions remain in effect.

SUBJECT FOA
This award is subject to the conditions set forth in PA/RFA OD-PAR11-136, "Title," which are hereby incorporated by reference as special terms and conditions of this award. Copies of this

Funding Opportunity Announcement can be found at the following link: http://grants.nih.gov/grants/guide/pa-files/PAR-11-136.html.

RESTRICTION ON CHIMPANZEE RESEARCH
All NIH-sponsored biomedical and behavioral and social science research involving NIH-owned and -supported chimpanzees must be in accordance with the policies and procedures described in NOT-OD-14-024 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-024.html) and NOT-OD-15-097 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-097.html). Any questions in regard to the NIH policies for the use of chimpanzees in research can be sent to your NIH ORIP Program Director and/or DPCPSI@nih.gov<mailto:DPCPSI@nih.gov>.

ORIP FUNDING PLAN FOR FY2015
This non-competing award reflects the NIH Fiscal Policy for Grant Awards for FY2015 (see NIH Guide Notice NOT-OD-15-050) and the implementation of the ORIP FY2015 grants funding policy: http://dpcpsi.nih.gov/orip/rf/fyg_fp2015

CONSORTIUM
This award includes funds awarded for consortium activity with the The University of Texas Health Science Center at San Antonio. Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at: http://grants.nih.gov/grants/policy/nihgps_2013/nihgps_ch15.htm.

BREEDING MORATORIUM
The National Academy of Sciences Report on "Chimpanzees in Research: Strategies for their Ethical Care, Management, and Use" (July, 1997) recommended a 5 year moratorium for chimpanzee breeding activities. This is consistent with the NCRR recommendation made in 1995 for the CBRP colonies, and the moratorium has been extended periodically by the ChiMP working group. Currently the moratorium is in effect and will be periodically recalculated. Therefore, as a condition of this award, a moratorium on breeding activities within the NIH supported CBRP colonies will remain in effect for the duration of the Project Period, unless notified in writing by OD staff.

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SALARY CAP
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KEY PERSONNEL
In addition to the PI, the following individuals are named as key personnel (individuals who have effort that ORIP staff is tracking):

Excluded by Requester

Written prior approval is required if any of the individual(s) named above withdraws from the project entirely, is absent from the project during any continuous period of 3 months or more, or reduces time devoted to the project by 25 percent or more from the level that was approved at the time of award.

DIRECT CHARGES OF F&A-TYPE COSTS
Funds requested for general office, administrative office supplies, computers and computer supplies. Therefore, the allowability of direct cost charges to this project for this/these purposes is predicated on the awardees compliance with the provisions of applicable OMB Circulars. Regarding allowability of selected items of cost, attention is called to the NIH Grants Policy Statement (2013). The Selected Items of Cost section is found at http://grants.nih.gov/grants/policy/nihgps_2013/nihgps_ch7.htm#selected_cost_items

PRIOR APPROVAL REQUEST
Any prior approval request (e.g., changes to key personnel as noted on the award, changes in human and animal subjects requiring prior approval, carryover requests) must be submitted to the assigned Grants Management Specialist and Programmatic Official. Please refer to the NIH Grants Policy Statement for the activities and/or expenditures that require NIH approval at **http://grants.nih.gov/grants/policy/nihgps/nihgps.pdfCOMMUNICATIONS/PRESS RELEASE**
If the grantee plans to issue a press release concerning the outcome of ORIP grant-supported research, it should notify Ms. Patricia Newman, ORIP Communications at 301-435-0744, in advance to allow for coordination.

The ORIP WWW home page is at http://dpcpsi.nih.gov/orip/.

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Jean Richelsen
Email: richelsj@mail.nih.gov **Phone**: 301-594-9446 **Fax**: 301-480-3777

Program Official: John D. Harding
Email: hardingj@mail.nih.gov **Phone**: 301-435-0776 **Fax**: 30- 480-3819

SPREADSHEET SUMMARY
GRANT NUMBER: 5P51OD011133-17 REVISED

INSTITUTION: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Budget	Year 17
Salaries and Wages	$2,269,321
Fringe Benefits	$642,222
Personnel Costs (Subtotal)	$2,911,543
Travel Costs	$24,772
Other Costs	$1,200,689
Consortium/Contractual Cost	$14,555
TOTAL FEDERAL DC	$4,151,559
TOTAL FEDERAL F&A	$3,215,854
TOTAL COST	$7,367,413

Facilities and Administrative Costs	Year 17
F&A Cost Rate 1	78.6%
F&A Cost Base 1	$4,091,417
F&A Costs 1	$3,215,854

A. OVERALL COVER PAGE

Project Title: The Southwest National Primate Research Center	
Grant Number: 5P51OD011133-17	**Project/Grant Period:** 06/06/1999 - 04/30/2016
Reporting Period: 05/01/2014 - 04/30/2015	**Requested Budget Period:** 05/01/2015 - 04/30/2016
Report Term Frequency: Annual	**Date Submitted:** 02/27/2015
Program Director/Principal Investigator Information: ROBERT W GRACY , PHD BS **Phone number:** (817) 735-5400 **Email:** rgracy@txbiomed.org	**Recipient Organization:** TEXAS BIOMEDICAL RESEARCH INSTITUTE TEXAS BIOMEDICAL RESEARCH INSTITUTE BOX 760549 7620 NW Loop 410 SAN ANTONIO, TX 782450549 **DUNS:** 007936834 **EIN:** 1741109630A1 **RECIPIENT ID:**
Change of Contact PD/PI: N/A	
Administrative Official: ANA M BIEDIGER 7620 NW Loop 410 San Antonio, TX 782275301 **Phone number:** 210-258-9507 **Email:** abiediger@txbiomed.org	**Signing Official:** WILLIAM H CASKEY 7620 NW Loop 410 San Antonio, TX 782275301 **Phone number:** (210)258-9544 **Email:** whcaskey@txbiomed.org
Human Subjects: No	**Vertebrate Animals:** Yes
hESC: No	**Inventions/Patents:** No

B. OVERALL ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

The mission of the Southwest National Primate Research Center (SNPRC) is to improve the health of our global community through innovative biomedical research with nonhuman primates. Consistent with this mission, the SNPRC is committed to translational research. The administration, primate resources, veterinary resources, and research infrastructures supported by the base grant enable the SNPRC to be responsive to national biomedical research needs and to accommodate investigators who want to access Center resources for collaborative research purposes. The unique strengths of the SNPRC include a wide variety of primate species to meet diverse research needs. The baboon colony represents the largest and oldest pedigreed nonhuman primate population available for research. Two colonies of Indian-origin rhesus macaques primarily support HIV research. Two genetically distinct colonies of marmosets are utilized for infectious disease, metabolic disease, aging and regenerative medicine research. The research opportunities at SNPRC and its host institute Texas Biomed include high containment research in primates at ABSL-3 and ABSL-4. SNPRC and Texas Biomed have a long history of research emphasis on genetic factors influencing common chronic diseases, development of vaccines, and therapeutics for infectious disease. More recently programs in regenerative medicine using stem cell biology and aging have been developed.

The SPECIFIC AIMS of the SNPRC as a whole are unchanged from the last competitive renewal and are listed below.
1) To maintain healthy and well-characterized breeding and research colonies of several nonhuman primate species that are required for biomedical research, and to make them available to qualified investigators.
2) To maintain and enhance veterinary and research technical capacities for research with nonhuman primates and to make them available to investigators.
3) To maintain and to enhance the physical and administrative infrastructure of the NPRC so that it can best serve biomedical research.
4) To advance training of staff, students, and visitors in the care and use of nonhuman primates in biomedical research.
5) To contribute to advances in science and translational medicine via publication of results obtained from research with nonhuman primates and educational outreach to the public.

B.1.Have the major goals changed since the initial competing award or previous report?
This is the first report since the last competitive renewal. Unfunded Info
Unfunded Info we created a Genomics Core Laboratory to fulfill the needs for genetic management of the primate colonies, reviewers' comments reviewers' comments The Core is currently funded by host support, but will be part of the next renewal as a Core Laboratory. The activities of this core do not represent the unfunded Unfunded Info

B.1.a Have the major goals changed since the initial competing award or previous report?

Yes

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

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B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

For this reporting period, is there one or more Revision/Supplement associated with this award for which reporting is required?

Yes

Revision/ Supplements #	Revision/ Supplements Title	Specific Aims	Accomplishments
	The Southwest National Primate Research Center- Supplement Establishment of a New England National Primate Research Center-origin Marmoset Colony	The specific aims are: (1) transfer a portion of the New England Primate Research Center (NEPRC) marmoset colony to the SNPRC; (2) maintain the SNPRC and NEPRC populations as separate entities, and design and implement plans to define the genetic diversity in the two populations, to structure a long-term management plan to most effectively maintain the diversity present in the populations; (3) design and implement plans to determine the effects of dietary change upon health in these two populations, ultimately defining the	NEPRC animals were transferred to SNRPC in two shipments in late 2014 and early 2015 (designated as SNPRC Marmoset Colony 2). Colony 1 is the historical SNPRC marmoset colony that was moved to SNPRC in 2001. The Colony 2 is being maintained physically and genetically separate from the SNPRC Colony 1. In preparation for the arrival of these animals SNPRC renovated a building with this supplement to the P51 base grant. The first year of support for Colony 2 was provided from the same supplement. Several studies will

		best diet for continued use; and (4) specifically manage the population to best characterize and ensure the availability of select phenotypes of value for study.	capitalize on the arrival of marmosets with a different genetic background and that have been maintained on a different diet including studies on comparative microbiome.

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

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B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

Outreach
The leader of the Outreach effort for SNPRC is Excluded by Requester A major component of the Outreach effort is coordinated through the Public Relations Office of Texas Biomed. The new director of this office participates with the other NPRCs with regard to the need for and the public image of nonhuman primate research.

The Public Relations Office handles all of the public media needs of SNPRC including local and national press inquiries. Public Relations coordinates a number of publications for Texas Biomed and SNPRC. These publications make biomedical research with nonhuman primates understandable to the general reader and explains how this research can positively impact the lives of people in San Antonio, Texas, the US and worldwide.
Roundup is the official newsletter of SNPRC and is published 3 times per year.
Progress is the newsletter of the host institute Texas Biomed and includes stories on SNPRC.
Annual report.--The Texas Biomed Annual Report highlights for the general public the year's major scientific achievements and other institutional initiatives.
Scientific report.--This publication, produced biannually, describes the work of each scientist at Texas Biomed and the SNPRC. For each faculty member, the report includes a research summary, a list of recent publications, and a relevant science image. This publication is sent to officials of major medical schools, government agencies, scientific organizations, and science libraries. It serves as a way to inform the scientific peer community of the work of Texas Biomed and the SNPRC and is also a recruiting tool.
Other Community Outreach and Education Efforts
Tours.--Approximately 40 times during the year, the SNPRC welcome various community groups for tours of the facilities to inform participants about the extraordinary research resources at the SNPRC and Texas Biomed, and how they are being put to use for the benefit of human health. A tour of the primate facilities, including instruction about the value of nonhuman primates in research, is generally a highlight of these events.
Student tours.--Each spring, Texas Biomed and the SNPRC host a series of 10-15 campus tours for upper-level high school students who are members of honors programs and/or advanced science classes. These tours, which are meant to foster goodwill with area schools and encourage bright young students to consider careers in science.
Community requests.--In addition to these outreach opportunities coordinated in collaboration with Texas Biomed support groups, the organization responds to requests from community groups and schools to arrange for speakers at their events. Multiple requests are accepted each year for representatives from the SNPRC or Texas Biomed to address one local groups.

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

The specific aims remain unchanged for SNPRC as a whole; however as mentioned above under B2, SNPRC has undertaken major new initiatives. The coming year will be dedicated in large part to the characterization of two new primate colonies, marmoset and macaque, obtained from NEPRC. The scope of this effort from a veterinarian and behavioral context is large, but justified by the many new scientific initiatives that involve comparisons of the two colonies, SNPRC vs NEPRC, as well as new initiatives possible due to the increased size of the colonies. The Genomics Core will begin generating total genome sequence from baboon, macaque and marmosets that will bring new opportunities for genetic management and scientific inquiry. The implementation of LabKey will provide new tools for analysis of the colonies, as well as the data generated by scientist using the colonies. The development of an STLV-1 SPF colony for baboons will provide a new resource for scientists that use the baboon model and will provide an opportunity to understand the impact of STLV-1 infection on the baboon health by comparisons of the SPF and non-SPF colonies. SNPRC has begun a new initiative on Regenerative Medicine and Aging. Two new faculty members were recruited that use stem cell technology for therapeutic approaches to disease. The Excluded by Requester nt of as an Associate Director of Research (see Directors Office) provides new strength in this area with an increased collaboration with the Barshop Institute for Longevity and Aging comes to SNRPC from the Barshop Institute a Excluded by Requester to maintain programs in collaboration with the Barhop.

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

A series of significant changes are in progress at SNPRC. This progress report will directly address these changes. In addition, to the scientific changes, SNPRC has undergone major changes in the administration of the center and these are discussed under the progress report for the Directors Office.

Establishment of SNPRC Rhesus Macaque Colony 2. SNPRC received a portion of the NEPRC Indian-origin rhesus macaque colony, designated at SNPRC Rhesus Colony 2. SNPRC Colony 1 is the historical SPF Indian-origin macaque colony that was obtained from the U.S. Air Force in 2000. The new colony will be maintained physically and genetically separate from our existing colony. We renovated a new building for this colony and have plans to renovate a second building for expansion of the colony. The first shipment of animals occurred on Jan 22, 2015. Once all of the new animals are on campus, the census will be approximately 900 animals. Together, these colonies provide an innovative resource for supporting AIDS-related research especially with the addition of managed breeding based on genetic diversity.

Establishment of SNPRC Marmoset Colony 2. SNPRC received a portion of the NEPRC marmoset colony, designated at SNPRC Marmoset Colony 2. Colony 1 is the historical SNPRC marmoset colony that was moved to SNPRC in 2001. The SNPRC Marmoset Colony 2 was derived from a portion of the NEPRC marmoset population. These animals were transferred to SNRPC in two shipments in late 2014 and early 2015. Colony 2 is being maintained physically and genetically separate from the SNPRC Colony 1. In preparation for the arrival of these animals SNPRC renovated a building with a supplement to the P51 base grant. The first year of support for Colony 2 was provided from the same supplement. Several studies will capitalize on the arrival of marmosets with a different genetic background and that have been maintained on a different diet including studies on comparative microbiome.

Formation of External Expert Panel on Infectious Disease Surveillance, EPIDS. SNPRC formed an Expert Panel on Infectious Disease Surveillance (EPIDS) and had a meeting at the SNPRC between March 26 and March 28, 2014. The panel formed to address concerns from the Summary Statement. The panel was provided copies of the Summary Statement, relevant sections of the base grant, and historical data prior to the meeting. Core Scientist gave presentations to the Panel on all aspects of infectious diseases in our colonies. The Panel was comprised of distinguished individuals with extensive expertise in primates and infectious diseases and included Excluded by Requester Excluded by Requester Excluded by Requester The full report of this panel was submitted to DCM and was highly supportive of the program at .

STLV-1 SPF Baboon Colony. The EPIDS recommended establishment of an SPF colony for STLV-1. Although there are no conclusive data to support that STLV-1 infection is a health issue in the baboon, the elimination of this agent has merit. We have aggressively pursued establishment of an STLV-1 negative colony with host institute support until renewal of the base grant. We have screened most of the animals under 5 years of age and a substantial part of the older colony by serology (Luminex). We have segregated 375 STLV-1 negative animals ages 1-5 into social groups. The first breeding group has been established. The screening will be repeated on a regular basis to establish the SPF status. We have determined that most infections occur after the age of four and that infection spreads very slowly through a social group to reach a prevalence of approximately 80% in older adults.

Creation of Genomics Core Laboratory for Genetic Management of Primate Colonies. SNPRC created a Excluded by Requester ic Core Laboratory with as the Director and developed a cost effective plan for genetic ement and characterization of all three breeding species at SNPRC; baboon, rhesus macaque and marmoset. The Core will use high throughput sequencing methods to collect high-resolution genetic information on each animal in each of the colonies. This data will be used to maximize genetic variation in the breeding structure of the colony. The approach of genotyping by sequencing provides a cost effective means to identify variants in regions of the genome that harbor single copy genes. The new genetic data will dramatically increase the value of our NHP resources by providing the means to perform detailed investigations into gene by environment interactions in our NHP models of human disease. More specifically, the genetic data integrated with pedigree data will facilitate the discovery of functional variants in genes and

regulatory regions of genes that influence human health and disease by allowing investigators to select specific animals in a colony based on specific genetic variants.

Implementation of the LabKey EHR. SNPRC has a begun the implementation of LabKey Electronic Health Record (EHR) database and web-based interface. LabKey is currently used by both Oregon NPRC and Wisconsin NPRC as the animal database system and is being considered by other NPRCs. This will allow all NRPCs to interact with regard to animal demographics and data on a common format. It will also increase utility of the animal data by SNPRC and external investigators. We began importation of our demographic data into LabKey in November 2014 and expect to continue implementation of different functions through 2015.

Summer Intern Program. The goal of the Student Intern Program is to provide summer research training opportunities to undergraduate, graduate, and veterinary students during an 8-week program of biomedical research with nonhuman primates. Because of the major expenses associated with maintaining the infrastructure of nonhuman primate research facilities, the NPRCs are among a few institutions in the world that are capable of providing extensive and varied opportunities for students to gain first-hand experience in biomedical research with nonhuman primates and in veterinary care of these important animals. The NRPCs are absolutely crucial for providing training opportunities in the care and use of nonhuman primates to the nation's students in science and veterinary medicine; the vast majority of universities conduct little if any direct research with nonhuman primates.

The Summer Intern Program provides training through a series of general seminars for all interns, in addition to the more specific training interns receive from their assigned mentors. Seminars cover the ethics of nonhuman primate research, regulatory issues affecting primate research and animal research in general, environmental enrichment, and behavioral programs for reducing animal stress among other topics. The interns also attend an overview of current research at Texas Biomed presented by investigators and technical staff during the "Science Teachers' Day at Texas Biomed" symposium.

Training

A comprehensive training program is essential to the success of a laboratory animal facility. Over the last three years, the SNPRC has significantly enhanced its Training Program for technical staff with the goals of developing a comprehensive training program and generating systematic documentation of that training. The updated Training Program includes new methods and forms for documenting training, and defined procedures for selecting and training staff trainers. Skills training is standardized across the Center and there are clear guidelines for employee advancement. The Training Program provides customized student/intern training, general interest training sessions, and training sessions focused on achieving AALAS Certification. SNPRC financially supports those seeking AALAS certification and provides immediate salary incentives for those gaining certification. The Training Program is continually monitored to ensure that it remains relevant to all areas of the SNPRC. The program has been valuable for training employees and for collecting skill proficiency data.

C. OVERALL PRODUCTS

C.1 PUBLICATIONS

Are there publications or manuscripts accepted for publication in a journal or other publication (e.g., book, one-time publication, monograph) during the reporting period resulting directly from this award?

Yes

Publications Reported for this Reporting Period

Public Access Compliance	Citation
Excluded by Requester Process at NIHMS	Histological features of layers and sublayers in cortical visual areas V1 and V2 of chimpanzees, macaque monkeys, and humans. Eye and brain. 2014; 6(Suppl 1):5. NIHMSID: 663003.
Complete	Excluded by Requester Successful cells islet regeneration in streptozotocin-induced diabetic baboons using ultrasound-targeted microbubble gene therapy with cyclinD2/CDK4/GLP1. Cell Cycle. 2014;13(7):1145-51. PubMed PMID: 24553120; PubMed Central PMCID: PMC4013164.
N/A: Not Peer Reviewed	Excluded by Requester Primate short-wavelength cones share molecular markers with rods. Adv Exp Med Biol. 2014;801:49-56. PubMed PMID: 24664680.
Complete	Excluded by Requester Excluded by Requester Body composition and cardiometabolic disease risk factors in captive baboons (Papio hamadryas sp): sexual dimorphism. Am J Phys Anthropol. 2014 Jan;153(1):9-14. PubMed PMID: 24318937; PubMed Central PMCID: PMC4025923.
Excluded by Requester mplete	Stereotypic behavior in nonhuman primates as a model for the human condition. ILAR J. 2014;55(2):284-96. PubMed PMID: 25225307; PubMed Central PMCID: PMC4240438.
Complete	Excluded by Requester Excluded by Requester Analysis of prostate-specific antigen transcripts in chimpanzees, cynomolgus monkeys, baboons, and African green monkeys. PLoS One. 2014;9(4):e94522. PubMed PMID: 24732672; PubMed Central PMCID: PMC3986117.
Complete	Excluded by Requester Developmental origins of pregnancy loss in the adult female common marmoset monkey (Callithrix jacchus). PLoS One. 2014;9(5):e96845. PubMed PMID: 24871614; PubMed Central PMCID: PMC4037172.
Complete Excluded by Requester	Excluded by Requester Early endothelial damage detected by circulating particles in baboons fed a diet high in simple carbohydrates in conjunction with saturated or unsaturated fat. Am J Cardiovasc Dis. 2014;4(3):123-32. PubMed PMID: 25360390; PubMed Central PMCID: PMC4212887.
Complete Excluded by Requester	Excluded by Requester Evolutionary genetics and implications of small size and twinning in callitrichine primates. Proc Natl Acad Sci U S A. 2014 Jan 28;111(4):1467-72. PubMed PMID: 24379383; PubMed Central PMCID: PMC3910650.
Excluded by Requester A: Not Peer Reviewed	Better mousetrap: getting cap labels to stick in liquid nitrogen and vial transfer. ISBER News. 2014 February; 14(1):11.
Complete Excluded by Requester	Excluded by Requester Fetal baboon sex-specific outcomes in adipocyte differentiation at 09 gestation in

	response to moderate maternal nutrient reduction. Int J Obes (Lond). 2014 Feb;38(2):224-30. PubMed PMID: 23748190; PubMed Central PMCID: PMC3883997.
Complete	Excluded by Requester Differential responses of disease-resistant and disease-susceptible primate macrophages and myeloid dendritic cells to simian hemorrhagic fever virus infection. J Virol. 2014 Feb;88(4):2095-106. PubMed PMID: 24335289; PubMed Central PMCID: PMC3911543.
Complete	Excluded by Requester Excluded by Requester Validation of lower body negative pressure as an experimental model of hemorrhage. J Appl Physiol (1985). 2014 Feb 15;116(4):406-15. PubMed PMID: 24356525; PubMed Central PMCID: PMC4073981.
Complete	Excluded by Requester Excluded by Requester Hyperglycemic Challenge and Distribution of Adipose Tissue in Obese Baboons. Int J Diabetol Vasc Disease Res. 2014 Feb 17;2(1)PubMed PMID: 25429366; PubMed Central PMCID: PMC4241571.
Complete	Excluded by Requester A human-specific mutation limits nonhuman primate efficacy in preclinical xenotransplantation studies. Transplantation. 2014 Feb 27;97(4):385-90. PubMed PMID: 24445925; PubMed Central PMCID: PMC4271973.
Complete	Excluded by Requester Excluded by Requester Variable temporoinsular cortex neuroanatomy in primates suggests a bottleneck effect in eastern gorillas. J Comp Neurol. 2014 Mar;522(4):844-60. PubMed PMID: 23939630; PubMed Central PMCID: PMC4195240.
Complete	Excluded by Requester In vivo baseline measurements of hip joint range of motion in suspensory and nonsuspensory anthropoids. Am J Phys Anthropol. 2014 Mar;153(3):417-34. PubMed PMID: 24288178; PubMed Central PMCID: PMC4023689.
Complete	Excluded by Requester Excluded by Requester Down-regulation of placental mTOR, insulin/IGF-I signaling, and nutrient transporters in response to maternal nutrient restriction in the baboon. FASEB J. 2014 Mar;28(3):1294-305. PubMed PMID: 24334703; PubMed Central PMCID: PMC3929672.
Non-Compliant	Excluded by Requester T cell interleukin-15 surface expression in chimpanzees infected with human immunodeficiency virus. Cell Immunol. 2014 Mar-Apr;288(1-2):24-30. PubMed PMID: 24565973; NIHMSID: 567245.
Complete	Excluded by Requester Excluded by Requester Liver mTOR controls IGF-I bioavailability by regulation of protein kinase CK2 and IGFBP-1 phosphorylation in fetal growth restriction. Endocrinology. 2014 Apr;155(4):1327-39. PubMed PMID: 24437487; PubMed Central PMCID: PMC3959599.
Complete	Excluded by Requester Periodontitis in pregnant baboons: systemic inflammation and adaptive immune responses and pregnancy outcomes in a baboon model. J Periodontal Res. 2014 Apr;49(2):226-36. PubMed PMID: 23710643; PubMed Central PMCID: PMC3969847.
Complete	Excluded by Requester Excluded by Requester Impact of a hormone-releasing intrauterine system on the vaginal microbiome: a prospective baboon model. J Med Primatol. 2014 Apr;43(2):89-99. PubMed PMID: 24266633; PubMed Central PMCID: PMC3954920.

Non-Compliant	Excluded by Requester Abnormal behavior and associated risk factors in captive baboons (Papio hamadryas spp). Am J Primatol. 2014 Apr;76(4):355-61. PubMed PMID: 24323406; NIHMSID: 663770.
Complete	Excluded by Requester Transcriptional regulation of proteoglycan 4 by 17-estradiol in immortalized baboon temporomandibular joint disc cells. Eur J Oral Sci. 2014 Apr;122(2):100-8. PubMed PMID: 24621258; PubMed Central PMCID: PMC4323157.
Complete	Excluded by Requester Excluded by Correlation between presence of Trypanosoma cruzi DNA in heart tissue of baboons and cynomolgus monkeys, and lymphocytic myocarditis. Am J Trop Med Hyg. 2014 Apr;90(4):627-33. PubMed PMID: 24567317; PubMed Central PMCID: PMC3973505.
Complete	Excluded by Requester Craniofacial trauma as a clinical marker of seizures in a baboon colony. Comp Med. 2014 Apr;64(2):135-9. PubMed PMID: 24674589; PubMed Central PMCID: PMC3997292.
Complete	Excluded by Requester Excluded by Requester Evolution of a cell culture-derived genotype 1a hepatitis C virus (H77S2) during persistent infection with chronic hepatitis in a chimpanzee. J Virol. 2014 Apr;88(7):3678-94. PubMed PMID: 24429362; PubMed Central PMCID: PMC3993530.
Complete	Excluded by Requester Development of adrenal cortical zonation and expression of key elements of adrenal androgen production in the chimpanzee (Pan troglodytes) from birth to adulthood. Mol Cell Endocrinol. 2014 Apr 25;387(1-2):35-43. PubMed PMID: 24576611; PubMed Central PMCID: PMC4016767.
Non-Compliant	Excluded by Requester Antenatal corticosteroids alter insulin signaling pathways in fetal baboon skeletal muscle. J Endocrinol. 2014 May;221(2):253-60. PubMed PMID: 24756099; NIHMSID: 571928.
Complete	Excluded by Requester Reovirus-associated meningoencephalomyelitis in baboons. Vet Pathol. 2014 May;51(3):641-50. PubMed PMID: 23892376; PubMed Central PMCID: PMC3964136.
Complete	Excluded by Requester Excluded by Hair loss and hypothalamic-pituitary-adrenocortical axis activity in captive rhesus macaques (Macaca mulatta). J Am Assoc Lab Anim Sci. 2014 May;53(3):261-6. PubMed PMID: 24827567; PubMed Central PMCID: PMC4128563.
Complete	Excluded by Requester Excluded by Requester Evolution of the primate trypanolytic factor APOL1. Proc Natl Acad Sci U S A. 2014 May 20;111(20):E2130-9. PubMed PMID: 24808134; PubMed Central PMCID: PMC4034216.
Complete	Excluded by Requester Mortality in captive baboons (Papio spp): a-23-year study. J Med Primatol. 2014 Jun;43(3):169-96. PubMed PMID: 24483852; PubMed Central PMCID: PMC3989440.
Complete	Excluded by Requester Excluded by Requester Epigenetic regulation by chromatin activation mark H3K4me3 in primate progenitor cells within adult neurogenic niche. Sci Rep. 2014 Jun 20;4:5371. PubMed PMID: 24947819; PubMed Central PMCID: PMC4064326.

Non-Compliant	Excluded by Requester Blood cell telomere lengths and shortening rates of chimpanzee and human females. Am J Hum Biol. 2014 Jul-Aug;26(4):452-60. PubMed PMID: 24633909; NIHMSID: 625458.
Non-Compliant	Excluded by Requester Erythrocytes from GGTA1/CMAH knockout pigs: implications for xenotransfusion and testing in non-human primates. Xenotransplantation. 2014 Jul-Aug;21(4):376-84. PubMed PMID: 24986655; NIHMSID: 666186.
Complete	Excluded by Requester Using 2D Correlation Analysis to Enhance Spectral Information Available from Highly Spatially Resolved AFM-IR Spectra. J Mol Struct. 2014 Jul 8;1069:284-289. PubMed PMID: 25024505; PubMed Central PMCID: PMC4093835.
Complete	Excluded by Requester Development of pro-apoptotic peptides as potential therapy for peritoneal endometriosis. Nat Commun. 2014 Jul 22;5:4478. PubMed PMID: 25047118; PubMed Central PMCID: PMC4109024.
PMC Journal - In process	Excluded by Requester Comparative metabolomics in primates reveals the effects of diet and gene regulatory variation on metabolic divergence. Sci Rep. 2014 Jul 28;4:5809. PubMed PMID: 25069065.
Non-Compliant	Excluded by Requester Reduced binding of human antibodies to cells from GGTA1/CMAH KO pigs. Am J Transplant. 2014 Aug;14(8):1895-900. PubMed PMID: 24909344; NIHMSID: 663772.
Complete	Excluded by Requester Characterization of T cells in naive and HIV-infected chimpanzees and their responses to T-cell activators in vitro. J Med Primatol. 2014 Aug;43(4):258-71. PubMed PMID: 24660852; PubMed Central PMCID: PMC4232220.
Complete	Excluded by Requester Impaired development of fetal serotonergic neurons in intrauterine growth restricted baboons. J Med Primatol. 2014 Aug;43(4):284-287. PubMed PMID: 25431504; PubMed Central PMCID: PMC4242092.
Complete	Marmoset Genome Sequencing and Analysis Consortium. The common marmoset genome provides insight into primate biology and evolution. Nat Genet. 2014 Aug;46(8):850-7. PubMed PMID: 25038751; PubMed Central PMCID: PMC4138798.
Complete	Excluded by Requester Developmental profiles of the intrinsic properties and synaptic function of auditory neurons in preterm and term baboon neonates. J Neurosci. 2014 Aug 20;34(34):11399-404. PubMed PMID: 25143619; PubMed Central PMCID: PMC4138346.
Complete	Excluded by Requester Pharmacokinetics of 3 formulations of meloxicam in cynomolgus macaques (Macaca fascicularis). J Am Assoc Lab Anim Sci. 2014 Sep;53(5):502-11. PubMed PMID: 25255073; PubMed Central PMCID: PMC4181692.
Complete	Excluded by Requester Excluded by Requester Why primate models matter. Am J Primatol. 2014 Sep;76(9):801-27. PubMed PMID: 24723482; PubMed Central PMCID: PMC4145602.
Complete	Excluded by Requester Quantitative determination of telavancin in pregnant baboon plasma by solid-phase extraction and LC-ESI-MS. J Pharm Biomed Anal. 2014 Sep;98:107-12. PubMed PMID: 24905291; PubMed Central

	PMCID: PMC4127372.
Complete	Excluded by Requester Excluded by Requester Metabolism and disposition of bupropion in pregnant baboons (Papio cynocephalus). Drug Metab Dispos. 2014 Oct;42(10):1773-9. PubMed PMID: 25097227; PubMed Central PMCID: PMC4164976.
Complete	Excluded by Requester Excluded by Requester A new rhesus macaque assembly and annotation for next-generation sequencing analyses. Biol Direct. 2014 Oct 14;9(1):20. PubMed PMID: 25319552; PubMed Central PMCID: PMC4214606.
Non-Compliant	Excluded by Requester Further evidence for phenotypic signatures of hybridization in descendant baboon populations. J Hum Evol. 2014 Nov;76:54-62. PubMed PMID: 24935168; NIHMSID: 655818.
Complete	Excluded by Requester Excluded by Requester Two novel simian arteriviruses in captive and wild baboons (Papio spp). J Virol. 2014 Nov;88(22):13231-9. PubMed PMID: 25187550; PubMed Central PMCID: PMC4249091.
Complete	Excluded by Requester Studying variations in bone composition at nano-scale resolution: a preliminary report. Calcif Tissue Int. 2014 Nov;95(5):413-8. PubMed PMID: 25155443; PubMed Central PMCID: PMC4192085.
Complete	Excluded by Requester Excluded by Requester Multi-region hemispheric specialization differentiates human from nonhuman primate brain function. Brain Struct Funct. 2014 Nov;219(6):2187-94. PubMed PMID: 23928747; PubMed Central PMCID: PMC4219928.
Non-Compliant	Excluded by Requester Multimodality vaccination against clade C SHIV: partial protection against mucosal challenges with a heterologous tier 2 virus. Vaccine. 2014 Nov 12;32(48):6527-36. PubMed PMID: 25245933; NIHMSID: 628907.
Complete	Excluded by Requester Neutral nuclear variation in Baboons (genus Papio) provides insights into their evolutionary and demographic histories. Am J Phys Anthropol. 2014 Dec;155(4):621-34. PubMed PMID: 25234435; PubMed Central PMCID: PMC4339869.
Excluded by Requester mplete	Kinematics of primate midfoot flexibility. Am J Phys Anthropol. 2014 Dec;155(4):610-20. PubMed PMID: 25234343; PubMed Central PMCID: PMC4337791.
PMC Journal - In process	Excluded by Requester Developmental regulation of key gluconeogenic molecules in nonhuman primates. Physiol Rep. 2014 Dec 1;2(12)PubMed PMID: 25524279.
PMC Journal - In process	Excluded by Requester Excluded by Requester Brucella papionis sp nov, isolated from baboons (Papio spp). Int J Syst Evol Microbiol. 2014 Dec;64(Pt 12):4120-8. PubMed PMID: 25242540.

C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)

NOTHING TO REPORT

C.3 TECHNOLOGIES OR TECHNIQUES

NOTHING TO REPORT

C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES

Have inventions, patent applications and/or licenses resulted from the award during the reporting period?

No

C.5 OTHER PRODUCTS AND RESOURCE SHARING

C.5.a Other products

NOTHING TO REPORT

C.5.b Resource sharing

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The SNPRC has implemented a new Resource Sharing Plan. Requests to use SNPRC resources are submitted through the SNPRC external website using a Veterinary Services (VS) Request form. The VS Request Form has been modified to include a Data Sharing Plan section. The Data Sharing Plan section of the VS request will be completed by all investigators requesting to use SNPRC resources for federally funded research that does not involve select agents. Consistent with NIH guidelines for data sharing plans, the SNPRC will provide investigators with the opportunity to share data after the first publication of major results through the SNPRC databases. The new section of the VS Request is as follows.

DATA SHARING PLAN. If this project will generate data that may be shared with qualified investigators, please include a brief description of the final data that will be shared. Data useful to other investigators may include routine clinical data generated for project animals in addition to research results.

D. OVERALL PARTICIPANTS

D.1 WHAT INDIVIDUALS HAVE WORKED ON THE PROJECT?

Commons ID	S/K	Name	SSN	DOB	Degree(s)	Role	Cal	Aca	Sum	Foreign Org	Component (s)	Country	SS
eRA Commons User Name	Y	GRACY, ROBERT W	SSN	DOB	BS,PHD	PD/PI	EFFORT						NA
	N	Excluded by Requester				Staff scientist (Doctoral level)					Core-7328 (Behavioral Services)		NA
	N					Staff scientist (Doctoral level)					Core-7335 (Immunology Core Laboratory)		NA
	N				PHD	Scientist					Admin Core-7258 (Director's Office)		NA
	N					Core Lead					Core-7332 (Clinical and Anatomic Pathology)		NA
	Y					Veterinarian					Admin Core-7258 (Director's Office)		NA
	N					Core Lead					Core-7329 (Biocontainment)		NA
	N					Core Lead					Core-7342 (Summer Intern Program)		NA
	N					Core Lead					Core-7330 (Biomaterial Services)		NA
	N					Core Lead					Core-7327 (Baboon Colony)		NA
	N					Core Lead					Core-7341 (Research Coordination)		NA
	N					Veterinarian					Core-7331 (Chimpanzee Colony)		NA
	N				PHD	Core Lead					Core-7334 (DNA and Tissue Repository)		NA
	N				PHD	Core Lead					Core-7335 (Immunology Core		NA

										Laboratory)		
eRA Commons User Name	N	Excluded by Requester	SSN	DOB	PHD	Core Lead	EFFORT			Core-7340 (Pilot Research Program)		NA
	N					Associate Veterinarian				Core-7329 (Biocontainment)		NA
	N				DVM,MS	Associate Veterinarian				Core-7332 (Clinical and Anatomic Pathology)		NA
	Y				PHD,BS	Director				Admin Core-7258 (Director's Office)		NA
	Y				PHD,BS	Scientist				Admin Core-7258 (Director's Office)		NA
	N				PHD,BS	Core Lead				Core-7338 (Marmoset Colony)		NA
	N				PHD,MA,BA	Scientist				Admin Core-7258 (Director's Office)		NA

Glossary of acronyms:
S/K - Senior/Key
DOB - Date of Birth
Cal - Person Months (Calendar)
Aca - Person Months (Academic)
Sum - Person Months (Summer)
Foreign Org - Foreign Organization Affiliation
SS - Supplement Support
RE - Reentry Supplement
DI - Diversity Supplement
OT - Other
NA - Not Applicable

D.2 PERSONNEL UPDATES

D.2.a Level of Effort

Will there be, in the next budget period, either (1) a reduction of 25% or more in the level of effort from what was approved by the agency for the PD/PI(s) or other senior/key personnel designated in the Notice of Award, or (2) a reduction in the level of effort below the minimum amount of effort required by the Notice of Award?

No

D.2.b New Senior/Key Personnel

Are there, or will there be, new senior/key personnel?

No

D.2.c Changes in Other Support

Has there been a change in the active other support of senior/key personnel since the last reporting period?

Yes

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D.2.d New Other Significant Contributors

Are there, or will there be, new other significant contributors?

No

D.2.e Multi-PI (MPI) Leadership Plan

Will there be a change in the MPI Leadership Plan for the next budget period?

NA

OTHER SUPPORT

Excluded by Requester

ACTIVE

2 P51 OD011133-16 (Gracy) 05/01/14 - 04/30/16 EFFORT
NIH/OD/ORIP $434,644
Southwest National Primate
Research Center

This is the SNPRC base grant that supports the infrastructure of the Southwest National Primate Research Center. The funds listed represent the total funds from the components that provide support for Excluded by Requester serves as the Director of the SNPRC and Leader of the Infectious Disease and Biodefense Group under the Center Operations Director's Office to coordinate collaborative activity in Virology research. He also provides leadership to the marmoset colony and serves on the Marmoset Advisory Committee.

5 R01 AI095680-03 Excluded by Requester 07/15/11 - 06/30/15 EFFORT
NIH/NIAID $290,072
The Innate Immune Response in the
Marmoset Model of GBV-B Infections: A Surrogate

The major goal is to use locked nucleic acid antisense technology to knock-down key regulators of the innate immune response and evaluate their role in viral clearance and persistence in GBV-B infected marmosets, as a surrogate for hepatitis C virus infections.

5 U42 OD011184-03 Excluded by Requester 09/05/11 - 07/31/16 EFFORT
NIH/OD/ORIP $736,859
NIH-Owned Chimpanzee Research
Resource at the SNPRC

The major goal is to maintain a cohort of chimpanzees as a national resource and to further develop its utility and value for biomedical research.

5 U42OD010442-13 Excluded by Requester 04/01/12 - 02/28/15 EFFORT
NIH/OD/ORIP $436,504
Establishment of a Specific Pathogen-
Free Rhesus Macaque Colony

The major goal of this project is to maintain a colony of Indian-origin rhesus macaque Monkeys and produce specific pathogen free off-spring for use in AIDS-related research.

OVERLAP

There is no scientific or budgetary overlap.

E. OVERALL IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES?

Not Applicable

E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE?

NOTHING TO REPORT

E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER?

Not Applicable

E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)?

NOTHING TO REPORT

F. OVERALL CHANGES

F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE

Not Applicable

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

No significant challenges encountered.

F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS

F.3.a Human Subjects

No Change

F.3.b Vertebrate Animals

No Change

F.3.c Biohazards

No Change

F.3.d Select Agents

No Change

G. OVERALL SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

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G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

G.4.a Does the project involve human subjects?

No

G.4.b Inclusion Enrollment Data

Not Applicable

G.4.c ClinicalTrials.gov

Does this project include one or more applicable clinical trials that must be registered in ClinicalTrials.gov under FDAAA?

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

Are there personnel on this project who are newly involved in the design or conduct of human subjects research?

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Does this project involve vertebrate animals?

Yes

G.8 PROJECT/PERFORMANCE SITES

Organization Name:	DUNS	Congressional District	Address
Primary: Texas Biomedical Research Institute	007936834	TX-020	TEXAS BIOMEDICAL RESEARCH INSTITUTE BOX 760549 SAN ANTONIO TX 782450549
SOUTHWEST FOUNDATION FOR BIOMEDICAL RES	007936834		Texas Biomedical Research Institute 7620 NW Loop 410 SAN ANTONIO TX 782275301

G.9 FOREIGN COMPONENT

No foreign component

G.10 ESTIMATED UNOBLIGATED BALANCE

G.10.a Is it anticipated that an estimated unobligated balance (including prior year carryover) will be greater than 25% of the current year's total approved budget?

No

G.11 PROGRAM INCOME

Is program income anticipated during the next budget period?

Yes

Anticipated Amount	Source(s)
3152536	Per Diem, Use fees, Animal sales, Total services

G.12 F&A COSTS

Not Applicable

G.1. Special Reporting Requirements

A. Colony Statistics Tables

i) Nonhuman primates supported partially, or in whole by the P51 base grant[1].
Census date: January 2015

Genus, Species	Breeding Colony[2]				Animals not in breeding colony[3]				Total Colony Census
	M	F	U[4]	Total	M	F	U[4]	Total	
Callithrix jacchus	94	79	0	173	20	43	0	63	236
Macaca mulatta	175	285	8	468[5]	55	95	0	150	618
Pan troglodytes	0	0	0	0	35	49	0	84	84
Papio spp.	13	205	0	218	606	567	7	1180	1398
Saguinus midas	0	0	0	0	5	3	0	8	8
Totals	282	569	8	859	721	757	7	1485	2344

[1] In a footnote, indicate if this colony is also supported by a SPF U24 or U42 grant
[2] Total number of animals in breeding colony including adult breeding animals and designated juvenile replacements at time of report
[3] Animals on protocol or otherwise not in the breeding colony at the time of report.
[4] Sex undetermined
[5] Macaca mulatta breeding colony (468 animals) also supported by a U42 grant

ii) Nonhuman primates not supported by the P51 base grant[1].
Census date: January 2015

Genus, Species	Breeding Colony[2]				Animals not in breeding colony[3]				Total Colony Census
	M	F	U[4]	Total	M	F	U[4]	Total	
Cebus spp.	6	5	0	11	0	0	0	0	11
Macaca fascicularis	0	0	0	0	66	94	0	160	160
Macaca nemestrina	0	0	0	0	4	0	0	4	4
Pan troglodytes	0	0	0	0	12[5]	8[5]	0	20	20
Totals	6	5	0	11	82	102	0	184	195

[1] In a footnote, indicate if this colony is supported by a SPF U24 or U42 grant
[2] Total number of animals in breeding colony including adult breeding animals and designated juvenile replacements at time of report.
[3] Animals on protocol or otherwise not in the breeding colony at the time of report.
[4] Sex undetermined
[5] Chimpanzees supported by a U42 grant

B. The Biomaterial Services component has distributed:
i) 2,726 tissues, blood and hair samples
ii) 50 requests

C. Number of projects: There are 2 Management, 39 Research, and 13 Pilot projects.

D. The percentage of P51 grant dollars that are AIDS-related is 29.4.

E. Number of investigators: There are 23 Core Scientists, 62 Affiliate Scientists, and 6 Visiting Scientists.

F. Number of Publications: There are 48 peer-reviewed journal articles, no book chapters, and 10 other publications. See section C of the Overall RPPR for a list of publications.

G. Investigators trained at SNPRC: There were 3 post-doctoral students, 9 graduate students, 6 undergraduate students and 7 others trained at the SNPRC.

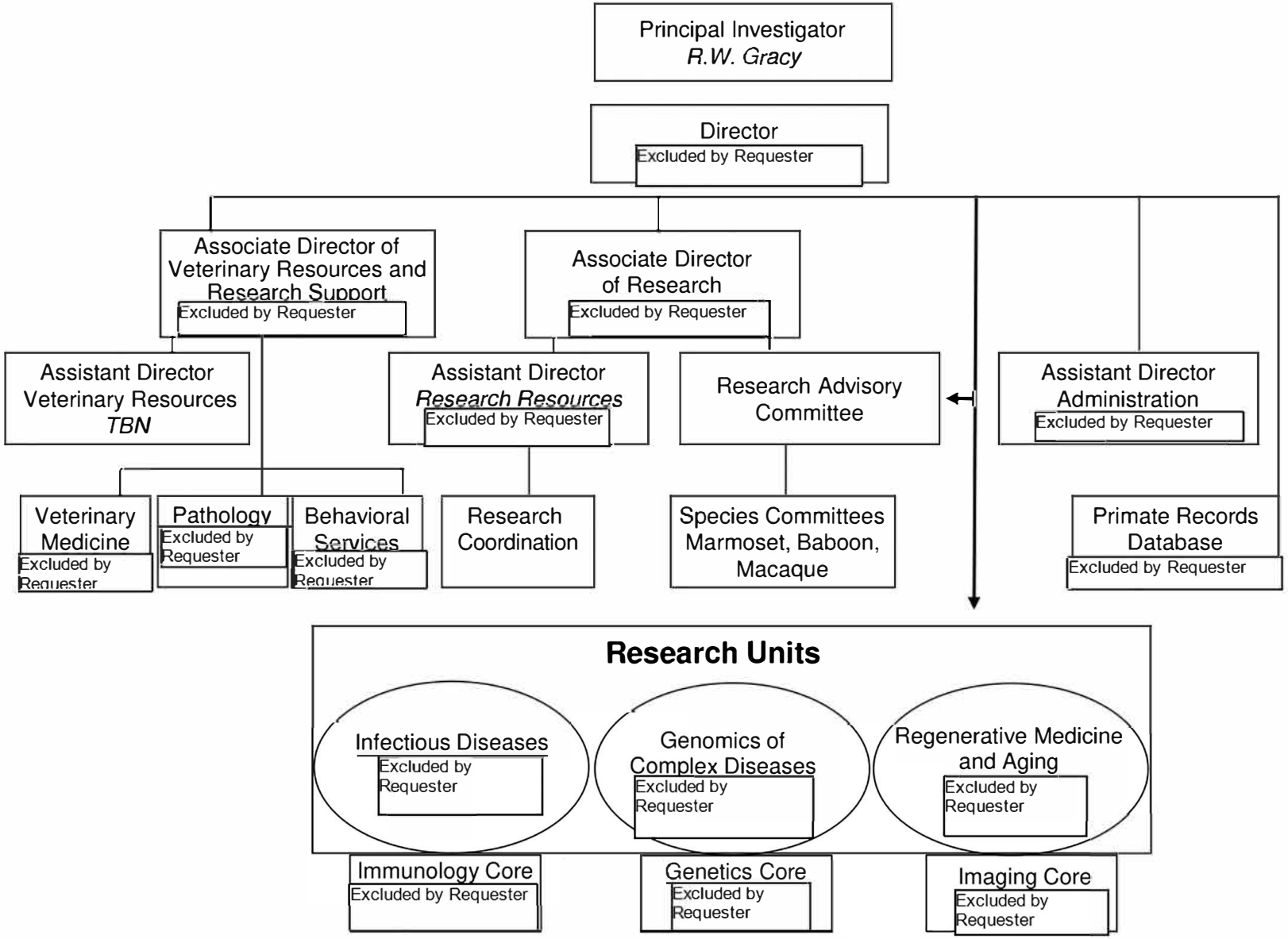
H. Organizational Chart (see next page)

2. Project Descriptions (start on the page following the Organizational Chart)

3. Infrastructure Improvements: Equipment purchased during the report period includes stainless steel cabinets, autoclave, cage racks, Kawasaki Mule, transport chutes, portable ultrasound machine, and aluminum paired housing units. See Core 7336, Improvement and Modernization, for a description of changes to facility structures.

4. Publications (see section C, Products, in Overall)

SOUTHWEST NATIONAL PRIMATE RESEARCH CENTER



Project Title: Pharmacokinetics, Maternal and Fetal Toxicity of Telavancin in Pregnant Baboons

Core Scientists associated with the project Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester PhD; Excluded by Requester MD and Excluded by Requester PhD; University of Texas Medical Branch, Galveston, TX

Project Description and progress: Determine the PK of telavancin in pregnant baboons. Determine the effects of the antibiotic on maternal and neonatal outcomes. Experiments were carried out using two animals during 2014. No adverse effects were identified. Data analysis is ongoing. If a need arises for another animal and other source funding is identified, we will notify the Southwest National Primate Research Center.

Funding Sources: U10HD047891

Percentage of P51 support: 0.29

Project Title: Novel Vaccine for Chagas Disease: Efficacy testing in Baboons

Core Scientists associated with the project: Excluded by Requester

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester PhD, University of Texas at El Paso; Excluded by Requester PhD; University of Texas Rio Grande Valley

Project Description and progress: Chagas disease is the leading cause of heart disease in South and Central America and is an emerging public health threat in Texas. The disease results from long-term infection with *Trypanosoma cruzi*, a parasite that is transmitted by blood sucking insects. In addition to the importance of *T. cruzi* infection as a medical problem in Texas, it is a health threat to the nonhuman primate populations at Texas Biomed's Southwest National Primate Research Center (SNPRC) as well as to dogs (especially hunting dogs) in South Texas.

Chagas disease affects 10-12 million people in Latin America and hundreds of thousands of the people in the U.S.; there are no vaccines, prophylactic drugs, or effective therapeutic drugs for this disease. However, Excluded by Requester the Principal Investigators of this proposal, [redacted] from the University of Texas at El Paso, veloped a vaccine that is highly effective in preventing infection by *T. cruzi* in mice. In order to determine if this vaccine is effective in preventing infection in primates (including humans), we propose to test its efficacy in baboons.

Under previous support from NIH and Private Source and current support from Private Source Private Source Excluded by Requester and his collaborators and staff at the Southwest National Primate Research Center C) have developed baboons and cynomolgus monkeys as validated models for research on Chagas disease; and they have developed a repertoire of sophisticated technologies for conducting work with this model. Recently, Excluded by Requester to seek his help and advice in transferring his vaccine trials from mice to nonhuman primates, and this proposal grew out of their discussions.
We anticipate that the vaccine will be at least partially effective and that the results will pave the way for refining the vaccine so that it can enter into large scale studies in nonhuman primates at the SNPRC to determine if it will protect the animals from becoming infected while living outdoors under natural conditions. It is possible that the vaccine could be committed to human clinical trials within 10 years.

The first year (January–December 2014) of the project was devoted to the IACUC protocol approval and the synthesis of the two vaccines to be tested. The first vaccine contains the trisaccharide Galα1,3Galβ1,4GlcNAc covalently linked to human serum albumin (Galα3LN-HSA). The second vaccine comprises the *T. cruzi* synthetic MASP peptide covalently attached to keyhole limpet hemocyanin (MASPpep) Excluded by Requester. These vaccines will be tested alone and combined in the presence of the adjuvant liposomal monophosphoryl lipid A (L-MPLA). The control group will receive L-MPLA alone. The animals (baboons, n=4 per group) will be vaccinated with four doses of the vaccines at week 0, 6, 12 and 24. Animals will be challenged with an autochthonous isolate of *T. cruzi* metacyclic trypomastigotes at week 40. The endpoint will be in week 60. Protection against *T. cruzi* will be measured by the titers of lytic, protective antibodies and parasitemia (by qRT-PCR). The vaccination experiments were initiated on February 11, 2015 ad will end on April 6, 2016.

Funding Sources: Private Source

Percentage of P51 support: 1.09

Project Title: Acid Maltase Deficiency Gene Therapy in a Non-human Primate

Core Scientist associated with the project: Excluded by Requester PhD

Affiliate or visiting scientist with institutional affiliation: Excluded by Requester PhD, Michigan State University, East Lansing, MI

Project Description and progress: The overall objective is to develop safe and efficacious gene therapy for AMD patients. We are attempting to demonstrate that liver delivery of the gene missing in patients affected by Acid Maltase Deficiency, otherwise known as Pompe disease, can result in treatment of their muscle disease. Efficient delivery of the gene known as acid alpha glucosidase (GAA) into the liver of mice and quails has been previously performed. We proved that efficient delivery of GAA resulted in high level liver secretion of GAA, and the liver secreted GAA could be efficiently taken up by skeletal and cardiac muscle cells throughout the bodies of these species. Additionally, once taken up, GAA can be utilized by skeletal or cardiac muscle cells to reduce abnormal accumulations of lysosomal glycogen (stored sugars that accumulate in the muscles of Acid Maltase Deficiency/Pompe patients. We have proven this concept in both mouse models, and quail models of Pompe disease. This project is to use a baboon-based model as a direct prelude to human clinical trials. To accomplish this we will constructed fully deleted Adenovirus vector expressing the simian version of the acid alpha glucosidase gene (FDAd-sGAA). We have utilized a novel, balloon catheter mediated technique for delivery of fully deleted Adenovirus vectors into the baboon liver, allowing for safer gene delivery, and more effective gene delivery at lower vector doses.

We finished the last baboon using the specified adenovirus based vector expressing the baboon GAA gene via catheter and balloon facilitated introduction into the baboon liver. This project has been completed.

Funding Sources: University of Michigan

Percent P51 dollars: 0.29

Project Title: Baboon Visceral Lipectomy Using Tissue Liquefaction Technology

Core Scientists associated with the project: Excluded by Requester

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester, Private Source, Tustin, CA; and Excluded by Requester, Private Source, Bronx, NY

Project Description and progress: The objective of this study is to evaluate a novel surgical method for the ablation (i.e. reduction and removal) of abdominal fat and improvement of metabolic health. Animals will first undergo a metabolic characterization (body composition by DEXA, glucose sensitivity/insulin resistance status via a euglycemic clamp, and a general lipid profile from a fasting blood sample). Following these baseline assessments the animals will undergo an experimental treatment to liquefy and remove visceral fat. Following the surgery the animals will be allowed to recover and will be maintained in clinical housing for up to 2 months and then will undergo a second round of metabolic characterization prior to euthanization.

We have utilized one animal to date, and while we were able to achieve the desired effect in regards to the removal of abdominal fat, this session did highlight some issues with the instrument that needed to be address. The source of this problem has now been identified (a manufacturing error) and it has been corrected. We plan to continue to evaluate the performance of the equipment along with the efficiacy of the procedure for removing abdominal fat and improving metabolic parameters. Pending Support Pending Support

Funding Sources: Industry

Percentage of P51 support: 0.16

Project Title: Diet-Induced Monocyte Priming in Non-Human Primates

Core Scientists associated with the project: Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester PhD, UTHSCSA, San Antonio, TX

Project Description and progress: Obesity and diabetes increase one's risk of cardiovascular diseases, including atherosclerosis. Atherosclerosis is a disease that causes plaque buildup and hardening of the arteries and increases the risk of cardiovascular complications like high blood pressure and heart attack. The cells that are responsible for the development and progression of arterial plaques are called monocytes, a type of white blood cell. These cells move toward chemoattractants released at the site of injury and can infiltrate the arterial wall, a concept called chemotaxis. High blood sugar (glucose) and high blood lipids (specifically low density lipoproteins or LDL), two characteristics of obesity and diabetes, have shown to increase the sensitivity of blood monocytes to chemotaxis, a term we coined "priming." Many of the pathways elucidated in murine models and THP-1 cells (a human monocyte cell line) have linked high levels of glucose and lipids to increased oxidative stress and to enhanced sensitivity of monocytes to chemoattractants. We have also elucidated mechanisms associated with this metabolic-induced priming that include increased NADPH Oxidase 4 (Nox4) and decreased mitogen-activated protein kinase phosphatase 1 (MKP-1) activity, leading to increased p38 mitogen-activated protein kinase (MAPK) and extracellular signal-regulated kinases (ERK) signaling. Recently, we have also found that primed THP-1 monocytes exhibit changes in histone proteins, including S-glutathionylation and acetylation. Therefore, in this study we will assess how alteration of fat and sugar in the diet of non-human primates (baboons) (i) alters monocyte priming, (ii) alters histone modifications in blood monocytes, and (iii) alters monocyte cellular metabolism (changes the ATP:AMP ratio, an indicator of energy levels, citric acid cycle (TCA) intermediates, and AMPK activity).

We began the study with 2 pilot animals that were injected with matrigel on Monday and had it extracted on Friday. Upon extraction and realized that the cell counts (using Calcein-AM) indicate that there was no difference between the Vehicle-loaded plugs and the MCP-1-loaded plug (I was able to get about 1x106 cells from each plug). I think a major issue was getting the "connective tissue" off of the plug before the Dispase treatment, which I do manually. With this data in mind, it wouldn't seem reasonable to do the Matrigel assay in the large animal study. At the moment the pilot portion of this study has been extended to include 3 additional animals to see if the issues in regards to connective tissues can be resolved. The next set of Matrigel injections are currently scheduled for February 9th. At day 2 and day 3 they will extract the matrigel and determine if suitable results are obtained, this is the determining factor of whether or not the study proceeds.

Funding Sources: SNPRC Funded Pilot Program

Percentage of P51 support: 0.77

Project Title: Immune Response in STLV-1 Infected Baboons

Core Scientists associated with the project: Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation Excluded by Requester PhD, Private Source Coral Gables, FL

Project Description and progress: HTLV-1 was the first human retrovirus found to cause the neoplastic disease, adult T-cell leukemia/lymphoma (ATLL) and the neurodegenerative disorder HTLV-1-associated myelopathy/tropical spastic paraparesis (HAM/TSP). Around 20 million people worldwide are estimated to be infected with HTLV-1 with 3-5% of infected individuals developing ATLL after a prolonged latent pe rio d . Desnite advances in treatment regimens, ATLL remains an incurable and invariably fatal disease Excluded by Requester Excluded by Requester Simian T- lymphotropic virus type 1 (STLV-1) is the nonhuman primate counterpart of human T-cell tropic virus type 1 (HTLV-1). The two viruses are almost identical at the nucleotide sequence level. Baboons are naturally infected with STLV-1; furthermore, their immune system is very similar to the human, which makes them a good model to study HTLV-1 infection Excluded by Requester . CD4+ and CD8+ T cell immune responses against the entire STLV-1 proteome have not been previously analyzed in detail. We are currently studying the entire T cell immune response from STLV-1 infected baboons (*Papio anubis*) against every STLV-1 protein. We will then use this information to guide our vaccine insert design.

Funding Sources: Private Source Miami FL.

Percentage of P51 support: 0.12

Project Title: Efficacy of Intermittent Benznidazole Treatment on *Trypanosoma cruzi* Infection in Primates

Core Scientists associated with the project: Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation: Co-investigator: Excluded by Requester PhD and Excluded by Requester Excluded by Requester PhD, Center for Tropical and Emerging Global Diseases, University of Georgia, Athens, GA; Excluded by Requester PhD, University of Texas Rio Grande Valley

Project Description and Progress: The primary goal of this proposal is to test the efficacy of intermittent treatment protocols to cure *Trypanosoma cruzi* infection in a non-human primate model of infection. A secondary goal is to identify appropriate markers of treatment efficacy that will facilitate the expansion of this pilot project to a full NIH-funded study. We established two protocols for treatment of *T. cruzi* infected baboons that were explored in this pilot study: 1) treatment of 3 baboons with benznidazole at optimal dosage (10mg/kg twice daily) for 60 consecutive days. 2) Treatment of 3 baboons with benznidazole, 10 mg/kg given twice a day every 5th day for total treatment period of 65 days (13 doses of BZ at a 5 day interval). Because drug treatment can suppress infection below the level of detection we will immunosuppress baboons with oral administration of 5 doses of the immunosuppressant cyclophosphamide and then assay for the exacerbation of infection using multiple assays. We will also monitor the ability of PCR, multiplex serology, and T cell responses to *T. cruzi* antigens for up to 18 months post-treatment, to provide information on treatment success.

Last year the baboons were identified based on their *T. cruzi* infection status and completed a trypanocidal treatment with benznidazole. In addition, the animals were submitted to pre-treatment, 1, 2, 6, and 12 months post-treatment bleedings. This current year the 18 months post-treatment bleeding will take place and PCR assays as well as T cells responses will be performed in order to determine the level of parasite load in blood and the immune status after trypanocidal treatment. In addition, the animals will be submitted to an endpoint immunosuppression to establish parasite persistence after treatment. All the data collected will be analyzed and a final scientific report will be written.

Funding Sources: SNPRC Pilot Study

Percentage of P51 support: 0.77

Project Title: Impact of Diet on Microparticle Formation in Baboons

Core Scientists associated with the project: Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester PhD, University of Texas Rio Grande Valley; and Excluded by Requester PhD, TxBioMed

Project Description and progress: Variation in dietary fats is suspected to directly impact an individual's risk for development of multiple diseases including heart disease, diabetes, and obesity. As part of ongoing research utilizing baboons focusing on the interaction of diet and genotype in susceptibility for heart disease, we wish to evaluate the impact of a diet high in saturated fat on microparticle formation and their relationship to vascular damage contributing to the development of atherosclerosis. Initially we collected a fasting blood sample on 28 adult baboons for determination of baseline inflammatory state, and based on this assessment we selected 21 animals to enter into the study. Five of these animals were designated as controls and the remaining 16 animals were split into two cohorts of 8 animals for the dietary challenge portion of the study. The two experimental cohorts were then fed a diet high in both saturated fat and cholesterol. All 21 animals had blood samples and biopsies (femoral artery and bone marrow) collected at baseline and then one cohort of 8 animals were resampled (blood draw, bone marrow, and the collection of a biopsy of the contralateral femoral artery) at the end of 3 weeks, and the second cohort of 8 animals were were resampled at the end 7 weeks. The control animals were maintained on the standard diet following the collection of the baseline sample and were then resampled at the end of 7 weeks in order to better understand any non-diet related changes resulting from the surgical procedures. It is our expectation that exposure to a diet high in both saturated fat and cholesterol will induce damage to the vessel walls resulting in the production and release of microparticles and tissue resident stem cells. The sampling time frame for the study will also provide insight into whether such a response is acute (within the first 3 weeks of exposure) or continues to increase over the length of the exposure (i.e. up to 7 weeks). This work will aid in identifying key biomarkers of cellular damage to blood vessels associated with exposure to a diet high in saturated fats and cholesterol and could assist in the early detection of cardiovascular disease and novel routes of treatment.

We have completed the dietary challenge and collection of the samples and analyses is ongoing. Endothelial cells were harvested from the femoral artery biopsies and currently being cultured along with the bone marrow samples for use in our analyses.

Funding Sources: NHLBI P01 HL028972

Percentage of P51 support: 0.37

Project Title: Stem Cell Therapy in Non-Human Primate Model of Parkinson's Disease

Core Scientists associated with the project: Excluded by Requester PhD, and Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester PhD, Excluded by Requester PhD, and Excluded by Requester MD, UTHSCSA, San Antonio, TX

Project Description and Progress: The main objective of this study is to demonstrate the safety and the therapeutic benefits of transplanting dopaminergic neurons derived from neural stem cells into the brain of an authentic non-human primate (marmoset) model of Parkinson's disease.
The marmosets are subcutaneously injected with MPTP to make them parkinsonians. The neurological deficits are assessed using a clinical rating scale. The clinical rating scale correlates highly with striatal dopamine levels in the basal ganglia detected by postmortem immunohistopathology and it is modeled on the Unified Parkinson's Disease Rating Scale and the Hoehn & Yahr scale used clinically to categorize Parkinson's disease patients. After the neurological deficits stabilize the animals are stereotaxically injected into the putamen with dopaminergic neurons derived from neural stem cells. The extent of motor function restoration by the neural stem cell grafts using is measured by: (1) Behavioral outcomes measured by the clinical rating scale. (2) Dopamine content by Mass Spectrometric biochemical assessment. (3) MRI and PET imaging (4) Distribution and phenotype of grafted cells by immunocytochemistry on brain sections. (5) Markers of inflammation, immunocytochemical staining.

We have developed a way of labeling the neural stem cells with ferromagnetic particles, of transplanting and tracking them in marmoset and baboon brain using magnetic resonance imaging approach. We are now implementing this approach in Parkinson's disease model.

Funding Sources: Private Source

Percentage of P51 support: 0.24

Project Title: CCHFV disease in Marmosets

Core Scientists associated with the project: Excluded by Requester PhD, Excluded by Requester DVM

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester PhD, TxBioMed; and Excluded by Requester PhD, Centers for Disease Control, Atlanta, GA

Project Description and progress: Infection by Crimean-Congo Hemorrhagic fever virus (CCHFV) results in high mortality rates up to 40%. There are currently no licensed vaccines or effective FDA-approved therapeutics available to treat the disease. CCHFV is a bunyavirus endemic to much of Eastern Europe, the Middle East, Asia, and Africa, although recent studies have detected CCHFV in ticks collected in Spain, indicating an expanding geographic distribution. At present, one of the biggest barriers to studying CCHFV disease has been the lack of a suitable animal model. Neonate mice do succumb to infection; however, the route of infection requires intracranial inoculation, and disease does not mimic that observed in humans. Cynomolgus macaques become viremic, but the disease does not manifest itself in rash or hemorrhage, typical clinical symptoms seen in human patients, and does not result in the high mortality rates seen in people [1]. Marmosets have become invaluable as a small NHP model to study several hemorrhagic fever viruses, including Ebolavirus and Lassa fever virus [2, 3]. Our intent was to test marmosets as an animal model for CCHFV disease. If marmosets were to develop the disease, they would be the only practical animal model likely to be adopted by the scientific community, including the CDC.

Three strains of CCHFV were used in this study. Turkey and Oman strains, primary isolates from human patients, were obtained from the CDC. The third strain was a well-characterized laboratory strain, Ibr10200. A total of six animals were challenged, two per virus strain. Animals were monitored for 21 days after virus inoculation, with blood analyzed on days 6 and 15. None of the animals showed marked clinical signs of disease. However, blood analysis of the two animals challenged with Ibr10200 strain showed that the animals had a significant decrease in platelet and neutrophil counts on day 6. Also, serum ALT levels were significantly elevated as compared to the other two groups of animals. By day 15 each parameter had returned to normal. Our colleague in Turkey provided us with data showing a similar drop in these cell populations and increase in ALT level in blood of human patients with CCHFV disease. While the animals did not exhibit clinical symptoms seen in humans, the blood work showed a potential to be used as a disease correlate. For this reason, two more animals were chosen for a second round of the study. Two males inoculated with the Ibr10200 strain were monitored for 9 days, with blood analyzed every 2 days. Unfortunately, this time, blood chemistry and cell profiles showed no correlation to the human disease. This disappointing outcome suggested the model is either invalid or at least inconsistent. When virus loads in the blood were evaluated by plaque or immunofluorescence assays, no evidence of viremia was present. This may indicate that blood contains little viable virus or the animals were not actually infected. Titration of the virus inocula indicated that virus was present. The samples will be further analyzed by qRT-PCR to determine virus genome copies.

Overall, we conclude that use of the marmoset as an animal model for CCHFV disease is promising, but will require a much more extensive investment in terms of funding and animal resources. In addition, the virus will most likely have to be adapted to marmosets before overt disease is seen. This is a time-consuming approach with unpredictable results, and therefore we anticipate this work to be difficult to fund further. We will attempt to report our observations in a scientific journal once we obtain the qRT-PCR data for virus genome levels in animal blood.

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Funding Sources: SNPRC Pilot study

Percentage of P51 support: 0.67

Project Title: Administration of Proellex and Androxal in Cycling Female Baboons

Core Scientists associated with the project: Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester PhD, Private Source, The Woodlands, TX

Project Description and progress: This study will compare two different compounds that are under clinical development by Private Source The Woodlands, TX. Androxal® is an anti-estrogen underdevelopment for testosterone replacement in men with secondary hypogonadism and Proellex® is an anti-progestin under development for treatment of uterine fibroids. Capsules of the four compounds will be given daily by mouth. Small samples of blood will be collected each month for hormonal analysis during the study. Uterine biopsies will be collected prior to dosing and at the end of the study. Ultrasound examinations will be performed throughout the study. DEXA analysis will be conducted prior to dosing, during the study and at the end of the study to determine effects on bone formation by the study compounds. Study animals will be observed daily for any signs of distress. Due to anti-estrogenic and anti-progesterone effects of the two compounds changes in hormone reproductive secretion and reproductive tissues should be observed. Changes in bone development, either formation or absorption will be determined. This study will be used in the process required to approve a drug for the treatment of a medical need. Androxal causes an increase in testosterone, FSH and LH in men, and results in increased bone parameters. Effects in women have not been extensively investigated. Use of approved injectable or absorbable gels containing testosterone results in decreases in muscle mass or bone density. Proellex causes the reduction in size of uterine fibroids in women. Current therapies in women for treatment of fibroids results in bone loss. Use in normal women to determine changes in uterine tissue has not been fully investigated. The dual administration of the two compounds has limited data. Oral administration of the compounds to a mini-porcine model resulted in limited data due to the fact that in the female pigs do not cycle in a fashion comparable to humans. Data obtained from this oral administration could lead to development of drugs for use in women to treat uterine fibroids or cancer without the bone loss seen in current therapies.

Project procedures are completed.

Funding Sources: Industry

Percentage of P51 support: 0.97

Project Title: Epithelial Cells as Mucosal Adjuvant for Life-long Immunity

Core Scientists associated with the project: Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation: None

Project Description and progress: Transmission of HIV occurs predominantly across genital or rectal mucosal surfaces. Although our knowledge of the initial target cells involved in mucosal transmission is still evolving, it appears increasingly clear that the initial site of productive infection occurs at the mucosal surface; therefore, an ideal vaccine strategy would be to target HIV at mucosal entry sites to prevent infection. Such a novel strategy relies on the activation of mucosal immune response via presentation of viral antigens by the mucosal epithelial cells. The use of a terminally differentiated epithelial cell promoter to drive expression of antigens leading to viral protein production in the upper layers of the epithelium is central to the success of this approach. We have established optimal conditions to produce concentrated pseudotyped VSV-G viral particles to transduce basal epithelial stem cells at the mucosal sites of entry of SIV in our animal model.

A total of 6 naïve adult Indian rhesus macaques, obtained from the SPF colony at SNPRC, were used for vaccination. Longitudinal study was first performed to establish baseline levels of hormones, antibodies, and cytokine profiles during each female cycling. Endoscopic colposcopy followed by optical coherence tomography (OCT) was used to monitor each macaque cervical-vaginal epithelium to provide quantitative thickness changes overtime. Overall, we found that Colposcopy and OCT imaging (vagina, fornix, cervix) correlated with hormone levels and biopsies imaging. Longitudinal study (5 weeks) in naturally cycling macaques showed clear epithelial thickness differences. Vaginal OCT images reveled that vaginal epithelium is thinner during menses. Altogether, those findings helped assessing the optimal procedure for reducing vaginal epithelial thickness prior mucosal vaccination. Animals were inoculated with high dose vaccine-labeled with GFP using the three major routes of inoculation (subcutaneous, intravaginal, intrarectal). Animals were monitored over time for GFP expression either by tape stripping for epidermis or by using saline-moistened cotton swabs for rectal/vaginal secretions. This phase was essential to determine the optimal routes of immunization to be used in further studies. Animals were sacrificed in pairs at 8 weeks (epithelium has turned over 8 times) or 6 months post-vaccination. Biopsies included: bronchoalveolar lavages (BAL), LN, skin and vaginal/rectal biopsies. Overall, significant increases of Perforin and granzyme B productions were detected in all vaccinated animals. The effectiveness of our vaccine approach was clearly dependent on the antigens expression leading to enhancement of SIV- specific CD4+ and CD8+ T-lymphocytes. Strong and long-term induction of SIVgag- and SIVenv-specific T cell-mediated immune responses were also detected using ELISPOT assays. We found that this vaccine strategy was safe and well tolerated by all macaques. No adverse reactions or illnesses were induced even after mucosal administration of multiple high doses.
Next we investigated the protective efficacy of the vaccine in rhesus macaques challenged with homologous SIV strains. A total of 12 naïve animals (6 males and 6 females) were obtained from the SNPRC SPF colony. Animals were divided into 2 groups: vaccine group 1 (n=8; 4 females and 4 males) and control unvaccinated group 2 (n=4; 2 females and 2 males). The efficiency of induction of mucosal immunity and its relationship to protection following vaginal or rectal SIV challenge were compared post-vaccine (optimum route of vaccine inoculation, as defined earlier). Antigen-specific T cells were quantitated using tetramer, ELISPOT and ICS. Animals were monitored for 12 weeks post-challenge for clinical disease, plasma viral load, CD4+ T cell counts, and SIV-specific immune responses. We detected Gag-specific $CD8^+$ T cells in spleen, lymph nodes, ileum, colon, and vaginal mucosa. SIV-specific $CD4^+$ T cell responses were detectable in blood and vagina as early as week 4 post-vaccination. Ag-experienced T cells were typically characterized as central memory or effector memory cells, with central memory cells releasing IL-2 upon stimulation, whereas effector memory cells produced markers of degranulation, such as CD107. Using these molecules, along with IFN-γ and TNF-α production, we characterized the cytokine profile of SIV Gag-specific memory ($CD95^+CD28^{+/-}$) cells induced by vaccination. We found that the majority of memory circulating cells induced by this vaccine modality are monofunctional (i.e., secrete only one cytokine). The antibody responses and experiments are still in process.

Funding Sources: R01 AI090705

Percentage of P51 support: 4.26

Project Title: Development of a novel recombinant papillomavirus-based vaccine expressing highly immunogenic HIV antigens

Core Scientists associated with the project: Excluded by Requester, PhD

Affiliate or visiting scientists with institutional affiliation: None

Project Description and progress: One of the key obstacles to the development of an effective AIDS vaccine has been our inability to deliver antigen for a sufficient period of time leading to weak and transient protection. The development of an effective vaccine that restricts viral replication at mucosal portals of entry remains our best hope for controlling the HIV pandemic. Here we propose to develop a novel genetic vaccine strategy based on genital papillomavirus (PV) generated immunity to be delivered to epithelial stem cells at the basal layer of the epithelium. Our strategy relies on the design of RhPV-1 L1/SIV chimera in which the L1 major capsid protein of RhPV-1 contains SIV-specific epitopes (RhPV-SIVEp chimeras). These RhPV-1 L1/SIV chimeras will be used to produce infectious particles by complementation in 293T cells and will be used as vector for our vaccine. We hypothesize that using a RhPV as SIV vaccine in macaque followed by SIVmac challenge will be the best model possible to investigate the potential of HPV as an anti-HIV vaccine in human. Phase 1 was to design recombinant RhPV expressing SIV epitopes (RhPV/SIVep). Two highly immunogenic SIV antigens, CM9 (Gag protein) and SL8 (Tat protein), were incorporated into RhPV L1 major capsid proteins known to generate strong cellular immune response and/or neutralizing antibodies. The HPV L1 major capsid protein is highly conserved amongst different HPV and is composed of a highly structured core of beta-sheets. The SIV epitopes were cloned in the variable loops to induce T cells and antibody response. The choice of T-cells epitopes was driven by their immunogenicity and availability of soluble tetrameric Mamu-A*01 MHC class I tetramers specific for SIVmac239 immuno-dominant epitopes (CM9 and SL8), which will be a useful tool to analyze the immunological responses after vaccination. T-cells epitopes were cloned in the connecting loop and at the C-term domain. After sequence verification, these constructs were checked for hybrid RhPV-L1-SIVep protein expression by western blot after transfection in 293T cells. Proper folding of hybrid RhPV-L1-SIVep proteins were assessed by the formation of chimeric RhPV-1 L1/SIV viral particle after expression in 293T cells, concentration and visualization by scanning electron microscopy. Infectious recombinant hybrids RhPV-1-SIVep viral particles were then produced by complementation in HPV-16 L1 and L2 expressing 293T cells. These viruses were then titered and used for testing of B and T-cells epitopes immunogenicity.
Phase 2 was to experimentally immunize female macaques with rRhPV-SIVep (high dose) and investigate the immune responses induced. Macaque RhPV infections were optimized based on previous mucosal vaccination Excluded by Requester eliminary RhPV infection Excluded by Requester RhPV-SIVep virions were inoculated onto the cervix/vaginal area. s were monitored for 12 weeks post-vaccine. Blood samples and vaginal/cervical biopsies were performed pre and at weeks 8 post-vaccine for cytological analysis, cellular immune response in the blood and at the mucosal sites using ELISPOT assay (IFN-g) and Intracellular Cytokine Staining (ICS) assay for the detection of IFN-gamma, TNF-alpha, IL-2, IL-4, and IL-10. Although the responses were low, all females were challenged with multiple low doses of homologous SIVmac239 (intra-vaginal). Additional animals served as unvaccinated controls and were infected in the same condition with homologous SIVmac239. Animals will be monitored for an additional 12 weeks for clinical disease, plasma viral loads, antibody response, CD4+ T cell counts, and SIV-specific immune responses. To characterize the quality and quantity of the cellular immune responses elicited by the rRhPV-SIVEp, we performed immuno-phenotyping and functional assays of SIV-specific T cells in the blood of the immunized macaques. We are now optimizing techniques to evaluate SIV-specific T lymphocyte responses in mucosal tissues including cervical/vaginal and GALT at euthanasia, facilitating serial analysis of SIV-specific responses. Although those experiments are still on going, we found that one dose of 10e6 vaccine may not be sufficient to induce effective immune responses since the immune response were generally low and not as protective as expected. Thus, the data presented so far in this study warrant the further testing of the efficacy of this vaccine approach in protection SVmac239 infection. The project should be completed within the next 6-8 months.

Funding Sources: SNPRC Pilot Grant 2013

Percentage of P51 support: 0.64

Project Title: Development of a Novel HIV Vaccine Approach using Chimeric SIV/Varicella Virus

Core Scientists associated with the project: Excluded by Requester, PhD

Affiliate or visiting scientists with institutional affiliation: None

Project Description and progress: The development of a safe, effective, easily administered and inexpensive AIDS vaccine is urgently needed to resolve the current HIV-1 acquired immunodeficiency syndrome (AIDS) epidemic. The live, attenuated varicella zoster virus (VZV) vaccine has been used for many years in the US and other countries, and proves to have been safe and efficient even in compromised individuals. Simian varicella virus (SVV) is a counterpart of human VZV in the nonhuman primate model for AIDS. The SVV and VZV genomes are collinear with respect to gene organization and, share extensive homology. Here we proposed to develop SVV-based vaccine for AIDS in the Simian model. The goals were to: 1) attenuate the SVV though BAC-engineering technique to develop a recombinant simian varicella virus (rSVV) expressing the simian immunodeficiency virus (SIV) gag and envelope (env) antigens; 2) induce humoral and cellular immune responses to SIV antigens in immunized rhesus macaques; and, 3) investigate the efficacy of this SVV-SIV vaccine to protect again challenge with SIVmac239.

We generated SVV-BAC constructs with human CMV promoter-driven SIV envelope (env) or foot-and mouth disease F2A joined env and gag (env-F2A-gag) antigens in *e.coli* DH10B, and reconstitute env-expressing and env-expressing env-F2A-gag recombinant SVV in vero cells by transfection for inoculation of macaques. All rSVV viruses (rSVV-SIVenv, rSVV-SIVenv/gag) were expanded and titrated prior to the animal's inoculation. Six naïve juvenile male macaques were selected based on the expression of the Mamu-A*01 class I MHC allele to investigate the nature of anti-SIV immune responses induced by our vaccine. Briefly, all macaques were vaccinated either at week 0 (n=3) with a subcutaneous inoculation of 3×104 pfu of rSVV-SIVenv/gag or at weeks 0 and 6 (n=3) with a subcutaneous and an intratracheal inoculations of 3×104 pfu of rSVV- SIVenv/gag. Animals were monitored over 12 weeks post-vaccine and were either euthanized to investigate SIV-specific immune responses in each tissue/organ or, challenged with homologous SIVmac239 (intra-rectal, 300 TCID50). Two additional naïve juvenile male macaques were used as unvaccinated challenged controls. SIV viremia was monitored post-challenge by harvesting peripheral blood mononuclear cells (PBMCs) using Ficoll–Hypaque gradients. Tissues were harvested and flash-frozen for further analyses.

Our results demonstrated that rSVV-SIV vaccination induced cell-mediated immune responses in all experimental animals against SIV env and SIV gag. We found that rSVV-SIV vaccination induced low levels of neutralizing antibodies in all immunized macaques. Humoral antibody responses to SIV antigens, as determined by ELISA, were initially low, but detectable, at the time of SIV challenge. However, our results demonstrate that the rSVV-SIV boosting at week 6 effectively primed a stronger immune response resulting in augmented against SIV-env antigen responses. Following SIV challenge, the experimental animals immunized with rSVV-SIVenv/gag generated a rapid anamnestic immune response to SIVmac with 2–8 fold increases in SIV antibody titer by day 14 post challenge and higher titers at day 28. The results indicated that the rSVV-SIV vaccine induced SIV-specific humoral responses in the immunized animals. In contrast, the unvaccinated control animals did not have an elevated SIV antibody response until day 28 following SIV challenge, indicative of a primary antibody response to the challenge virus. IFN-γ ELISPOT analyses of longitudinally collected PBMCs from each of the animals were tested for specific cellular responses against SIV env and SIV gag. Three of the six experimental rSVV-SIV immunized animals that received a boost at week 6 showed responses to the SIVenv peptides. Intracellular flow cytometry cytokine assays were performed and confirmed strong SIV-specific CD8+ T cell responses against end and gag. Following challenge with SIVmac239, the animal that received the 2 vaccinations (weeks 0 and 6) was protected compared to the 2 animals that received only 1 vaccination (week 0, n=2) and the unvaccinated controls (n=2). We are currently still analyzing the data.

Funding Sources: RO1 AI090705 and Private Source

Percentage of P51 support: 0.41

Project Title: Novel Nanoparticle-DNA Recombinant Flu Vaccine Against Mucosal SIV Challenge

Core Scientists associated with the project: Excluded by Requester PhD, Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation: None

Project Description and progress: Mucosal tissues are the primary route of transmission for most respiratory and sexually transmitted diseases, including human immunodeficiency virus (HIV). It is widely believed that immune responses must function at the mucosal barrier to disrupt sexual transmission of HIV. This study will test the hypothesis that a DNA/Flu vaccine against SIV that targets mucosal surfaces will focus the immune response to the site of pathogen entry, thereby curbing early virus replication. We have demonstrated that plasmid DNA coding for the full complement of SIV proteins can be encapsulated in biodegradable nanoparticles, can be delivered to mucosal surfaces, and is able to prime the immune system. We have also developed a chimeric protein between SIV gp41 and the extracellular domain of the costimulatory molecule CD154; this chimeric protein forms trimers that retain the antigenic structure of gp41, the biological activity of CD154, and can stimulate antigen-presenting cells. We are now testing the immunogenicity of a prime-boost approach composed of priming with plasmid DNA-containing nanoparticles (NP-DNA) made with a novel combination of poly(lactic-co-glycolic acid) and poly(β-amino) ester (PLGA-PBAE) complex followed by boosting with recombinant live influenza viruses expressing SIV Gag and the CD154-SIV gp41 fusion protein; this viral vectors are based on the attenuated, FDA-approved Flu vaccine currently used in humans. The treatment group will receive vaccination with nanoparticles containing plasmid DNA that expresses SIV antigens followed by intranasal vaccinations with the attenuated recombinant flu viruses. The control group will be vaccinated with terpolymer-PEG nanoparticles containing control plasmid followed by intranasal application of empty flu vector. Humoral and cellular immune responses will be evaluated at the systemic and mucosal level. Both groups will be challenged with pathogenic SIV by the intrarectal route.

Although we proposed to use recombinant Flu viruses for immunization, the recombinant viruses were not stable and could not be propagated. Thus, we made recombinant Vaccinia viruses as vectors to express the same SIV antigens, including CD154-SIV gp41. The 6 macaques that received the NP-DNA vaccine were divided into 2 groups of 3 animals each. Group 1 received two immunizations with VV expressing SIV Gag, gp160, and Nef. Group 2 received two immunizations with VV expressing SIV Gag, Nef, and a fusion protein between gp41 and CD154 (CD154-HL-gp41). Group 3 (with 3 animals) received two immunizations with a control VV. Immune responses against SIV were only detected after VV vaccination, and the anti-gp41 titers were similar between Groups 1 and 2; strangely, anti-SIV Gag antibodies titers were much lower in Group 2 animals. The three groups were challenged with SIVmac251 by the intrarectal route, following a repeated low dose schedule. All animals became infected after 10 rounds of SIV challenge, and peak viral loads were similar for all groups. These results suggest that the priming provided by the NP-DNA vaccine was not very strong, and that the immune response induced by CD154-HL-gp41 antigen did not provide additional advantage over regular SIVgp160.

Funding Sources: SNPRC Pilot Study

Percentage of P51 support: 0.43

Project Title: Culture and Transplantation of Baboon Spermatogonial Stem Cells

Core Scientists associated with the project: Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester PhD, Department of Biology, University of Texas San Antonio

Project Description and Progress: This project seeks to generate preliminary data relevant to spermatogonial stem cell (SSC) transplantation in nonhuman primates to further develop this avenue to treat some cases of male infertility. While feasibility of SSC transplantation has already been established (based on previous work in rhesus performed by the PI), obtaining sufficient numbers of autologous SSCs for transplantation is a major barrier to successful application of SSC transplantation in the clinic. This project is designed to investigate two strategies to generate sufficient SSCs for transplant based on previous work in in rodents and humans. First, we will seek to develop in vitro SSC culture to expand the number of SSCs. Second, we will attempt derivation of SSC-like cells from autologous induced pluripotent stem cells (iPSCs). For both objectives, we will use a busulfan-treated baboons as recipients for autologous SSC transplantation to provide definitive endpoints (experimental transplant) for the identity and biological activity of the cells generated in the laboratory. Parallel autologous transplants of un-manipulated cells will serve as positive controls. We expect that bona fide SSCs will colonize the testes of busulfan-treated baboons and regenerate spermatogenesis. If successful, these studies will justify further investigation of SSC culture/derivation as means of overcoming the critical barrier of limited SSC number available for transplant. Beyond the research objectives, we anticipate that the results of this pilot research project will generate essential preliminary data for additional major grant applications that will investigate the biology of primate SSCS, establish a working model for human SSCs/iPSCs manipulations and the use of baboons as transplant recipients (e.g., R01), and develop research resources for baboon stem cell research.

We have made substantial progress since this grant was awarded in May 2014 towards establishing the logistics of this complex pilot project. First, we successfully obtained rDNA, Biosafety and IACUC approval to perform the proposed studies in late summer 2014. Second, in October 2014 we performed a series of SSC transplants with live animals prior to necropsy to refine the ultrasound-guided rete testis procedure using facilities and resources available at SNPRC. Specifically, this involved training of SNPRC staff and research Excluded by Requester ovided by Excluded by DVM, an expert in SSC transplant who was involved in the initial rhesus at the University of Pittsburgh. Third, we refined bone marrow harvesting procedures which will be used to reconstitute the hematopoietic system after busulfan treatment and validated our laboratory assessments of bone marrow quantity and quality. Fourth, using tissue obtained from necropsy animals (not on this study), we have begun developing the SSC culture procedures at UTSA (with advice from Excluded by Requester U Penn), although assessments are ongoing. Lastly, we have staff in place at UTSA (through Excluded by Req Excluded by Requester) to perform the autologous iPSC derivation and germ cell studies. At this time, we are finalizing plans for performing the first baboon procedures in the late February to early March 2015 time-frame.

Funding Sources: SNPRC Pilot Program and various philanthropic organizations

Percentage of P51 support: 0.77

Project Title: Stem Cell Therapy in the Marmoset: Preliminary Trial of Intranasal Delivery

Core Scientists associated with the project: Excluded by Requester PhD

Affiliated scientists with institutional affiliation Excluded by Requester PhD, UTHSCSA, San Antonio, TX

Project Description and Progress: The marmoset is an ideal small animal nonhuman primate model for regenerative medicine. The proposed experiments take advantage of a recently developed and validated novel mode of stem cell administration, which is to use an intranasal mode of cell delivery. In the first specific aim we are testing the feasibility of intranasal stem cell delivery in sedated, but not anesthetized, marmosets. We are studying 10 animals in a sequential scheme, allowing modifications of the technique as it is developed. Neural progenitor cells derived from marmoset iPS cells are prepared in vitro to a stage suitable for cell transplantation. In order to permit tracking of the cells, they are labeled with nanoparticles that are easily visualized (upconverting nanoparticles; emitting green fluorescence when exposed to 980 nm infrared light) and are trackable by MRI. Brains of the animals following euthanization are examined for the location and numbers of the administered stem cells. The upconverting nature of the labeling nanoparticles will be used to determine the location of cells. Parts of the CNS that show accumulation of the administered cells will then be used for histological analysis to test the interaction of the administered cells with the endogenous marmoset tissues.

We studied 3 animals in the first year of the project and we are studying 7 in the second year. In the work in the first year we solved many technical issues. The detection of the administered cells by fluorescence in the marmoset tissues was shown to be possible. At 24 hours post cell administration we detected the cells attached to the olfactory epithelium (the target region in the nasal cavity) and they appear to be penetrating through the epithelium into the neighboring tissues.

We initiated a modification to the project, which was approved, which enabled us to investigate whether autolgous cell administration would produce a different/superior outcome to allogeneic cell administration. In preparation for autologous cell administration, skin biopsies and blood samples were obtained from 3* animals. We reprogrammed the cells to iPS cells and then to neural stem cells. We plan to administer the cells intranasally to the same animals next month, March. At the same time we will administer the same clones of cells to the other 4 animals forming the allogeneic group. These experiments will permit us to determine if there is a superior survival, with possibly a lack of immune rejection, in the animals that received their own cells following reprogramming and differentiation. Because the same cells will also be administered to the allogeneic group of animals, differences in cell behavior due to the use of different cell populations will be avoided.

Funding sources: SNPRC Pilot Program

Percentage of P51 support: 0.32

Project Title: Polidocanol Foam for Female Permanent Contraception

Core Scientists associated with the project: Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester MD, MPH; Excluded by Requester PhD; and Excluded by Requester PhD; Oregon National Primate Research Center, Portland, OR

Project Description and Progress: The development of novel, non-surgical methods of permanent female contraception may improve access to this important method of fertility control and thus reduce the number of unintended pregnancies. Polidocanol foam administered through the cervix via a small balloon catheter by a non-physician health care worker could revolutionize access to permanent contraception. We could move sterilization from a risky surgical technique to a safe, well tolerated procedure easily accessible to women in any village. The purpose of this study is to develop a single treatment approach to permanent female contraception using transcervical administration of polidocanol foam (PF) in a baboon model.

The project was approved 9/4/12, and the first experiments were performed on 10/30/12. A total of 39 female baboons have been assigned to the protocol, and tissues have also been obtained from the tissue donation program from one additional female scheduled for necropsy for reasons unrelated to the protocol. Although the protocol has remained open, there have been no animals assigned to this protocol or used in 2014. Results from this protocol support the hypothesis that polidocanol foam can block the intramural portion of the fallopian tubes, and that the effect is dose-related, and that depomedroxyprogesterone acetate (DMPA) may improve the treatment results.

Funding Sources: Private Source

Percentage of P51 support: 1.25

Project Title: Polidocanol Foam for Female Permanent Contraception: Contraceptive Trial

Core Scientist associated with the project: Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester MD, MPH; Excluded by Requester PhD; and Excluded by Requester PhD; Oregon National Primate Research Center, Portland, OR

Project Description and progress: The development of novel, non-surgical methods of permanent female contraception may improve access to this important method of fertility control and thus reduce the number of unintended pregnancies. Polidocanol foam administered through the cervix via a small balloon catheter by a non-physician health care worker could revolutionize access to permanent contraception. We could move sterilization from a risky surgical technique to a safe, well tolerated procedure easily accessible to women in any village. The purpose of this study is to test whether a single treatment approach for permanent female contraception using transcervical administration of polidocanol foam (PF) in a baboon model can prevent pregnancy in fertile female baboons co-housed with a fertile male.

A total of 22 animals were assigned to the protocol. Of these 5 were treated with 5% PF with doxycycline, 4 were treated with 3% PF with doxycycline, and 4 with 3% PF with benzalkonium chloride; all of these treatments were followed by DMPA. An additional 9 females were examined but not treated with PF. These animals also received DMPA. The final treatments occurred on 2/7/14, and the females were socially housed with fertile males in two breeding groups. To date, there have been one pregnancy in each treatment group, and 7/9 females in the control group became pregnant. The study will continue into 2015.

Funding Sources: Private Source

Percentage of P51 support: 1.25

Project Title: Targeting Oviductal Epithelium with Hypertonic Saline for Permanent Contraception: A Pilot Study in Baboons

Core Scientists associated with the project: Excluded by Requester, PhD

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester, MD, MPH; Excluded by Requester PhD; and Excluded by Requester PhD; Oregon National Primate Research Center, Portland, OR

Project Description and progress: The development of novel, non-surgical methods of permanent female contraception may improve access to this important method of fertility control and thus reduce the number of unintended pregnancies. The purpose of this study is to evaluate the effect of intrauterine administration of hypertonic (23.5%) saline on the fallopian tubes using the baboon model. The acute effect of treatment will be evaluated by evaluating tissue 24 hours after treatment, and the ability of the treatment to result in tubal occlusion will be evaluated histologically after 30 days.

No animals were enrolled in this protocol during 2014.

Funding Sources: SNPRC Pilot Program

Percentage of P51 support: 0.77

Project Title: Maternal Nutrient Restriction: Effects on Offspring Immune Function

Principal Core Scientist associated with the project: Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester, PhD and Excluded by Requester PhD, UTHSCSA, San Antonio, TX

Project Description and progress: Poor maternal nutrition during pregnancy has been associated with increased neonatal mortality and susceptibility to infection and a higher incidence of chronic diseases including cardiovascular disorders, childhood asthma and diabetes. Many of these complications could be due to common underlying immune deficits elicited *in utero* by the lack of appropriate nutrition. To address the effects of MNR (maternal nutrient restriction) on developmental programming in non-human primates (NHP), the Center for Pregnancy and Newborn Research has developed a cohort of baboon offspring whose mothers received a diet restricted to 70% of the caloric value eaten by the ad lib fed controls (R24 RR0213667). It has been demonstrated that these MNR offspring have lower birth weights and exhibit physiological changes that persist into childhood. The immune health of these NHP offspring will be tested when they are 5-6 years old, equivalent to post-pubertal 15-16 year old humans. This will allow us to use assays that have been optimized for young adults for an ongoing aging study (R01AG030119). We hypothesize that the offspring of MNR pregnancies will have altered immune developmental programming, resulting in defects in the regulation of innate and adaptive immunity. To address this hypothesis, the baboons will be challenged with a protein vaccine to assess the functional capability of their antigen-specific adaptive immune responses (Aim I). Parameters of both B cell and T cell immunity will be measured in response to primary (naive) and secondary (memory or boost) immunizations. The functional capacity will then be correlated with parameters of immune health to be assessed in Aim II in the absence of an immune challenge. These will include: serum cytokine levels, blood cell populations, T cell repertoire, thymic function, and cell population-specific expression profiling to identify genes regulated in lymphocytes by MNR relative to control. In addition, we have begun to characterize the oral, fecal and vaginal microbiomes in these baboon offspring.

To begin to address the effect of maternal nutrient restriction (MNR) on immune development, we performed studies with two cohorts of baboon offspring when they were 5-6 years old. The animals were immunized twice with F1/alum, four months apart. Blood was collected prior to immunization (preimmune) and at designated intervals following the primary and secondary immunizations. Using the 2 week bleeds, T cell proliferation assays were performed; there was no significant difference detected between the MNR and control offspring in either polyclonal activation or antigen (F1) - specific T cell activation. There was also no significant decline in antibody production and if anything, the MNR offspring had slightly higher levels, although this was not statistically significant. However, we will conduct two additional sets of assays which should provide insights into the functional capabilities of the elicited antibodies and T cells: i) isotype specific ELISAs to see whether the antibody produced, although similar in titer, would be skewed to a more or less functional isotype and ii) cytokine assays on culture supernatants taken from the T cell proliferation assays. Significant progress has also been made with Specific Aim 2, the study of general immune parameters. Specifically, we have measured serum cytokine levels, used flow cytometry to assess blood lymphocyte subsets, and measured TREC levels in thymus at 165 days of gestation. Thus far, no significant differences have been demonstrated between the MNR and control offspring. However, we have now obtained samples from earlier in gestation and are repeating these experiments (as appropriate) to determine whether differences present early become masked by later changes in overall immune regulation. Lastly, as noted in the introductory letter, we did find some surprising differences between the microbiomes of MNR and control offspring; these are currently being explored and will form the foundation for a planned R01 application.

Excluded by Requester

(2014) Maternal nutrient restriction and the oral microbiome in baboon offspring. International Association for Dental Research (IADR), Charlotte, NC, March 2014 (selected for oral presentation)

Funding Sources: R21HD072518

Percentage of P51 support: 1.16

Project Title: Baboon Model of Liver Cancer

Core Scientists associated with the project: Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation: None

Project Description and progress: Liver cancer or specifically hepatocellular carcinoma (HCC) is one of the most intractable cancers for treatment, second only to pancreatic cancer, and is one of the cancers listed in The Recalcitrant Cancer Research Act. This proposal aims to develop a primate model of liver cancer by genetic engineering of primary primate hepatocytes and transplantation of these cells into the autologous host. The central hypothesis of the proposal is that cancer can be readily induced in primates by directly engineering the target tissue to express combinations cancer driver genes (oncogenes and tumor suppressor genes) known to be involved in liver cancer, thus circumventing the multi-step process that may require decades in primates. As proof-of-concept, we have induced liver cancer in immunodeficient mice with primate hepatocytes transformed in vitro and in immunocompetent primates via autologous cell transplantation.

We have cloned and expressed the baboon genes for numerous cancer driver genes. Activating mutations were introduced into p53, Myc, hRas, kRas, β catenin and AKT. The genes have been cloned into lentiviral vectors. Primary baboon hepatocytes were transformed in vitro and the cells were tested for oncogenicity in SCID mice. Only those combinations that induced tumors in mice are tested for tumor induction in immunocompetent baboons. The original baboon hepatocyte donor receives its own transformed cells, homologous baboon donor or autologous cell transplantation. We have been very successful in induction of liver cancer in SCID mice with baboon hepatocytes from ten different donors. The cells are directly injected into the liver in a gel matrix that retains the cells at the site of injection. The best combination of oncogenes results in tumors in 100% of the mice in 3-4 weeks. Cells isolated from the mouse tumors have been cultured in vitro and examined for cancer markers and gene expression. The same cells were introduced into the original baboon donors (autologous cell transplantation). Three baboons developed liver cancer in 3-4 months post injection. The tumors were initially detected by MRI. The third baboon had a biomarker engineered for secretion into the serum and could be detected at high levels by ELISA within 14 days after autologous cell transplantation, providing a sensitive marker for monitoring tumors during therapeutic trials. Additional combinations of oncogenes are being evaluated using baboon hepatocytes in SCID mice, to develop a series of oncogenic cell lines that display different phenotypes observed in hepatocellular carcinoma.

Funding Sources: various philanthropic organizations

Percentage of P51 support: 0.28

Project Title: Establishment of a SPF Rhesus Macaque Colony

Core Scientists associated with the project: Excluded by Requester PhD, Excluded by Requester DVM, Excluded by Requester PhD, Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation: None

Project Description and progress: The goal of this project is to increase the nation's capacity to produce Indian-origin rhesus monkeys (*Macaca mulatta*) that are specific pathogen-free (SPF) for herpes B virus, SIV, SRV, and STLV-1. The colony will continue to produce high quality genetically characterized animals for use in AIDS-related research by NIH grantees based at SNPRC and at other research institutions. Most of the founding stock of the SNPRC Colony 1 was obtained through acquisition of an existing SPF colony from the U.S. Air Force (USAF). The breeding colony enables an annual production of 70 animals per year for AIDS-related research. This program has been expanded to include a new SPF colony, SNPRC Colony 2. This year, we will receive approximately 260 macaques from NEPRC to form a new colony, SNPRC Colony 2. A building was renovated to house the new colony. These animals will be maintained genetically and physically separate from SNPRC Colony 1. This colony will be expanded to provide 55 new animals per year for research. From Colony 1, we recorded 81 live births in 2014, and 156 animals were used by investigators. A major use of animals this year was a new Private Source funded vaccine trial conducted by Dr. Excluded by Requester We continue to outsource MHC typing to Wisconsin NPRC. Typing was performed on 180 s. We have instituted the new NIH guidelines for SPF verification. As in the past, the initial screening will be for serology using the Luminex technology. Confirmatory screening by western blot and PCR will be outsourced to California NPRC and the National B virus laboratory. Consistent with the new guidelines, we will add PCR screening for SRV for the entire colony in the coming year. We have begun a new initiative to genotype by high throughput total genome sequencing. High throughput sequencing will provide the genetic markers to ensure Indian origin and pedigree, but will also increase our capacity for genetic management of the colony and the ability to provide animals with greater genetic characterization to investigators.

Funding Sources: U42 OD010442

Percentage of P51 support: 3.24

Project Title: NIH-Owned Chimpanzee Research

Core Scientists associated with the project: Excluded by Requester PhD, Excluded by Requester DVM, and Excluded by Requester DVM

Affiliate or visiting scientists with institutional affiliation: None

Project Description and progress: The specific aims are as follows: 1. To maintain a stable, healthy, well defined population of chimpanzees and to make them available for research within NIH guidelines. 2. To maintain a cohort of well characterized chimpanzees persistently infected with HBV, HCV or HIV for research on hepatitis and AIDS and for efficacy testing of new therapeutic approaches. 3. To provide high quality care and enrichment for those chimpanzees that NIH does not permit to be used for research until they die of natural causes or are euthanized for humane reasons. 4. To manage chimpanzees assigned to experimental protocols at the SNPRC.

Twenty NIH-owned chimpanzees are currently supported by this project. Their research histories and infectious status with regard to HBV, HCV, and HIV had been well documented and computerized. There are no active NIH-supported programs utilizing these animals at this time. The Southwest National Primate Research Center (SNPRC) responded to NOT-OD-14-075, Request for Information (RFI): Ethologically Appropriate Environments and Facilities that House and Maintain Chimpanzees Used in NIH-Supported Research to demonstrate the readiness of the facility for research if NIH grants are approved for funding. SNPRC was site visited by the Office of Laboratory Animal Welfare in January of 2015 with regard to the RFI response. The findings of the site visit determined that the requirements for providing EAE are either already in place at SNPRC or could be met with minimal additional effort and that the procedures and facilities in place to support EAE are conducive to the well-being of the resident chimpanzees.

Funding Sources: U42 OD011184

Percentage of P51 support: 5.09

Project Title: The Innate Immune Response in the Marmoset and Tamarin Model of GBV-B Infections: A Surrogate Model for HCV

Core Scientists associated with the project: Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation: None

Project Description and progress: Hepatitis C virus infections affect approximately 2% of the population and often progress to cirrhosis and liver cancer. Some of the characteristics associated with a failed adaptive immune response in chronic infection have been identified, yet the events that precede and determine the failed immune response are less clear and may involve the innate immune response. Research on HCV has been impeded by the lack of a small animal model. In this proposal, GBV-B infected marmosets are used as a surrogate model of HCV infection. The project involves an innovative approach to evaluate knockdown of a series of target genes involved in the innate immune response. GBV-B is the virus most closely related to HCV and it induces hepatitis in marmosets and tamarins. The central hypothesis of this project is that the innate immune response is essential for limiting viral spread in the liver and for orchestrating the adaptive immune response for the successful clearance of infected cells. However, the overarching goal is to develop a nonhuman primate model of gene knockdown for a variety of research areas.

We have cloned 7 of the target genes involved in the innate immune response from the marmoset and have been screening LNA antisense for the ability to knockdown these targets in vitro in primary marmoset hepatocytes. The lead target for Lock Nucleic Acid antisense is currently the interferon lambda receptor (IL28RA). To examine the efficiency of LNA antisense in vivo in the marmoset GBV-B model, we selected a positive control LNA designated Miravirsen, the LNA antisense to miR122 that showed efficacy in chimpanzees infected with HCV and progressed to phase II human trials. We determined that GBV-B is dependent on miR122 in the same fashion as HCV using GBV-B infected primary marmoset hepatocytes. GBV-B has 2 miR122 binding sites at the 5' end of the genomic RNA. We have demonstrated that Miravirsen has equivalent antiviral potency for GBV-B as observed for HCV in vitro. The initial in vivo studies revealed that depletion of miR122 with Miravirsen completely protected marmosets from GBV-B challenge. Current studies are expanding this observation. In vivo studies are ongoing with LNAs that target IL28RA (the receptor for interferon lambdas, aka IL28-IL29) in marmosets. We anticipate that disruption of the receptor for IL28-29 in GBV-B infections will provide new information on the role of interferon lambda on HCV infections, resolution vs chronic infection.

Funding Sources: R01 AI095680

Percentage of P51 support: 3.11

Project Title: Leptin Determination in Newborn Baboons

Core Scientists associated with the project: Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester UTHSCSA, San Antonio, TX

Project Description and progress: This project served to collect neonatal blood samples to measure plasma leptin and determine if baboons exhibit the same neonatal peak in leptin demonstrated in rodents. We still need to collect a few more samples as allowed on our existing IACUC.

Funding Sources: Internal UTHSCSA funds

Percentage of P51 support: 0.07

Project Title: Developmental Programming of Mismatch and of Pre- and Postnatal Nutrition

Core scientist associated with the project: Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester MD, PhD, UTHSCSA, San Antonio, TX

Project Description and progress: This project is an R24 funded by ORIP to develop a cohort of offspring baboons whose mothers were undernourished during pregnancy and over nourished in the postnatal period – the so called mismatch paradigm. It is now clear that animals that develop as fetuses in a nutrient deficient environment suddenly fed with a normal but certainly excessive diet has an altered trajectory development with long term consequences such as obesity.

The cohort is being formed. We have had several deliveries of offspring and the cohort now numbers 15.

Funding Sources: R24OD011183

Percentage of P51 support: 0.54

Project Title: Developmental Programming, Obesity and Over Nutrition

Core Scientist associated with the project: Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation Excluded by Requester MD, PhD, UTHSCSA, San Antonio, TX

Project Description: This project is an R24 supported by ORIP and it is to develop a cohort of animals whose mothers were obese prior to pregnancy and ate an obesogenic diet during pregnancy. There is now considerable interest in the observations hat maternal obesity has programming effects on the offspring.

The purpose of this program is not to conduct science but develop a cohort and this is being done. We have completed this R24 on December 31st 2014 and the final report is being prepared for NIH due March 31st 2015.

Funding Sources: R24 RR025866

Percentage of P51 support: 0.54

Project Title: Glucocorticoid Programming of the Pituitary Adrenal Axis

Core Scientist associated with the project: Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester MD, PhD, UTHSCSA, San Antonio, TX

Project Description and progress: This project involves the maintenance of a cohort of offspring of mothers who received antenatal glucocorticoids during pregnancy. Antenatal glucocorticoids are administered to pregnant women who threaten premature labor. The rationale for the treatment is that is accelerates fetal lung maturation and decreases neonatal morbidity and mortality. While this treatment has certainly saved many newborn babies lives and improved their neonatal course, there is now considerable concern that fetal exposure to levels of glucocorticoids higher than is normal at particular times of fetal development has long-term consequences in later life, including hypertension. We have shown that there are behavioral problems with the baboons that experienced exposure to antenatal glucocorticoids in utero.

Progress has been excellent. Pending Support Work is still on hold as we have ~~no funding~~.

Funding Sources: HD021350

Percentage of P51 support: 0.82

Project Title: Hepatocyte Gene Therapy with Viral Vectors

Core Scientist associated with the project: Excluded by Requester, PhD

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester PhD, Private Source Houston, TX

Project Description and progress: Adeno-associated virus (AAV) has shown tremendous potential for liver-directed gene therapy. In small (mice) and large animal (rhesus and dog) studies, AAV can mediate long-term therapeutic transgene expression without acute or chronic toxicities. We propose to inject adeno-associated virus (AAV) expressing human coagulation factor IX (hFIX) at a dose no higher than $2x10^{13}$-vector genomes (vg)/kg. AAV vectors do not contain any viral genes and one significant advantage of this vector is that it causes very little, if any, toxicity. Indeed, $2x10^{13}$ vg/kg of AAV-hFIX has been injected (via hepatic artery or peripheral vein) into rhesus macaques without any evidence of toxicity while providing long term therapeutic levels of transgene expression. Furthermore, doses up to $2x10^{12}$ vg/kg of AAV have been injected in humans via hepatic artery or peripheral vein in recent human trials without toxicity. Thus, we would like to determine if our percutaneous balloon occlusion catheter method of vector administration can further increase the therapeutic index of AAV which would be important to further enhance safety by reducing vector dose.

During this reporting period, we injected have $3x10^{12}$ vg/kg of AAV expressing human coagulation factor IX (scAAV8-hFIX) into two rhesus macaques. For one animal, the vector was administered by simple peripheral intravenous injection. For the other animal, the vector was administered by our percutaneous balloon occlusion catheter method whereby the vector is delivered directly into the liver by injecting into the hepatic artery while at the same time blood was prevented from leaving the liver by a balloon inflated in the inferior vena cava. The preliminary results revealed that up to 4.5-fold higher levels of hFIX is obtained if the vector is delivered by the balloon occlusion catheter method compared to simple peripheral IV injection. We are in the process of repeating this experiment to confirm the findings.

Funding Sources: NIH/NIDDK 2R01DK067324, SNPRC Pilot Program

Percentage of P51 support: 0.77

Project Title: Self-Injurious Behavior and Primate Wellbeing

Core Scientists associated with the project: Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester PhD, University of Massachusetts, Amherst, MA

Project Description and progress: The presence of self-injurious behavior (SIB) in laboratory housed nonhuman primates compromises animal welfare, the quality of the animal research resource, and can adversely impact research protocols. Based on previous findings, it is believed that SIB arises from adverse life events, is maintained by dysregulation of several neurochemical and physiological systems, and functions to reduce anxiety. Unfortunately SIB is resistant to treatment. Hair plucking (a potential form of SIB) and more generally hair loss have come under increased scrutiny from federal regulators. Consequently, the scope of this project includes analysis of hair loss, testing the hypothesis that hair loss in captive primates can result from several different factors, including hair plucking, stress, and anxiety. The goal of this study is to identify key risk factors associated with SIB and hair loss. These risk factors will be assessed by behavioral testing, hair cortisol profiles, hair loss patterns, and retrospective analysis of life history events through the animal records. To determine the generality of this hypothesis, factors contributing to SIB onset will be studied at three national primate research centers (SNPRC, ONPRC, WaNPRC) and at the NIH Animal Center.

During the 2014 reporting period, we collected intruder challenge data from 10 animals. Data collection for the intruder challenge included obtaining a hair sample for cortisol measurement, three photos to assess hair coat, and two videotaped human intruder challenges per animal. We also collected follow-up hair samples and photos on 26 of the subjects at approximately 6-months after the initial sample. Additionally, hair samples and photographs were collected from 120 females in the breeding colony to assess the impact of pregnancy on stress and alopecia. Hair samples were also collected from 209 baboons to assess species differences in hair . The videos and the photos have been sent to laboratory at the University of chusetts for alopecia and behavioral scoring. The hair samples have been shipped to Excluded by Requester laboratory at the University of Massachusetts for cortisol assay.

Funding Sources: R24OD01180

Percentage of P51 support: 0.29

Project Title: Cardiac Microlesion Formation During Invasive Pneumococcal Disease

Core Scientists associated with the project: Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester PhD, Department of Microbiology & Immunology, UTHSCSA, San Antonio, TX; Excluded by Requester MD and Excluded by Requester MD, School of Medicine, UTHSCSA, San Antonio, TX

Project Description and progress: *Streptococcus pneumoniae*, a Gram-positive bacterium, is a leading cause of community-acquired pneumonia and invasive disease. Approximately 15-20% of adults hospitalized for invasive pneumococcal disease (IPD) experience some form of an adverse cardiac event (i.e. arrhythmias, congestive heart failure, infarction). Those that do have double the mortality rate. Following infectious disease resolution, individuals hospitalized for IPD remain at elevated risk for sudden cardiac-related death for up to ten years. Thus, some form of lasting cardiac damage is incurred during IPD. Our research group has recently shown that *S. pneumoniae* can directly suppress cardiac function by forming bacteria-filled microscopic lesions (i.e. microlesions) in experimentally challenged mice. Herein, we proposed to challenge baboons with *S. pneumoniae* and Aim 1) determine if cardiac microlesions develop, and Aim 2) if cardiac scarring occurs thereafter. This line of experimentation would: 1) test for and potentially confirm that cardiac microlesion formation can occur in primates, and thus humans, 2) provide a direct link between microlesions and aberrant cardiac electrophysiology and function, 3) provide blood samples that could be tested to determine if biomarkers of cardiac damage such as troponin are viable indicators, 4) establish baboons as a human-relevant model to study the long-term consequences of cardiac microlesion formation.

To date we have infected two baboons as part of Aim 1. The 3rd and last baboon that is part of Aim 1 will be infected February 19, 2015. We have with these two animals optimized the regimen for analgesics and *i.v.* fluid administration, which will us to continue forward with Aim 2. Animals were tethered to allow for continuous electrocardiogram (ECG) and temperature monitoring. Prior to the infection we assessed cardiovascular function by transthoracic echocardiogram and 12 lead ECG. Baboons were infected intratracheally with *Streptococcus pneumoniae* TIGR4 (3.0×10^8 CFU) in 2 ml saline. Daily follow-up of the animals included CBCs and measure for organ failure markers (i.e. renal, liver and microcirculatory systems).

Proprietary Info

We expect to begin Aim 2 experiments in March 2015.

Funding Sources: SNPRC Pilot Program, 1R01AI114800-01 Excluded by Requester, Private Source Excluded by Requester

Percentage of P51 support: 0.77

Project Title: Advanced Development of Multivalent Filovirus (Ebola and Marburg) Hemorrhagic Fever Vaccine

Core Scientists associated with the project: Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester PhD TxBioMed

Project Description and progress: Viruses of the family Filoviridae are single-stranded, negative-sense viruses that cause severe and often lethal hemorrhagic fever in humans and nonhuman primates. Ebolavirus and Marburgvirus are the two genera that comprise the family Filoviridae. Filoviruses have been associated with human disease outbreaks in Africa with case fatality rates up to 90%. Nonhuman primate (NHP) models of this infectious disease demonstrate that this virus is highly virulent and high mortality rates approaching 100% are seen. The purpose of this project is to test the immunogenicity and protective efficacy of adeno vectored vaccines against filovirus induced disease. Cynomolgus macaques were immunized twice with adenovirus based filovirus vaccines 28 days apart. The immunization induced a robust cellular and humoral response. The response was protective in greater than 60% of immunized animals. Scope has not changed. Results are proprietary.

Funding Sources: NIH, HHSN272200800056C

Percentage of P51 support: 2.55

Project Title: A Dual Vaccine Strategy Against Filovirus Infection

Core Scientists associated with the project: Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester PhD, and Excluded by Requester PhD, TxBioMed

Project Description and progress: Viruses of the family Filoviridae are single-stranded, negative-sense viruses that cause severe and often lethal hemorrhagic fever in humans and nonhuman primates. Ebolavirus and Marburgvirus are the two genera that comprise the family Filoviridae. Filoviruses have been associated with human disease outbreaks in Africa with case fatality rates up to 90%. Nonhuman primate (NHP) models of this infectious disease demonstrate that this virus is highly virulent and high mortality rates approaching 100% are seen. The overall aim of our project is to develop a safe and effective Ebola/Marburg combination vaccine based on Virus-Like Particles (VLPs) to induce protective immunity to these highly pathogenic viral agents. We expect that the DNA vaccines encoding filovirus genes and VLP vaccines composed of filovirus protein will induce a robust immune response to specific antigens as evaluated by ELISA. Scope has not changed. Results are proprietary.

Funding Sources: Private Source, 5 R01 AI093406-04

Percentage of P51 support: 1.98

Project Title: In Vivo Consequence of Filovirus Stock Particle to Plaque Forming Units (PFU) Ratio in Macaques

Core Scientists associated with the project: Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation Excluded by Requester PhD, TxBioMed

Project Description and progress: In vitro culture of ebolavirus generates virus stock with varying ratios of particle to plaque forming units (pfu). Published data suggests that a single pfu of Zaire ebolavirus can be composed as few as 30 virions. More recently, Zaire NHP challenge stocks produced at Texas Biomedical Research Institute have particle to pfu ratio of >10,000:1. An obstacle to identifying criteria for well-characterized challenge stock material for filovirus efficacy studies is the role that particle to pfu ratio may have on pathogenicity. To address potential increase in virulence imparted by Zaire ebolavirus stock with high particle to pfu ratio we propose inoculate macaques with dilutions of Zaire ebolavirus stock that have either high particle to pfu ratio or a relatively low particle to pfu ratio. This study is ongoing.

Funding Sources: DOD, W911QY-12-C-0076

Percentage of P51 support: 12.72

Project Title: Evaluation of Virus-like Particle Filovirus Vaccine with Adjuvant in Cynomologus Macaques

Core Scientists associated with the project: Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester PhD, TxBioMed

Project Description and progress: To date, no commercial vaccine is available to protect against infection with filoviruses which causes fatal hemorrhagic fever. The overall aim of our project is to develop a safe and effective Ebola/Marburg combination vaccine based VLPs to induce protective immunity to these highly pathogenic viral agents. In support of this, this study seeks to test the efficacy of VLP vaccines in the cynomolgus macaque model. This study is ongoing.

Funding Sources: HHSN2722012000031

Percentage of P51 support: 8.41

Project Title: Cognitive Dysfunction in the Marmoset EAE Model

Core Scientists associated with the project: Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester PhD, Private Source San Antonio, TX

Project Description and progress: The objective of this pilot study is to explore cognitive dysfunction in the marmoset experimental autoimmune encephalomyelitis (EAE) model, and investigate whether increased physical activity shows promise in improving spatial working memory performance. The marmoset EAE model reflects more closely the clinical, anatomical, and neuropathological aspects of MS than any of the other current EAE models. However, quantitative functional deficits – including cognitive function – have yet to be interrogated in the marmoset EAE model. Such data would further validate this model, and will have application for investigating novel therapeutic strategies, including pharmacological treatments and lifestyle factors.

The specific aims of this study are: Aim 1. To evaluate the effects of low impact exercise on spatial working memory in the marmoset EAE model. We will assess cognitive dysfunction via a) serum brain-derived neurotrophic factor (BDNF), and b) performance on a radial arm maze (to test spatial memory). We hypothesize that marmoset EAE subjects that engage in regular, low impact exercise will show higher levels of BDNF and improved performance on spatial memory as the disease progresses than those EAE subjects that do not engage in exercise.

Aim 2. To pilot means of getting marmosets to engage in low impact exercise. As there are no established means of getting marmosets to engage in exercise, we will implement different strategies to do so. We are optimistic that a modified "Roto-rod" or "treadmill" will encourage subjects to engage in sustained locomotion for periods up to 30 minutes. Development of a valid and reliable method to increase activity in marmosets would have application to projects outside of the present proposal.

The experiment was conducted and completed during 2014. Twelve marmosets were randomly assigned into one of four treatment conditions - EAE-exercise ($n = 4$); EAE-no exercise ($n = 4$); Control-exercise ($n = 2$); Control-no exercise ($n = 2$). Those in the EAE condition were inoculated with myelin oligodendrocytic glycoprotein 34-56 to induce EAE. The subjects in the exercise group engaged in moderate exercise, treadmill running, for 30 min a day, 3 times a week. All subjects were tested weekly on spatial working memory. Blood draws were acquired from all subjects at four time points: initial assignment to the project, end of project, and two points in between (spaced 4 weeks apart). One subject underwent MRI scanning. However, due to difficulties gaining access to the MRI scanner, that component of the research was abandoned after acquiring this one scan.

With respect to the two Specific Aims: We are in the process of analyzing the cognitive data, serum, and biological tissues collected during the project. We successfully completed Aim 2 of the proposal: developing a method to have marmosets safely and reliably engage in low-intensity moderate exercise. A manuscript describing this is currently In Review

Submitted

Funding Sources: SNPRC Pilot Program

Percentage of P51 support: 0.49

Project Title: Do Early Maternal Antibodies Facilitate Oral Transmission of HIV in Infants?

Core Scientist associated with the project: Excluded by Requester MD, PhD

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester PhD and Excluded by Requester PhD, Private Source Chicago, IL; Excluded by Requester PhD, Excluded by Requester DVM, PhD, Excluded by Requester Excluded by Requester and Excluded by Requester PhD, TxBioMed

Project Description and progress:

The aims of this project, which remain unchanged, are to:

1. Examine the physical status of virions in breastmilk of HIV+ women and in milk of rhesus monkeys (RMs) chronically infected with R5 clade C simian-human immunodeficiency virus (SHIV-C). We will test whether virions are antibody (Ab)-coated using immune complex (IC) capture assays and whether opsonized virions are infectious and bind to FcR- or complement receptor (CR)-bearing cells ex vivo.

2. Identify and enumerate the first virus target cells after exposing infant RMs via the tonsils to fluorescently labeled virus prepared either in standard culture medium or opsonized with non-neutralizing Abs (non-nAbs). These studies will be conducted with single-cycle virions labeled either with green or red fluorescent proteins (GFP or RFP) +/- opsonization with RM non-nAbs.

3. Test whether passive immunization of RM infants with non-neutralizing IgG (non-nIgG) isolated from R5 SHIV-C-challenged animals with early-stage infection (prior to the development of nAbs) will increase the infants susceptibility to oral R5 SHIV-C challenge. We will use endpoint titration to determine the minimal infectious virus dose in orally challenged naïve infants versus infants passively immunized with non-nIgG prior to oral virus challenge.

Project progress:
For Aim 2, we have enrolled four neonatal RMs and exposed them to fluorescently labeled virus via the tonsils and via bottle feeding. The test viruses are single-cycle viruses that encode luciferase. Thus, luciferase-positive cells represent the first virus target cells after oral exposure. From two of the four neonates, we found areas of luciferase activity in the upper GI tract. In tissues of the first RM, ten distinctly positive target cells could be identified; their cell surface markers are currently being studied.

For Aim 3, we have completed the collection of serum from RMs in the relatively early stages of infection with the R5-tropic SHIV-C, strain SHIV-2873Nip. We tested IgG isolated from multiple such RM donors for the ability to enhance the replication of a heterologous R5 SHIV-C, strain SHIV-115ipd3N4, in cultured cells in the presence of absence of complement. We have identified an IgG pool that enhanced SHIV-C replication in vitro, and thus termed this preparation "eSHIVIG", short for enhancing anti-SHIV IgG. IACUC approval has been obtained to test whether RMs pretreated with eSHIVIG will be more susceptible to mucosal virus acquisition. We expect to start this study shortly.

Funding Sources: R01 DE023049 and administrative supplement

Percentage of P51 support: 5.17

Project Title: Confirming the Efficacy of Virosomes Targeting gp41 in Indian Rhesus Macaques

Core Scientists associated with the project: Excluded by Requester MD, PhD,

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester PhD, Excluded by Requester PhD, and Excluded by Requester PhD, Private Source PhD, Excluded by Requester PhD, Excluded by Requester MD, Excluded by Requester PhD, Excluded by Requester PhD, TxBioMed

Project Description and progress: The overall goal of this project is to develop a safe, effective vaccine against HIV/AIDS capable of protecting a significant fraction of virus-exposed individuals from persistent, systemic infection. Vaccine development will be done in collaboration with Private Source that is developing vaccines based on virosomes, a vaccine platform that has already been used in humans for over 10 years with an excellent safety record. Virosomes have been engineered to display either P1, a peptide derived from the transmembrane protein the HIV gp41, or rgp41, a truncated version of gp41. The resulting virosomes are termed virosome-P1 or virosome-rgp41, respectively. When the combination of the two HIV gp41-based virosomes was tested in a small number of Chinese rhesus monkeys (RMs), all animals were protected from persistent systemic infection after multiple challenges with a simian-human immunodeficiency virus (SHIV) that carries the HIV envelope.

This current project seeks to confirm these results in Indian RMs that are commonly used in AIDS research and better characterized genetically. In parallel, we will also assess how well one of the vaccine components, virosome-P1, can protect Indian RMs when used as single agent. Of note, virosome-P1 has already undergone successful Phase I testing in healthy women. If a significant fraction of the vaccinated RMs is protected against multiple low-dose vaginal SHIV challenges, we will assess the correlates of protection.

Project progress:
We have enrolled 42 RMs that will be divided into 3 groups of 12 RMs each and 6 RMs that will be used for viral titration. The RMs have been prescreened for pregnancy, Mamu haplotypes, coinfection with other retroviruses, and the ability to support the replication of the challenge SHIV strain in their PBMC; the results of screen for Fcγ receptor (FcγR) 2a and 3a are pending. Pre-study lymph node and rectal biopsies as well as vaginal lavages and fecal samples have been collected. Once these are known, the RMs will be evenly divided into the experimental groups according to the various parameters. Virosomes have been generated by Mymetics, tested for quality, and shipped. The first vaccination is scheduled in about three weeks.

Funding Sources Private Source

Percentage of P51 support: 7.83

Project Title: Humoral Correlates of Protection Against HIV

Core Scientists associated with the project: Excluded by Requester MD, PhD

Excluded by Requester or visiting scientists with institutional affiliation: Excluded by Requester PhD, Excluded by Requester PhD, Excluded by Requester PhD, Excluded by Requester PhD, and Excluded by Requester PhD, Excluded by Requester PhD, TxBioMed

Project Description and progress: The Ruprecht lab has developed a new set of tools to determine the epitope specificity of protective antibodies from polyclonal sera. Our strategy consists of:
A) a differential biopanning using recombinant phage peptide libraries that will be positively selected with polyclonal antibodies (Abs) from vaccine-protected rhesus macaques (RMs). This will be followed by negative counterselection with polyclonal Abs from vaccinated, non-protected RMs. A total of three rounds of positive/negative selection will be used to isolate mimotopes linked to protection;
B) isolation of single B cells specific for a given, protection-linked mimotope/epitope;
C) PCR amplification of RM immunoglobulin variable regions; and
D) generation of monoclonal antibodies (mAbs). These novel Ab engineering approaches have led to the isolation of several new chimeric simian/human mAbs with the predicted epitope specificity.

The major goals and Specific Aims of this project remain unchanged. The Specific Aims are to:
1. characterize the epitopes recognized by polyclonal antibodies (Abs) from vaccine-protected rhesus monkeys (RMs) that are not present in RMs with vaccine failure by differential (subtractive) biopanning. As a first step, we will positively select recombinant phages encoding random peptide libraries by biopanning with plasma from protected RMs. This will be followed by negative counter-selection with plasma from vaccinated, unprotected RMs. After three rounds of positive/negative selection, recombinant phages will reflect mimotopes linked to protection. We will also reverse the sequence of biopanning to ask: did RMs with vaccine failure mount unfavorable Ab responses that are not found in vaccine-protected RMs? This important question may identify viral targets for Ab responses that represent a risk for increased viral acquisition in vaccinees.

2. isolate single B cells from the protected RMs using fluorescently labeled mimotopes by flow cytometry and to PCR amplify the heavy (VH) and light chain variable (VL) immunoglobulin regions, an approach for which we have generated and tested new RM-specific primers. We have proof-of-concept that our technology leads to the successful isolation of monoclonal antibodies (mAbs) with the predicted epitope specificity as well as potent neutralization.

3. perform passive immunization in RMs with the novel mAbs to demonstrate protection against mucosal challenge with a heterologous R5 SHIV.

Project Progress:
We have succeeded in isolating several protection-linked mAbs from RMs from our experimental RMs. The epitopes of some of these mAbs have been mapped to regions of the HIV-1 envelope that hitherto has not been linked to vaccine-induced protection. We are currently expanding these mAbs in cell culture in preparation for precise epitope mapping and structural studies. In addition, we plan a passive immunization study in the near future, using RMs born in the current birthing season.

Funding Sources: R01 AI100703

Percentage of P51 support: 1.00

Project Title: Infant immunoprophylaxis against a primate lentivirus

Core Scientists associated with the project: Excluded by Requester MD, PhD

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester, PhD, Excluded by Requester, PhD, and Excluded by Requester PhD, TxBioMed

Project Description and progress: This project strives to define novel simian-human immunodeficiency (SHIV) models of human infection, in order to permit passive immunization studies with either neutralizing monoclonal antibodies (mAbs) or mAbs that can provide protection to rhesus monkeys (RMs) via other mechanisms. The project has generated CCR5-tropic SHIV constructs, most notably the first R5 clade A SHIV (termed SHIV-A for short).

Project progress:
The parental SHIV-A construct has been passaged in monkeys using depletion of B cell and CD8+ cells to favor the replication of the virus in vivo. Passaged SHIV-A, strain SHIV-KNH1144p2, was pathogenic after adaptation and a stock has been prepared for mucosal infections. Virus from this stock has been administered to two rhesus monkeys that were followed prospectively for viremia, immune responses, and pathogenicity. During this past period, one of these two recipients, monkey RZy-11, had persistently high viral RNA loads and developed AIDS. Two additional virus stocks were prepared from virus isolated from RZy-11 (strains SHIV-KNH1144p3 and p4). The last isolate, p4, has retained its R5 tropism. We have evaluated the molecular evolution of the initial parental clone in the absence of pressure from adaptive immunity – and later on in RMs that were not immunodepleted – in the presence of antiviral T-cell and antibody responses. This project is nearing completion.

Additional RMs chronic clade C SHIV infection are also followed on this project for viral pathogenicity and development of cross-neutralizing antibodies.

Funding Sources: R37 AI034266

Percentage of P51 support: 2.72

Project Title: Optimized Adaptation of Simian-tropic R5 HIV Clade C to Pig-tailed Macaques

Core Scientist associated with the project: Excluded by Requester MD, PhD

Affiliate or visiting scientists with institutional affiliation Excluded by Requester PhD, and Excluded by Requester DVM, PhD, TxBioMed

Project Description and progress: HIV clade C (HIV-C) causes approximately 60% of all cases of HIV/AIDS in the world and predominates in sub-Saharan Africa and India. A non-human primate (NHP) model would greatly benefit the preclinical development of prevention strategies, including drugs, microbicides, and vaccines. We have generated a simian-tropic HIV-C clone, termed stHIV-C, by replacing HIV *vif* with SIVmac239 *vif* in an infectious molecular HIV-C clone from Zambia. The chimera is replication-competent in peripheral blood mononuclear cells (PBMC) of pig-tailed macaques (PMs; *Macaca nemestrina*). The parental clone was partially adapted by repeated passages through PMs, and we plan further adaptation to improve the replication fitness of stHIV-C in unselected members of this species.

The aims for this project are to:

1. Select stHIV-C progeny with improved replication fitness in the new species under prolonged depletion of CD8+ and CD20+ cells, which will allow unbridled viral replication in the absence of adaptive immunity.

2. Further adapt the virus by serial passage in immunocompetent PMs, re-isolate virus from the last recipient PM, generate a large stock and characterize its biological properties in vitro (tropism, ability to replicate in PBMC of unselected PM donors, including those that did not support the replication of parental virus initially, neutralization sensitivity, and quasispecies present in the stock).

3. Perform an intrarectal titration using seven PMs (without CD8+ or B-cell depletion) and assess viral infectivity and pathogenicity. The animals will be followed prospectively for vRNA loads in plasma and cerebrospinal fluid, signs of disease progression, and antiviral immunity. Rectal biopsies will be performed at 12 weeks post-inoculation to assess lymphocyte depletion during acute infection.

4. Assess the molecular evolution of stHIV-C in the absence and presence of adaptive immunity and during disease progression. We will also compare viral evolution in PBMC, lymph nodes, and brain.

Project Progress:
We have screened PBMC of several PMs for their ability to support the replication of the partially adapted stHIV-C without the need to deplete the CD8+ cells. We then purchased two additional PMs; the first one has been inoculated without prior ablation of either CD8+ or CD20+ cells a few days ago. The results are pending. If sufficiently high viral loads are detected, we will perform serial transfer from the viremic donor to a naïve recipient.

Funding Sources: R56 AI104430

Percentage of P51 support: 3.68

Project Title: Womb to Womb: Programming of Reproductive Development in the Female Marmoset Monkey

Core Scientists associated with the project: Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation Excluded by Requester University of Illinois at Chicago; Excluded by Requester Texas A&M University–San Antonio, TX; and Excluded by Requester Wisconsin National Primate Research Center, Madison, WI

Project Description and progress: Many reproductive disorders, including pregnancy loss, remain difficult to predict and treat, suggesting that we need to approach women's reproductive health in novel ways. Adult health is rooted in developmental events that occur early in life, even as far back as the fetal period. This study aims to track three generations of marmoset monkeys to determine how the womb in which a female develops affects the womb she will provide to her own offspring. To develop the womb to womb approach, we propose to track three generations of marmoset females starting with pregnant females, then their daughters from birth to adulthood, and their subsequent first pregnancies. We will use serial measures of body weight and composition, sonograms of uterine growth from birth to adulthood, and biomarkers of energetic, inflammatory, and reproductive status to determine how the daughter's intrauterine development programs their adult reproductive function. Marmoset monkeys are small-bodied primates that achieve sexual maturity by 15 months of age, allowing the direct observation of transgenerational processes in a short period of time. Marmoset monkeys display natural variation in litter size, with twins and triplets being common. Twins represent the "control" phenotype, whereas triplets represent the "programming" phenotype analogous to that exhibited by growth-restricted human neonates. The central hypothesis of this proposal is that triplet females will display suboptimal development of the reproductive system from juvenility into early adulthood. The long-term goal of our research is to understand how adult phenotypes of impaired reproductive function emerge from developmental processes. The translational goal is to identify pre-adult biomarkers to predict adult reproductive dysfunction and pregnancy loss in humans.

A total of 12 adult females have been enrolled in the study since work began in earnest in late 2013. Eight have been enrolled since the last progress report; 5 from SNPRC and 3 from UTHSCSA. Enrollment is based on ultrasound verification of pregnancy. These enrolled subjects have had monthly 1.2-1.5 mL blood draws starting at day 60 of pregnancy. These samples have been spun down to obtain 600 uL of serum and stored at negative 80ºC until such time as large enough of samples can be shipped to Co-Investigator Excluded by Requester at the Wisconsin National Primate Research Center for analysis. These subjects have also had r Excluded by Requester und exams starting from the first one that verifies pregnancy. So far, enrolled adult females have delivered a total of 9 viable daughters; 4 at SNPRC and 5 at UTHSCSA. These daughters have been automatically enrolled the second generation of the study and are weighed and measured monthly. Monthly fasted blood samples are also taken once the individuals reach 6 months of age.

We anticipated a rolling enrollment of adult females at a rate of about 12/year. This means adult females could be re-enrolled with each subsequent pregnancy for total sample of adult females of 12 throughout the study period. We have achieved this goal. We also anticipated an enrollment rate of their daughters of about 4/year, based on sex ratios and mortality at birth, for about. We have met this goal as well.

Funding Sources: NICHD: 1R01HD076018

Percentage of P51 support: 0.40

Project Title: Baboon Chagas Heart Disease-in-a-Dish

Core Scientists associated with the project: Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester MD, PhD, University of Texas Southwestern Medical Center, Dallas, TX

Project Description and progress: Chagas heart disease is a serious global public health issue caused by life-long and incurable infection with *Trypanosoma cruzi (T. cruzi)*, a protozoan that colonizes and destroys cardiomyocytes. Chagas disease is a leading cause of cardiovascular death in Central and South America. Moreover, Chagas disease is an escalating problem in the U.S., especially at institutions serving migrating populations like Parkland Memorial Hospital in Dallas. Indeed, as the largest city hospital in proximity to the southern U.S. border, Parkland is a major portal of entry of Chagas disease into the U.S. health care system. Options for patients with advanced Chagas heart disease are extremely limited. Globally, more than 10 million people are infected with *T. cruzi and* ~20,000 people die each year from *T. cruzi* heart disease. Traditionally a neglected tropical disease, Chagas critically impacts U.S. health care, and new treatment strategies are desperately needed. *T. cruzi* infection and Chagas disease are also common among baboons and other non-human primates held in captivity at the SNPRC and, although most often undiagnosed, a subset of seropositive baboons has clinically relevant and ultimately lethal Chagas heart disease. Recent advances in stem cell and regenerative biology have made it possible to study *T. cruzi* infection in cardiomyocytes derived from human (or baboon) induced pluripotent stem cells (iPSCs) generated from blood cells by Yamaka factor reprogramming.

Currently our group is working on establishing the first and thus far only fully functional iPSC lab at UT Southwestern Medical Center in Dallas. We are reprogramming blood cells into iPSCs and then differentiating these iPSCs into various lineages, focused primarily on muscle lineages. In conjunction with this, we have obtained blood samples (peripheral blood mononuclear cells) and 12-lead ECGs from *T. cruzi* seropositive captive baboons at SNPRC. We will produce iPSCs from baboon blood cells and then differentiate baboon iPSCs into cardiomyocytes to study the structure and function of these cells with an eye towards defining their suitability for future autologous cell therapy applications. Additionally, as in the figure above, we will study the direct effects of *T. cruzi* infection on baboon iPSC-derived cardiomyocytes establishing a baboon Chagas/*T. cruzi* heart disease-in-a-dish model to study biology as well as do chemical biology small-molecule screens.

Thus far, we have obtained frozen PBMCs from 5 (of 10 total) baboons, males and females, different ages, for reprogramming into iPSCs. Some of these baboons have abnormal 12-lead ECGs, suggesting that they might indeed have Chagas heart disease, although confirmatory study by echocardiography will be needed. Reprogramming of baboon blood cells is currently in progress. Briefly, after expanding the erythroblast subpopulation in specialized media to ~60% of the total cell population, confirmed by FACS for surface markers CD36 and CD71, we reprogrammed baboon erythroblasts using the Sendai virus Yamanaka factor protocol that we have successfully employed on human erythroblasts. For technical and perhaps biological reasons, we did not succeed with our first baboon erythroblast reprogramming experiment, but a repeat experiment is currently in progress. It is quite possible that conditions for reprogramming of baboon blood cells are distinctive and our protocol will need to be optimized, perhaps by the additional of coaxing small-molecules or other agents. When successful, we will differentiate baboon iPSCs into cardiomyocytes using the standard human pluripotent stem cell protocol. These cells will be studied in vitro before and after experimental infection with *T. cruzi* in collaboration with our New York parasitology collaborators. After establishing and characterizing a baboon Chagas heart disease-in-a-dish model, our future plans will include returning baboon-specific iPSC-derived cardiomyocytes to the corresponding baboon with diagnosed Chagas heart disease as a form of cardiac cell therapy, although additional will be required to contemplate these advanced clinical studies.

Funding Sources: NIH/NHLBI U01 HL100401 Progenitor Cell Biology Consortium, Excluded by Requester

Percentage of P51 support: 0.02

Project Title: Blood platelet count to two doses of Oxycyte in Baboons with and Without Inflammation (1370 PC)

Core Scientists associated with the project: Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester PhD (Emiritus), TxBioMed; and Excluded by Requester, Private Source Durham, NC

Project Description and progress: The objective of this study is to investigate the impact of low or high doses of a perfluorocarbon agent on platelet distribution in baboons. The perfluorocarbon agent, Oxycyte, is intended to attenuate destruction of brain tissue following traumatic brain injury by increasing the oxygen improving oxygen delivery to site of the brain injury.

An initial study has been completed documenting that both high and low doses of Oxycyte result in transient decreases in blood platelet count that reach a maximum by days 4-5 after dosing. The decreases in blood platelets were not associated with any significant changes in platelet function. This initial study also included documentation of change in platelet count after low dose Oxycyte during inflammation due to E. coli lipopolysaccharide (LPS) administration. LPS inflammation alone caused platelet activation and transient decreases in blood platelet count on the second day after treatment. The combination of LPS and low dose Oxycyte was associated with an interaction effect that increased the level of inflammation as indicate by measurement of pro-inflammatory plasma cytokine levels and exacerbated the transient decrease in blood platelet levels due to Oxycyte treatment.

A final study was planned for the reporting period where distribution of blood platelets after Oxycyte treatment would be determined by imaging the deposition of Indium-111 labelled platelets in major organs for 4 days after low or high dose Oxycyte treatment. A preliminary study was performed to determine if a continuous low dose infusion of LPS could be used to produce a mild state of systemic inflammation without causing a decrease in blood platelet counts. We found that continuous LPS infusion at doses 10 fold less than the bolus doses used in the initial study would produce a mild state of systemic inflammation. However, decreases in blood platelet levels were always associated with increased inflammation. The PI decided that it would not be possible to safely include LPS induced inflammation with perfluorocarbon treatment in this study.

Funding Sources: US Army Medical Research and Material Command Award Number W81XWH-11-2-0122/Industry

Percentage of P51 support: 0.22

Project Title: Hollow Fiber Catheter for Drug Delivery Into Prostate

Core Scientists associated with the project Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester PhD (Emeritus), TxBioMed; Excluded by Requester Excluded by Requester sident, Private Source Minneapolis, MN; [redacted] Co-Investigator, Obstetrics and blogy, and Excluded by Requester Co-Investigator, Urology, Texas A&M Health Science Center, Temple, TX

Project Description and progress: Project description: This project will test whether a novel microporous hollow fiber catheter in conjunction with a software controlled infusion system provides a more reliable system for drug delivery into solid tissues such as the prostate. The expected outcome of this study is that the catheter based infusion will provide a uniform delivery of drug along the length of the catheter resulting in optimal exposure of prostate tissue to drug with little to no leakage outside of solid tissue. In contrast, the needle delivery will result in exposure of prostate tissue limited to the tip of the needle with little to no distribution of drug around the needle shaft.

Up to 10 aged adult male baboons will be used and studied one at a time. The baboon will be transported to the UTHSCSA Research Imaging Institute, sedated and placed under isoflurane anesthesia. A high resolution magnetic resonance image of the prostate will be obtained and used to guide placement of a 22 g hollow fiber catheter in one side of the prostate. The prostate tissue will be infused with the test drug with serial images obtained during the infusion to observe the dispersion of infusate throughout prostate tissue. A post infusion high resolution image will be obtained. The opposite side of the prostate will then be infused using a traditional needle approach and a single injection of the same volume of drug after inserting the needle. A third high resolution image will be obtained. The baboon will be recovered from anesthesia and returned to the SNPRC at Texas Biomed for necropsy procedures.

Initial MRI sequence parameters have been developed using insitu baboon prostate collected at necropsy. Live animal studies will be accomplished during the 2015 budget year.

Funding Sources: NIH 2R44DK085810-02A1

Percentage of P51 support: 0.22

Project Title: Progenitors Derived from Embryonic Stem Cells for Cardiovascular Repair

Core Scientists associated with the project: Excluded by Requester PhD, Excluded by Requester DVM, Excluded by Requester DVM

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester MD, PhD, TxBioMed

Project Description: Deterioration of the vascular system is a pivotal condition of cardiovascular diseases; there is a need for novel alternative therapies. The delivery of vascular progenitor cells into human subjects may provide an advanced option to prevent and treat this disease. Embryonic stem cells (ESCs) are pluripotent stem cells and are able to differentiate into various progenitors; therefore, they are a potential source for therapeutic purposes. This study uses a large nonhuman primate, the baboon, for early stage translational research to establish the feasibility of a potential stem cell-derived cell therapy. We have developed techniques allows us to generate endothelial progenitors whose phenotypes are found in adult vasculatures. In this study, we define the optimal conditions for progenitor scale-up production, and will test rigorously the effectiveness and safety of stem cell derived vascular progenitors for further preclinical research.

This year, our effort is to optimize the conditions that maximally generate endothelial progenitor cells. Specifically, we tested ten different protocols to monitor the changes of endothelial progenitor cell subpopulations by varying the exposure time and dosage of different cytokines to recapitulate the development of endothelial progenitor cells in vivo. We also determined whether GSK inhibitor treatment, together with other cytokines, effectively drives differentiation of ESCs into mesodermal and endothelial cells. We used both flow cytometry and RT-PCR to determine their gene expression under these conditions. In addition, we compared whether there exist advantages in using aggregates (2-dimensional culture) rather than embryoid body (3-dimensional culture) to differentiate the HSCs. We found the frequencies of subsets changed as a result, which may be due to spontaneous differentiation in embryoid body culture. Additionally, we have also tested the effects of culture matrix on ESC specification. After we generated angioblasts, we cultured them in various plates including laminin, fibronectin, lysine, collagen IV, and BM-derived acellular matrix; and we found that collagen IV yielded the highest CD34+ cells. To prepare in vivo animal testing, we have submitted three applications: IACUC for animal use, Biohazard Application for chemical disposal and Recombinant Nucleic Acids Registration for GFP insertion.

Funding Sources: Private Source

Percentage of P51 support: 1.05

Project Title: Development of In Vitro and In Vivo Assays to Characterize Marmoset Mammary Stem/Progenitor Cells During Progressive Aging

Core Scientists associated with the project: Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester PhD and Excluded by Requester PhD, UTHSCSA, San Antonio, TX

Project Description and progress: The purpose of this pilot project is to develop in vitro and in vivo assays to qualify and quantify marmoset mammary stem/progenitor cells during progressive aging. We propose to carry out our study in two phases with Phase I mainly focusing on method development and Phase II to examine how marmoset stem/progenitor cell number and function change with progressive aging. For method development, mammary tissues from 14 adult marmosets will be obtained mainly from mastectomy. For studying the age effect, mammary tissues will be obtained from marmosets at four different age groups: prenatal stage, puberty, adulthood, and aged, each with 5 animals (a total of 20 animals). The pre-natal tissue will be acquired through timed C-sections. The post-natal tissues may be acquired by mastectomy procedures or from planned euthanasia of appropriate subjects. Dissociation of mammary tissue will be tested with both the human and mouse MaSC isolation protocols. Enrichment of stem/progenitor cells will be carried out with Fluorescence-Activated Cell Sorting (FACS).

We have obtained tissues from a total of 24 female marmosets (13 in 2014) and 6 male marmosets (0 in 2014) and have successfully developed all necessary in vitro assays for identification of mammary epithelial stem/progenitor cells in this species. Specifically, we found that stem/progenitor cells were enriched in CD49f positive cell population. These cells can form mammospheres in suspension culture, and some of these spheres were found to be able to differentiate into organoids in 3-dimentional extracellular matrix (BD Matrigel) culture. In addition, these organoids can be serial passaged in vitro, indicating the self-renewal property of stem/progenitors. Similarly, cells that can form discrete colonies in the presence of feeder layers of irradiated NIH 3T3 cells were also highly enriched in the CD49f positive population. In vivo xenograft of the 3D organoid-derived cells in NOD/SCID mice resulted in milk production upon pregnancy, suggesting the presence of epithelial stem/progenitors. We have also evaluated the effect of aging on stem/progenitor cells and found that luminal progenitor cells decreased with aging. We have submitted our manuscript entitled Submitted

Submitted

Funding Sources: SNPRC Pilot Program

Percentage of P51 support: 0.76

Project Title: Gastrin-Releasing Peptide Mediates Pulmonary Fibrosis in a Marmoset Model

Core Scientists associated with the project: Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester MD, PhD, Private Source Private Source Durham, NC

Project Description and progress:
1. The purpose of this study is to evaluate a novel therapy (gastrin releasing peptide receptor blocking molecule or GRP-blocking monoclonal antibody) in a radiation induced marmoset model of pulmonary fibrosis.
2. We expect that the marmosets exposed to thoracic irradiation will be normal on physical exam until1 0-15 weeks post irradiation when respiratory rate will begin to rise and oxygen saturation will begin to fall. The lungs in these animals should have significant interstitial and intraalveolar fibrosis with mild to moderate right ventricular hypertrophy. Marmosets treated with GRP monoclonal antibody 2A11 are expected to have improved respiratory function and no fibrosis. Normal control tissues will be obtained opportunistically on animals that are euthanized for colony health reasons.

Note: Experiments with the animals have not yet begun.

Funding Sources: SNPRC Pilot Program

Percentage of P51 support: 0.73

Project Title: Brain MRI and Histopathology of the Epileptic Baboon

Core Scientists associated with the project: Excluded by Requester PhD, Excluded by Requester DVM

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester MD, UTHSCSA, San Antonio, TX

Project Description and progress: The baboon represents a natural model for genetic generalized epilepsy in humans, electroclinically resembling juvenile myoclonic epilepsy. The baboon provides a unique opportunity to correlate MRI morphometric and functional changes with underlying histopathology in the same animals.
Specific Aim 1: Correlate morphometric MRI abnormalities with histopathological changes. We hypothesize that there are underlying abnormalities in functional connectivity and cortical morphometry detectable by MRI, and that these neuroimaging findings are related to histopathological changes in the baboon cortex. As part of the first aim, we collected MRI datasets from different studies, in part to compare epileptic and control brains with voxel-based morphometry and using resting-state functional MRI. Both of these datasets would then provide regional cortical targets for histopathological sampling in the second year of the grant.
Specific Aim 2: Compare global and regional FC between EP and CTL baboons and effects of AED therapy on FC. The hypothesis underlying this aim is that acute and chronic therapy can alter functional connectivity of abnormal, epileptic baboons brains, both at rest and during intermittent light stimulation, rendering them more similar to that seen in normal brains. Demonstrating treatment-induced changes in connectivity may provide a novel measure of therapeutic response to antiepileptic medications or neurostimulation therapies. We will compare 8 photosensitive, epileptic baboons and eight control baboons over two years.
Previously acquired structural MRI scans of EP baboons with abnormal EEGs due the presence of interictal epileptic discharges and a history of seizures were compared to baboons without a history of seizures or craniofacial trauma suggestive for a seizure and normal scalp EEG studies. We identified 51 CTL and 77 EP baboons. Structural variants were noted in 15 MRI scans, ranging from elongated occipital horns to occipital horn enlargement suggestive for porencephaly. We excluded 7 CTL and 8 EP baboons for this reason. Occipital horn extension was evenly distributed between the two groups. We preformed MRI voxel-based morphometry in 46 CTL and 69 EP baboons.

We also have structural MRI scans available on 7 EP and 3 CTL baboons that underwent imaging for this study. These baboons will undergo pathological examination of their brains to evaluate brain regions demonstrating differences in cortical thickness or gray matter volume. We have obtained CITES permission from Germany and will be clearing CITES in the United States in the next 2 months, at which time we will be sending 6 CTL and 14 EP baboons in 3-4 shipments during the course of the second year of this study.

We completed resting-state and ILS fMRI scans for the pre- and post-valproic acid sessions of 3 CTL and 5 EPI baboons.

In a group of 14 EP and 14 CTL animals, whose scans in a large part were acquired previously, we compared functional connectivity of intrinsic networks. We identified the resting-state networks initially by ICA, then using the maximal BOLD response in the clusters common to both EP and CTL groups to seed the same networks in both groups. Differences in connectivity were noted in multiple networks, connectivity being decreased in visual, motor and anterior cingulate networks of EP baboons, but increased in the default mode as well as parietal, temporal and basal ganglia networks. These findings are both important and necessary for our study they will networks that can be compared before and after acute and chronic administration of valproic acid to EP and CTL baboons, subsequently also comparing the two groups.

Funding Sources: R21NS084198

Percentage of P51 support: 0.09

Project Title: Diet and Genotype in Primate Atherosclerosis

Core Scientists associated with the project: Excluded by Requester PhD, Excluded by Requester PhD, Excluded by Requester PhD

Affiliate or visiting scientist with institutional affiliation: Excluded by Requester PhD, and Excluded by Requester PhD, University of Texas Rio Grande Valley

Project Description and progress: This research program uses the pedigreed baboon model to investigate the interactions of diet and genotype to determine variation in phenotypes related to macrovascular endothelial cell (EC) function, lipoproteins, oxidative damage, adiposity, and other risk factors for atherosclerosis. The overall goal of this program is to identify genes that contribute to variation in these phenotypes, and to define genotype × diet interactions that influence them. To achieve this goal, we will continue genome-wide scans to localize relevant genes, follow up previously detected linkage signals in order to identify the quantitative trait loci (QTLs) that are responsible for the signals, and determine the effects of a chronic high cholesterol, high fat (HCHF) dietary challenge on the expression of atherosclerotic risk factors and vascular function. Project 1 will isolate and culture ECs from biopsied femoral arteries of pedigreed baboons. These cells will be subjected to in vitro pro-atherogenic challenges. We will assess the genetics of response to these challenges by quantifying EC dysfunction markers measured before and after the cells are challenged. Project 1 also will assess the genetic control of the number of circulating endothelial progenitor cells (CEPCs); and the relationships between EC functional characteristics, number and differentiation capacity of CEPCs, and extent of atherosclerotic lesions after the HCHF challenge. Project 2 will identify and compare networks of genes underlying variation in clinical risk factors and transcriptional profiles in peripheral lymphocytes and ECs from baboons on basal diet with those following the chronic dietary challenge. Project 3 will focus on identifying genes for QTLs influencing phenotypes related to dyslipidemia, oxidative damage and hypertension using chromosomal region specific gene expression profiling, positional cloning, statistical genomic analysis and whole genome expression profiling. Project 4 will detect and localize genes that influence adiposity and adipokine expression, and will evaluate the effects of the HCHF challenge on adipose tissue and muscle and their relationships to risk of atherosclerosis. The research projects are supported by four core units that provide phenotyping, data management and computing, veterinary services, and administrative services. The use of baboons enables controlled genetic and experimental manipulations designed to detect genetic effects and interactions that may be difficult or impossible to identify in humans. In addition, the mechanisms of action of these genes and their interactions with dietary components can be established experimentally. This research will lead to a better understanding of the genes that control susceptibility to atherosclerosis and how they interact with dietary factors to determine individual susceptibility to this disease. The program project completed on June 30, 2014.

Funding Sources: NHLBI: P01 HL028972

Percentage of P51 support: 3.09

Project Title: Biomarkers for Assessing Efficacy of Therapeutics for Chagas Disease

Core Scientist associated with the project: Excluded by Requester FhD, Excluded by Requester PhD, Excluded by Requester Excluded by Requester PhD

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester PhD, University of Texas Rio Grande Valley; Excluded by Requester MSc, DSc, University of Texas at El Paso; Excluded by Requester University of Georgia, Athens, GA; Excluded by Requester Private Source; and Excluded by Requester Private Source

Project Description and progress: Primates, both human and non-human, are subject to infection by the parasite *Trypanosoma cruzi* which causes Chagas disease. The infection is transmitted by a bug bite or by animals eating infected bugs. A well tolerated and effective cure for Chagas disease would have major implications for individuals infected with the parasite. The purpose of this study is to assess the ability of PCR of serial blood samples post-therapeutic treatment to determine if monkeys were cured by the therapy, and to assess the value of other biomarkers to ascertain treatment success. Two drugs will be assessed. PK studies will be done to verify the optimal dosage of one of the drugs. Uninfected monkeys will be fed the drug, and blood samples will be collected to measure drug concentrations. Naturally infected animals will be divided into four groups. Group 1 will be treated with the best established therapeutic, benznidazole, at optimal dose; Group 2 will be treated intermittently with benznidazole; Group 3 will be treated with E1224; and Group 4 will be treated with vehicle. At regular intervals after the end of treatment, blood samples will be taken to assess blood parasitemia by PCR and to assess other biomarkers. Any animals that are consistently PCR-negative for 12 months post-treatment will be immunosuppressed to determine if parasites recrudesce in the blood. The treated groups will be compared to the non-treated group (control).

Dosing of all three groups has been completed, and all animals are in the 1-year follow-up period during which sequential blood samples are acquired and examined by PCR. Immune characteristics and other biomarkers that might reflect radical curve are being assessed.

Funding Sources: Private Source

Percentage of P51 support: 13.75

Project Title: Development of the Baboon Model for Vasalgel Male Contraceptive

Core Scientists associated with the project: Excluded by Requester, PhD, Excluded by Requester DVM Excluded by Requester DVM

Affiliate or visiting scientists with institutional affiliation: Excluded by Requester PHD, DABT, University of Illinois at Chicago; and Excluded by Requester MD, Private Source Vienna, VA

Project Description and Progress: Project Description: This study is intended to provide practical information on how a new male contraceptive (Vasalgel) is best administered and how reversal can be effectively performed in baboons, in preparation for human use. Seven baboons will undergo implantation of the compound in the vas deferens, and semen evaluation will elucidate the effectiveness of the compound to cause rapid infertility in baboons through the absence of sperm in ejaculates. At four months, three subjects will have the Vasalgel implant flushed from the vas deferens. Documenting the return of normal sperm counts in ejaculates of these subjects will demonstrate the capacity to effectively remove the blockage of sperm caused by the Vasalgel implant. The other four subjects will continued to be monitored for the remainder of the year to determine if the implant is durable.

Seven baboons were enrolled in the study and received Vasalgel implants the week of Jan 20, 2014. Semen evaluations demonstrated failure of the contraceptive in four baboons. This was probably due to the electroejaculation procedure. This procedure was discontinued when problems with the contraceptive became evident (sperm in the ejaculate). Due to this unforeseen situation we adjusted our approach, amended our protocol and attempted (and failed) to validate an alternative method of semen collection using vaginal lavage. Thus four of the baboons were dropped from the study at the end of April 2014 due to sperm in the ejaculate. The remaining three males were transferred to breeding cages with fertile females (Aug 4, 2014 - 27 total females) to evaluate the efficacy of the contraceptive by fertility. One animal was removed from the study (only one vas successfully injected with Vasalgel) due to a confirmed pregnancy of one female in his breeding group prior to reversal surgery. Animals were removed from breeding cages on Nov 24 and reversal surgery was performed on December 1 and 2, 2014 for two baboons retained in the study. After the reversal, we were informed that one of the males had impregnated a female in his group. He was dropped from the study. The remaining subject that underwent reversal surgery will remain in the breeding cages with the females for eight weeks (period ends on 30 March 2015).

Funding Sources: Private Source

Percentage of P51 support: 0.30

Project Title: Baboon Model to Evaluate Vasalgel Male Contraceptive Using a Mating Study Design

Core Scientists associated with the project: Excluded by Requester PhD Excluded by Requester DVM, Excluded by Requester DVM

Excluded by Requester or visiting scientists with institutional affiliation: PhD, DABT, University of Illinois at b; and Excluded by Requester MD, Private Source Vienna, VA

Project Description and progress: Project Description: This study is intended to provide practical information on how a new male contraceptive (Vasalgel) is best administered and how reversal can be effectively performed in baboons, in preparation for human use. Eight baboons will undergo implantation of the compound in the vas deferens, and placed in breeding cages with a group of females. At 12 weeks, four subjects will have the Vasalgel implant flushed from the vas deferens with a bicarbonate solution, or "reversed". They will then be returned to breeding cages for 8 weeks followed by electroejaculation to evaluate sperm quality. The other four subjects will undergo the same procedure at 24 weeks. Documenting the return of fertility for these subjects will demonstrate the capacity to effectively remove the blockage of sperm caused by the Vasalgel implant.

Nine baboons were selected for the study and implanted with Vasalgel. Five animals on 26-27 August, 2014, three on 9 September, 2014 and one on 29 October, 2014. Four weeks after surgery they were placed in the breeding cages with a group of females for each male. Reversal surgeries for four of the animals were completed on 13-14 January, 2015. They will be placed back in breeding cages in mid-February. One male had a pregnancy in his group shortly after being placed with females. An amendment is pending to evaluate his vas deferens. We envision that the long-term group will be extended to 12 months to evaluate longer term efficacy of the contraceptive.

Funding Sources: Private Source

Percentage of P51 support: 0.30

Composite Application Budget Summary

Categories	Budget Period
Salary, Wages and Fringe Benefits	2,911,543
Equipment	0
Travel	24,770
Participant/Trainee Support Costs	0
Other Direct Costs (excluding Consortium)	1,200,689
Consortium Costs	14,555
Direct Costs	4,151,557
Indirect Costs	3,215,856
Total Direct and Indirect Costs	7,367,413

Component Budget Summary

Components	Categories	Budget Period
7258-001 (Admin Core)	Salary, Wages and Fringe Benefits	344,921
	Equipment	0
	Travel	14,770
	Participant/Trainee Support Costs	0
	Other Direct Costs (excluding Consortium)	26,471
	Consortium Costs	14,555
	Direct Costs	400,717
	Indirect Costs	312,066
TOTALS	Total Direct and Indirect Costs	712,783
7343-001 (Core)	Salary, Wages and Fringe Benefits	564,204
	Equipment	0
	Travel	0
	Participant/Trainee Support Costs	0
	Other Direct Costs (excluding Consortium)	103,034
	Consortium Costs	0
	Direct Costs	667,238
	Indirect Costs	524,449
TOTALS	Total Direct and Indirect Costs	1,191,687
7327-002 (Core)	Salary, Wages and Fringe Benefits	233,893
	Equipment	0
	Travel	0

	Participant/Trainee Support Costs	0
	Other Direct Costs (excluding Consortium)	173,848
	Consortium Costs	0
	Direct Costs	407,741
	Indirect Costs	320,484
TOTALS	Total Direct and Indirect Costs	728,225
7332-003 (Core)	Salary, Wages and Fringe Benefits	192,429
	Equipment	0
	Travel	0
	Participant/Trainee Support Costs	0
	Other Direct Costs (excluding Consortium)	71,558
	Consortium Costs	0
	Direct Costs	263,987
	Indirect Costs	207,495
TOTALS	Total Direct and Indirect Costs	471,482
7328-004 (Core)	Salary, Wages and Fringe Benefits	187,345
	Equipment	0
	Travel	0
	Participant/Trainee Support Costs	0
	Other Direct Costs (excluding Consortium)	381
	Consortium Costs	0
	Direct Costs	187,726
	Indirect Costs	147,552
TOTALS	Total Direct and Indirect Costs	335,278

7329-005 (Core)	Salary, Wages and Fringe Benefits	80,512
	Equipment	0
	Travel	0
	Participant/Trainee Support Costs	0
	Other Direct Costs (excluding Consortium)	0
	Consortium Costs	0
	Direct Costs	80,512
	Indirect Costs	63,283
TOTALS	Total Direct and Indirect Costs	143,795
7330-006 (Core)	Salary, Wages and Fringe Benefits	129,631
	Equipment	0
	Travel	0
	Participant/Trainee Support Costs	0
	Other Direct Costs (excluding Consortium)	10,202
	Consortium Costs	0
	Direct Costs	139,833
	Indirect Costs	109,909
TOTALS	Total Direct and Indirect Costs	249,742
7331-007 (Core)	Salary, Wages and Fringe Benefits	520,074
	Equipment	0
	Travel	0
	Participant/Trainee Support Costs	0
	Other Direct Costs (excluding Consortium)	260,711
	Consortium Costs	0

	Direct Costs	780,785
	Indirect Costs	613,697
TOTALS	Total Direct and Indirect Costs	1,394,482
7337-008 (Core)	Salary, Wages and Fringe Benefits	57,120
	Equipment	0
	Travel	0
	Participant/Trainee Support Costs	0
	Other Direct Costs (excluding Consortium)	25,018
	Consortium Costs	0
	Direct Costs	82,138
	Indirect Costs	64,560
TOTALS	Total Direct and Indirect Costs	146,698
7336-009 (Core)	Salary, Wages and Fringe Benefits	11,759
	Equipment	0
	Travel	0
	Participant/Trainee Support Costs	0
	Other Direct Costs (excluding Consortium)	56,454
	Consortium Costs	0
	Direct Costs	68,213
	Indirect Costs	9,243
TOTALS	Total Direct and Indirect Costs	77,456
7335-010 (Core)	Salary, Wages and Fringe Benefits	122,673
	Equipment	0
	Travel	0

	Participant/Trainee Support Costs	0
	Other Direct Costs (excluding Consortium)	36,450
	Consortium Costs	0
	Direct Costs	159,123
	Indirect Costs	125,071
TOTALS	Total Direct and Indirect Costs	284,194
7334-011 (Core)	Salary, Wages and Fringe Benefits	115,626
	Equipment	0
	Travel	0
	Participant/Trainee Support Costs	0
	Other Direct Costs (excluding Consortium)	11,373
	Consortium Costs	0
	Direct Costs	126,999
	Indirect Costs	99,821
TOTALS	Total Direct and Indirect Costs	226,820
7338-012 (Core)	Salary, Wages and Fringe Benefits	43,703
	Equipment	0
	Travel	0
	Participant/Trainee Support Costs	0
	Other Direct Costs (excluding Consortium)	18,553
	Consortium Costs	0
	Direct Costs	62,256
	Indirect Costs	48,934
TOTALS	Total Direct and Indirect Costs	111,190

7339-013 (Core)	Salary, Wages and Fringe Benefits	0
	Equipment	0
	Travel	10,000
	Participant/Trainee Support Costs	0
	Other Direct Costs (excluding Consortium)	0
	Consortium Costs	0
	Direct Costs	10,000
	Indirect Costs	7,860
TOTALS	Total Direct and Indirect Costs	17,860
7342-014 (Core)	Salary, Wages and Fringe Benefits	71,914
	Equipment	0
	Travel	0
	Participant/Trainee Support Costs	0
	Other Direct Costs (excluding Consortium)	6,636
	Consortium Costs	0
	Direct Costs	78,550
	Indirect Costs	61,741
TOTALS	Total Direct and Indirect Costs	140,291
7341-015 (Core)	Salary, Wages and Fringe Benefits	188,117
	Equipment	0
	Travel	0
	Participant/Trainee Support Costs	0
	Other Direct Costs (excluding Consortium)	0
	Consortium Costs	0

	Direct Costs	188,117
	Indirect Costs	147,860
TOTALS	Total Direct and Indirect Costs	335,977
7340-016 (Core)	Salary, Wages and Fringe Benefits	47,622
	Equipment	0
	Travel	0
	Participant/Trainee Support Costs	0
	Other Direct Costs (excluding Consortium)	400,000
	Consortium Costs	0
	Direct Costs	447,622
	Indirect Costs	351,831
TOTALS	Total Direct and Indirect Costs	799,453
TOTALS		**7,367,413**

Categories Budget Summary

Categories	Components	Budget Period
R&R Budget - Senior/Key Person Funds Requested	7258-001 (Admin Core)	344,921
	7343-001 (Core)	116,278
	7327-002 (Core)	44,868
	7332-003 (Core)	67,530
	7328-004 (Core)	105,401
	7329-005 (Core)	68,047
	7330-006 (Core)	58,451
	7331-007 (Core)	65,604
	7337-008 (Core)	9,606
	7336-009 (Core)	11,759
	7335-010 (Core)	65,470
	7334-011 (Core)	10,583
	7338-012 (Core)	8,151
	7339-013 (Core)	0
	7342-014 (Core)	42,411
	7341-015 (Core)	32,991
	7340-016 (Core)	47,622
TOTALS		1,099,693
R&R Budget - Other Personnel Funds Requested	7258-001 (Admin Core)	0
	7343-001 (Core)	447,926
	7327-002 (Core)	189,025

	7332-003 (Core)	124,899
	7328-004 (Core)	81,944
	7329-005 (Core)	12,465
	7330-006 (Core)	71,180
	7331-007 (Core)	454,470
	7337-008 (Core)	47,514
	7336-009 (Core)	0
	7335-010 (Core)	57,203
	7334-011 (Core)	105,043
	7338-012 (Core)	35,552
	7339-013 (Core)	0
	7342-014 (Core)	29,503
	7341-015 (Core)	155,126
	7340-016 (Core)	0
TOTALS		1,811,850
R&R Budget - Section A & B. Total Salary, Wages and Fringe Benefits (A+B)	7258-001 (Admin Core)	344,921
	7343-001 (Core)	564,204
	7327-002 (Core)	233,893
	7332-003 (Core)	192,429
	7328-004 (Core)	187,345
	7329-005 (Core)	80,512
	7330-006 (Core)	129,631
	7331-007 (Core)	520,074

	7337-008 (Core)	57,120
	7336-009 (Core)	11,759
	7335-010 (Core)	122,673
	7334-011 (Core)	115,626
	7338-012 (Core)	43,703
	7339-013 (Core)	0
	7342-014 (Core)	71,914
	7341-015 (Core)	188,117
	7340-016 (Core)	47,622
TOTALS		2,911,543
R&R Budget - Section C. Total Equipment	7258-001 (Admin Core)	0
	7343-001 (Core)	0
	7327-002 (Core)	0
	7332-003 (Core)	0
	7328-004 (Core)	0
	7329-005 (Core)	0
	7330-006 (Core)	0
	7331-007 (Core)	0
	7337-008 (Core)	0
	7336-009 (Core)	0
	7335-010 (Core)	0
	7334-011 (Core)	0
	7338-012 (Core)	0
	7339-013 (Core)	0

	7342-014 (Core)	0
	7341-015 (Core)	0
	7340-016 (Core)	0
TOTALS		0
R&R Budget - Domestic Travel	7258-001 (Admin Core)	14,770
	7343-001 (Core)	0
	7327-002 (Core)	0
	7332-003 (Core)	0
	7328-004 (Core)	0
	7329-005 (Core)	0
	7330-006 (Core)	0
	7331-007 (Core)	0
	7337-008 (Core)	0
	7336-009 (Core)	0
	7335-010 (Core)	0
	7334-011 (Core)	0
	7338-012 (Core)	0
	7339-013 (Core)	10,000
	7342-014 (Core)	0
	7341-015 (Core)	0
	7340-016 (Core)	0
TOTALS		24,770
R&R Budget - Foreign Travel	7258-001 (Admin Core)	0
	7343-001 (Core)	0

	7327-002 (Core)	0
	7332-003 (Core)	0
	7328-004 (Core)	0
	7329-005 (Core)	0
	7330-006 (Core)	0
	7331-007 (Core)	0
	7337-008 (Core)	0
	7336-009 (Core)	0
	7335-010 (Core)	0
	7334-011 (Core)	0
	7338-012 (Core)	0
	7339-013 (Core)	0
	7342-014 (Core)	0
	7341-015 (Core)	0
	7340-016 (Core)	0
TOTALS		0
R&R Budget - Section D. Total Travel	7258-001 (Admin Core)	14,770
	7343-001 (Core)	0
	7327-002 (Core)	0
	7332-003 (Core)	0
	7328-004 (Core)	0
	7329-005 (Core)	0
	7330-006 (Core)	0
	7331-007 (Core)	0

	7337-008 (Core)	0
	7336-009 (Core)	0
	7335-010 (Core)	0
	7334-011 (Core)	0
	7338-012 (Core)	0
	7339-013 (Core)	10,000
	7342-014 (Core)	0
	7341-015 (Core)	0
	7340-016 (Core)	0
TOTALS		24,770
R&R Budget - Tuition/Fees/Health Insurance	7258-001 (Admin Core)	0
	7343-001 (Core)	0
	7327-002 (Core)	0
	7332-003 (Core)	0
	7328-004 (Core)	0
	7329-005 (Core)	0
	7330-006 (Core)	0
	7331-007 (Core)	0
	7337-008 (Core)	0
	7336-009 (Core)	0
	7335-010 (Core)	0
	7334-011 (Core)	0
	7338-012 (Core)	0
	7339-013 (Core)	0

	7342-014 (Core)	0
	7341-015 (Core)	0
	7340-016 (Core)	0
TOTALS		0
R&R Budget - Stipends	7258-001 (Admin Core)	0
	7343-001 (Core)	0
	7327-002 (Core)	0
	7332-003 (Core)	0
	7328-004 (Core)	0
	7329-005 (Core)	0
	7330-006 (Core)	0
	7331-007 (Core)	0
	7337-008 (Core)	0
	7336-009 (Core)	0
	7335-010 (Core)	0
	7334-011 (Core)	0
	7338-012 (Core)	0
	7339-013 (Core)	0
	7342-014 (Core)	0
	7341-015 (Core)	0
	7340-016 (Core)	0
TOTALS		0
R&R Budget - Trainee Travel	7258-001 (Admin Core)	0
	7343-001 (Core)	0

	7327-002 (Core)	0
	7332-003 (Core)	0
	7328-004 (Core)	0
	7329-005 (Core)	0
	7330-006 (Core)	0
	7331-007 (Core)	0
	7337-008 (Core)	0
	7336-009 (Core)	0
	7335-010 (Core)	0
	7334-011 (Core)	0
	7338-012 (Core)	0
	7339-013 (Core)	0
	7342-014 (Core)	0
	7341-015 (Core)	0
	7340-016 (Core)	0
TOTALS		0
R&R Budget - Subsistence	7258-001 (Admin Core)	0
	7343-001 (Core)	0
	7327-002 (Core)	0
	7332-003 (Core)	0
	7328-004 (Core)	0
	7329-005 (Core)	0
	7330-006 (Core)	0
	7331-007 (Core)	0

	7337-008 (Core)	0
	7336-009 (Core)	0
	7335-010 (Core)	0
	7334-011 (Core)	0
	7338-012 (Core)	0
	7339-013 (Core)	0
	7342-014 (Core)	0
	7341-015 (Core)	0
	7340-016 (Core)	0
TOTALS		0
R&R Budget - Other Participants/Trainee Support Costs	7258-001 (Admin Core)	0
	7343-001 (Core)	0
	7327-002 (Core)	0
	7332-003 (Core)	0
	7328-004 (Core)	0
	7329-005 (Core)	0
	7330-006 (Core)	0
	7331-007 (Core)	0
	7337-008 (Core)	0
	7336-009 (Core)	0
	7335-010 (Core)	0
	7334-011 (Core)	0
	7338-012 (Core)	0
	7339-013 (Core)	0

	7342-014 (Core)	0
	7341-015 (Core)	0
	7340-016 (Core)	0
TOTALS		0
R&R Budget - Section E. Total Participants/Trainee Support Costs	7258-001 (Admin Core)	0
	7343-001 (Core)	0
	7327-002 (Core)	0
	7332-003 (Core)	0
	7328-004 (Core)	0
	7329-005 (Core)	0
	7330-006 (Core)	0
	7331-007 (Core)	0
	7337-008 (Core)	0
	7336-009 (Core)	0
	7335-010 (Core)	0
	7334-011 (Core)	0
	7338-012 (Core)	0
	7339-013 (Core)	0
	7342-014 (Core)	0
	7341-015 (Core)	0
	7340-016 (Core)	0
TOTALS		0
R&R Budget - Materials and Supplies	7258-001 (Admin Core)	0
	7343-001 (Core)	84,733

	7327-002 (Core)	120,383
	7332-003 (Core)	50,090
	7328-004 (Core)	381
	7329-005 (Core)	0
	7330-006 (Core)	10,202
	7331-007 (Core)	214,277
	7337-008 (Core)	18,017
	7336-009 (Core)	0
	7335-010 (Core)	36,450
	7334-011 (Core)	9,746
	7338-012 (Core)	12,810
	7339-013 (Core)	0
	7342-014 (Core)	6,018
	7341-015 (Core)	0
	7340-016 (Core)	0
TOTALS		563,107
R&R Budget - Publication Costs	7258-001 (Admin Core)	0
	7343-001 (Core)	0
	7327-002 (Core)	0
	7332-003 (Core)	0
	7328-004 (Core)	0
	7329-005 (Core)	0
	7330-006 (Core)	0
	7331-007 (Core)	0

	7337-008 (Core)	0
	7336-009 (Core)	0
	7335-010 (Core)	0
	7334-011 (Core)	0
	7338-012 (Core)	0
	7339-013 (Core)	0
	7342-014 (Core)	0
	7341-015 (Core)	0
	7340-016 (Core)	0
TOTALS		0
R&R Budget - Consultant Services	7258-001 (Admin Core)	23,793
	7343-001 (Core)	0
	7327-002 (Core)	0
	7332-003 (Core)	0
	7328-004 (Core)	0
	7329-005 (Core)	0
	7330-006 (Core)	0
	7331-007 (Core)	0
	7337-008 (Core)	0
	7336-009 (Core)	0
	7335-010 (Core)	0
	7334-011 (Core)	0
	7338-012 (Core)	0
	7339-013 (Core)	0

	7342-014 (Core)	0
	7341-015 (Core)	0
	7340-016 (Core)	0
TOTALS		23,793
R&R Budget - ADP/Computer Services	7258-001 (Admin Core)	0
	7343-001 (Core)	0
	7327-002 (Core)	0
	7332-003 (Core)	0
	7328-004 (Core)	0
	7329-005 (Core)	0
	7330-006 (Core)	0
	7331-007 (Core)	0
	7337-008 (Core)	0
	7336-009 (Core)	0
	7335-010 (Core)	0
	7334-011 (Core)	0
	7338-012 (Core)	0
	7339-013 (Core)	0
	7342-014 (Core)	0
	7341-015 (Core)	0
	7340-016 (Core)	0
TOTALS		0
R&R Budget - Subawards/Consortium/Contractual Costs	7258-001 (Admin Core)	14,555
	7343-001 (Core)	0

	7327-002 (Core)	0
	7332-003 (Core)	0
	7328-004 (Core)	0
	7329-005 (Core)	0
	7330-006 (Core)	0
	7331-007 (Core)	0
	7337-008 (Core)	0
	7336-009 (Core)	0
	7335-010 (Core)	0
	7334-011 (Core)	0
	7338-012 (Core)	0
	7339-013 (Core)	0
	7342-014 (Core)	0
	7341-015 (Core)	0
	7340-016 (Core)	0
TOTALS		14,555
R&R Budget - Equipment or Facility Rental User Fees	7258-001 (Admin Core)	0
	7343-001 (Core)	0
	7327-002 (Core)	0
	7332-003 (Core)	0
	7328-004 (Core)	0
	7329-005 (Core)	0
	7330-006 (Core)	0
	7331-007 (Core)	0

	7337-008 (Core)	0
	7336-009 (Core)	0
	7335-010 (Core)	0
	7334-011 (Core)	0
	7338-012 (Core)	0
	7339-013 (Core)	0
	7342-014 (Core)	0
	7341-015 (Core)	0
	7340-016 (Core)	0
TOTALS		0
R&R Budget - Alterations and Renovations	7258-001 (Admin Core)	0
	7343-001 (Core)	0
	7327-002 (Core)	0
	7332-003 (Core)	0
	7328-004 (Core)	0
	7329-005 (Core)	0
	7330-006 (Core)	0
	7331-007 (Core)	0
	7337-008 (Core)	0
	7336-009 (Core)	56,454
	7335-010 (Core)	0
	7334-011 (Core)	0
	7338-012 (Core)	0
	7339-013 (Core)	0

	7342-014 (Core)	0
	7341-015 (Core)	0
	7340-016 (Core)	0
TOTALS		56,454
R&R Budget - Other Direct Cost 1	7258-001 (Admin Core)	2,678
	7343-001 (Core)	13,788
	7327-002 (Core)	36,911
	7332-003 (Core)	16,454
	7328-004 (Core)	0
	7329-005 (Core)	0
	7330-006 (Core)	0
	7331-007 (Core)	29,316
	7337-008 (Core)	4,246
	7336-009 (Core)	0
	7335-010 (Core)	0
	7334-011 (Core)	1,627
	7338-012 (Core)	4,528
	7339-013 (Core)	0
	7342-014 (Core)	309
	7341-015 (Core)	0
	7340-016 (Core)	400,000
TOTALS		509,857
R&R Budget - Other Direct Cost 2	7258-001 (Admin Core)	0
	7343-001 (Core)	3,051

	7327-002 (Core)	3,948
	7332-003 (Core)	1,884
	7328-004 (Core)	0
	7329-005 (Core)	0
	7330-006 (Core)	0
	7331-007 (Core)	4,868
	7337-008 (Core)	684
	7336-009 (Core)	0
	7335-010 (Core)	0
	7334-011 (Core)	0
	7338-012 (Core)	796
	7339-013 (Core)	0
	7342-014 (Core)	309
	7341-015 (Core)	0
	7340-016 (Core)	0
TOTALS		15,540
R&R Budget - Other Direct Cost 3	7258-001 (Admin Core)	0
	7343-001 (Core)	1,462
	7327-002 (Core)	12,606
	7332-003 (Core)	3,130
	7328-004 (Core)	0
	7329-005 (Core)	0
	7330-006 (Core)	0
	7331-007 (Core)	12,250

	7337-008 (Core)	2,071
	7336-009 (Core)	0
	7335-010 (Core)	0
	7334-011 (Core)	0
	7338-012 (Core)	419
	7339-013 (Core)	0
	7342-014 (Core)	0
	7341-015 (Core)	0
	7340-016 (Core)	0
TOTALS		31,938
R&R Budget - Section F. Total Other Direct Cost	7258-001 (Admin Core)	41,026
	7343-001 (Core)	103,034
	7327-002 (Core)	173,848
	7332-003 (Core)	71,558
	7328-004 (Core)	381
	7329-005 (Core)	0
	7330-006 (Core)	10,202
	7331-007 (Core)	260,711
	7337-008 (Core)	25,018
	7336-009 (Core)	56,454
	7335-010 (Core)	36,450
	7334-011 (Core)	11,373
	7338-012 (Core)	18,553
	7339-013 (Core)	0

	7342-014 (Core)	6,636
	7341-015 (Core)	0
	7340-016 (Core)	400,000
TOTALS		1,215,244
R&R Budget - Section G. Total Direct Cost (A thru F)	7258-001 (Admin Core)	400,717
	7343-001 (Core)	667,238
	7327-002 (Core)	407,741
	7332-003 (Core)	263,987
	7328-004 (Core)	187,726
	7329-005 (Core)	80,512
	7330-006 (Core)	139,833
	7331-007 (Core)	780,785
	7337-008 (Core)	82,138
	7336-009 (Core)	68,213
	7335-010 (Core)	159,123
	7334-011 (Core)	126,999
	7338-012 (Core)	62,256
	7339-013 (Core)	10,000
	7342-014 (Core)	78,550
	7341-015 (Core)	188,117
	7340-016 (Core)	447,622
TOTALS		4,151,557
R&R Budget - Section H. Indirect Costs	7258-001 (Admin Core)	312,066
	7343-001 (Core)	524,449

	7327-002 (Core)	320,484
	7332-003 (Core)	207,495
	7328-004 (Core)	147,552
	7329-005 (Core)	63,283
	7330-006 (Core)	109,909
	7331-007 (Core)	613,697
	7337-008 (Core)	64,560
	7336-009 (Core)	9,243
	7335-010 (Core)	125,071
	7334-011 (Core)	99,821
	7338-012 (Core)	48,934
	7339-013 (Core)	7,860
	7342-014 (Core)	61,741
	7341-015 (Core)	147,860
	7340-016 (Core)	351,831
TOTALS		3,215,856
R&R Budget - Section I. Total Direct and Indirect Costs (G +H)	7258-001 (Admin Core)	712,783
	7343-001 (Core)	1,191,687
	7327-002 (Core)	728,225
	7332-003 (Core)	471,482
	7328-004 (Core)	335,278
	7329-005 (Core)	143,795
	7330-006 (Core)	249,742
	7331-007 (Core)	1,394,482

	7337-008 (Core)	146,698
	7336-009 (Core)	77,456
	7335-010 (Core)	284,194
	7334-011 (Core)	226,820
	7338-012 (Core)	111,190
	7339-013 (Core)	17,860
	7342-014 (Core)	140,291
	7341-015 (Core)	335,977
	7340-016 (Core)	799,453
TOTALS		7,367,413

A. COMPONENT COVER PAGE

Project Title: Director's Office

Component Project Lead Information:

Excluded by Requester

B. COMPONENT ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

The goals of the Director's Office are to provide leadership and oversight to all aspects of the Center and to serve as a liaison to ORIP, the regional and national research communities, and the local public community. The personnel currently assigned to the Director's Office with leadership roles in the Center are the Center Director, the Associate Director of Research, the Associate Director for Veterinary Resources and Research Support, and the Assistant Director for Administrative Services. We currently are recruiting an Assistant Director for Veterinary Resources and Research Support.

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

File uploaded: Directors_Office_B2.pdf

B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

Not Applicable

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

NOTHING TO REPORT

B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

The Outreach Component will report the progress directly under this component. The Directors Office will report progress in the area of the Public Relations Office and other mechanisms for disseminating mission of the SNPRC to the public.

The Public Relations Office handles all of the public media needs of SNPRC including local and national press inquiries. Public Relations coordinates a number of publications for Texas Biomed and SNPRC. These publications make biomedical research with nonhuman primates understandable to the general reader and explains how this research can positively impact the lives of people in San Antonio, Texas, the US and worldwide.
Roundup is the official newsletter of SNPRC and is published 3 times per year.
Progress is the newsletter of the host institute Texas Biomed and includes stories on SNPRC.
Annual report.--The Texas Biomed Annual Report highlights for the general public the year's major scientific achievements and other institutional initiatives.
Scientific report.--This publication, produced biannually, describes the work of each scientist at Texas Biomed and the SNPRC. For each faculty member, the report includes a research summary, a list of recent publications, and a relevant science image. This publication is sent to officials of major medical schools, government agencies, scientific organizations, and science libraries. It serves as a way to inform the scientific peer community of the work of Texas Biomed and the SNPRC and is also a recruiting tool.
Other Community Outreach and Education Efforts
Tours.--Approximately 40 times during the year, the SNPRC welcome various community groups for tours of the facilities to inform participants about the extraordinary research resources at the SNPRC and Texas Biomed, and how they are being put to use for the benefit of human health. A tour of the primate facilities, including instruction about the value of nonhuman primates in research, is generally a highlight of these events.
Student tours.--Each spring, Texas Biomed and the SNPRC host a series of 10-15 campus tours for upper-level high school students who are members of honors programs and/or advanced science classes. These tours, which are meant to foster goodwill with area schools and encourage bright young students to consider careers in science.
Community requests.--In addition to these outreach opportunities coordinated in collaboration with Texas Biomed support groups, the organization responds to requests from community groups and schools to arrange for speakers at their events. Multiple requests are accepted each year for representatives from the SNPRC or Texas Biomed to address one local groups.

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

As discussed above, the senior Administration of SNPRC and the host institute, Texas Biomed, have changed over the past year (see B2). This provides an excellent opportunity to evaluate the Center and improve efficiencies and collaborations. The SNPRC is currently restructuring the center based on changes in scientific emphasis and the core scientists. With the addition of two new scientists in stem cell biology and the recruitment of Excluded by Associate Director of Research, SNPRC will create a Scientific Unit in Regenerative Medicine and Aging. This will be one of three Scientific Units at SNPRC and will represent a major new initiative. The other two Scientific Units will be Genomics and Physiology of Complex Diseases and Infectious Diseases, both well-established programs at SNPRC. The expansion of the marmoset and macaque colonies with the arrival of animals from NEPRC also provides new opportunities

for collaborations on comparison of the genotypes and phenotypes of the SNPRC and NEPRC animals and expanded collaborations due to the increased colony sizes. The implementation of LabKey as the electronic records system provides both challenges and opportunities. Changes in data entry will be essential to fully utilize the capacity of LabKey, but these changes will bring new abilities to utilize the data from the animal colonies and research programs.

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

Restructuring of the SNPRC and Texas Biomedical Research Institute Administrations. A number of significant changes have occurred in the leadership of both SNPRC and its host institute, Texas Biomedical Research Institute (Texas Biomed) during the past year. These changes have brought new strengths and expertise to the SNRPC Administration and have provided a clear delineation between the primate center and the host institute. The changes were initiated following the announcement by Excluded by Requester the Founding Director of SNPRC (1999), that he Personal Info was bot Excluded by Requester Director of SNPRC and the Chief Scientific Officer of Texas Biomed. The perceived conflict of interest fr Excluded by Requester sition and overextension of effort by had been an area of concern in previous reviews of C. Personal Info provided an opportunity to restructure both the SNPRC and its relationship to the host institute for the first time, since the inception of SNPRC in 1999.

Excluded by Requester was selected as the Interim Director. After a period of enthusiastic support by the leadership and staff of both SNPRC and Texas Biomed, assumed the role as permanent Dir Excluded by Requester on July 30, 2014. Excluded by Requester (President of Texas Biomed) visited NIH in April to m Excluded by Excluded by Requester and the ORIP leadership to discuss concerns for SNPRC, future plans, and the pledge of t by Texas Biomed to SNPRC and In September, Excluded by Requester announced ignation as the Deputy Director of SNPRC and the Chair of the Department of Genetics at Texas Biomed to become the Director of the South Texas Diabetes and Obesity Institute at the newly formed University of Texas Rio Grande Valley. Several of her close colleagues from the Department of Genetics will join her over the next few months in this new Institute. SNPRC will maintain close relationships with this group of outstanding scientists, since many will continue to have collaborations with scientists at SNPRC. Texas Biomed has pledged support to the staff of the Department of Genetics for the recruitment of new faculty that will emphasize new strengths by the reorganized department. These new strengths in the Department of Genetics will provide a greater diversity of expertise for collaborations within the SNPRC.

Excluded by Requester moved rapidly to replace the vacancy created by the move of Excluded by Requester recruiting Dr. Excluded by Requester to become the Associate Director of Research at SNPRC starting in January of 2015. Excluded by e on some of the previous responsibilities of Excluded by Requester but will do much more in the area of development of new research programs, building on our current strengths and development of new strengths. Excluded by Requester was previously the Associate Director of Research at SNPRC from 2001-2006. During the interim, s been the Director of the Marmoset Aging Center at the Barshop Institute for Longevity and Aging Studies at the University of Texas Health Science Center in San Antonio. During this period, Excluded by Requester continued to be a Core Scientist at SNPRC and the Leader of the Marmoset Colony. In collaboration with SNPRC, Excluded by Requester created a barrier colony for marmosets at the Barshop Institute, to allow long-term aging studies without the variable influences of infectious diseases. Excluded by C and the Barshop will both benefit from assuming this new position, as it is anticipated that Excluded by Requester will foster interactions between the two institutes on new programs in NHP aging and regenerative e. She will retain significant leadership roles in multiple projects at the Barshop and this in no way will diminish her contributions to SNPRC, to the contrary. The Assistant Director for Administrative Services, Excluded by Excluded by Req Excluded by Requester also resigned to accept a new position at UTRGV. This position was immediately filled by Excluded by Requester brings great strength to this position. She was previously the Manager of this unit and many aspects was performing the role of the Assistant Director. She has a long history at Texas Biomed. She was the Director of the Office of Sponsored Programs prior to taking the position in the director's office. Her strengths include being a CPA and extensive experience in database management including Oracle, the newly adopted system used by the businesses offices of SNPRC and Texas Biomed.

One other significant change in leadership occurred with the Personal Info as the President of Texas Biomed and the PI of the base grant. This change was anticipated. Dr. Robert Gracy moved from Chief Scientific Officer of Texas Biomed to the Interim President in a seamless transition. The Board of Trustees for Texas Biomed is currently searching for a new President that has both a strong scientific background and outstanding administrative skills. Texas Biomed is not currently seeking to replace the vacancy of Chief Scientific Officer. It is perceived that the right candidate for the position of President and distribution of some of the CSO responsibilities to other positions will make that position unnecessary. The Director of the SNPRC agrees with this assumption, but this decision will be made after a new President has been in office for a period of time.

Recruitment. The SNPRC's scientific programs have been greatly strengthened in recent years by several major recruitments into either Texas Biomed or SNPRC. In 2014, SNPRC recruited two scientists in the area of [Excluded by Requester] ell research, [redacted] works in the area of neural stem cells (Parkinson's Disease, stroke and [redacted] auma), and [Excluded by R equester] works on retinal stem cells (macular degeneration and eye trauma), as well as muscle stem cells (Muscular Dystrophy). Regenerative Medicine will be a clear focus in the renewal of the base grant with the creation of the Regenerative Medicine and Aging Scientific Unit lead by [Excluded by R equester]. [Excluded by Requester] A critical mass of stem cell regenerative medicine researchers in San Antonio has developed as a result [redacted] iting efforts at the University of Texas Health Science Center, San Antonio, the University of Texas, San Antonio, Texas Biomed, and the SNPRC. The success of this effort was recognized by the choice of San Antonio to host the 2014 World Stem Cell Summit, the largest meeting dedicated to stem cell advancements. [Excluded by R equester] ussed above, [redacted] was recruited in 2015 to be the Associated Director of Research for [redacted] C. Her strength in nonhuman primate research will impact nearly every research program on campus. This will be particularly evident in all research using marmosets. [redacted] is the most experienced scien[Excluded by Requester] the country in this area, but she will also collaborate in many of the efforts on aging, regenerative medici[redacted] reproductive biology, which are emerging disciplines at SNPRC.

Significant changes in other recently recruited scientist. Texas Biomed's Department of Virology and Immunology added a faculty member in 2012, [Excluded by R equester] who initiated his nonhuman primate research at ABSL4 this year with a pilot grant from SNPRC using marmosets. [Excluded by R equester] a proteomics specialist, joined the Department of Genetics in 2013 as a Scientist, but in 2014 was selected to become the Chair of the department with the departure of [Excluded by R equester] joined Texas Biomed [Excluded by Requester] Department of Virology and Immunology. [redacted] has a strong SIV/HIV research program that will [redacted] avily on the SPF macaque colony at SNPRC. In 2014, she initiated a large vaccine study funded by [Private Source] [Private Source]

Expansion of Administrative and Laboratory Facilities. The new Earl Slick Research Center officially opened in April of 2014. This complex includes new laboratory and administration space for the Southwest National Primate Research Center. The Office of the SNPRC Director, Associate Director of Research, and Assistant Director for Administrative Services is housed in this building. SNPRC occupies the first floor of this building with both office and laboratory space. The space includes 7,128 net square feet of assignable laboratory space (eight BSL-2 laboratory modules), 1,772 net square feet of shared support space (blood processing, freezers, autoclave, etc.), and 6,079 net square feet of office space for research staff and Center administration.

C. COMPONENT PRODUCTS

C.1 PUBLICATIONS

Not Applicable

C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)

Not Applicable

C.3 TECHNOLOGIES OR TECHNIQUES

NOTHING TO REPORT

C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES

Not Applicable

C.5 OTHER PRODUCTS AND RESOURCE SHARING

C.5.a Other products

NOTHING TO REPORT

C.5.b Resource sharing

NOTHING TO REPORT

D. COMPONENT PARTICIPANTS

Not Applicable

E. COMPONENT IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES?

Not Applicable

E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE?

Not Applicable

E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER?

NOTHING TO REPORT

E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)?

Not Applicable

F. COMPONENT CHANGES

F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE

Not Applicable

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

No significant challenges encountered.

F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS

F.3.a Human Subjects

No Change

F.3.b Vertebrate Animals

No Change

F.3.c Biohazards

No Change

F.3.d Select Agents

No Change

G. COMPONENT SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

Not Applicable

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

G.4.a Does the project involve human subjects?

No

G.4.b Inclusion Enrollment Data

Not Applicable

G.4.c ClinicalTrials.gov

Not Applicable

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

Not Applicable

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Not Applicable

G.8 PROJECT/PERFORMANCE SITES

Not Applicable

G.9 FOREIGN COMPONENT

Not Applicable

G.10 ESTIMATED UNOBLIGATED BALANCE

Not Applicable

G.11 PROGRAM INCOME

Not Applicable

G.12 F&A COSTS

Not Applicable

RESEARCH & RELATED BUDGET - SECTION A & B FINAL

ORGANIZATIONAL DUNS*: 007936834

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Excluded by Requester				Project Lead	Institutional Base Salary	EFFORT			91,650.00	25,937.00	117,587.00
2.						Deputy Director					54,990.00	15,562.00	70,552.00
3.						Associate Director of Research					61,100.00	17,291.00	78,391.00
4.						Scientist					15,275.00	4,323.00	19,598.00
5.		To Be		Appointed		Asst Director, Vet Resources		3.0			45,825.00	12,968.00	58,793.00
6.		Robert		Gracy		Principal Investigator		EFFORT			0.00	0.00	0.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **344,921.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
11	Secretarial/Clerical	102.0			0.00	0.00	0.00
11	**Total Number Other Personnel**					**Total Other Personnel**	**0.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**344,921.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	**0.00**
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	14,770.00
2. Foreign Travel Costs	0.00
Total Travel Cost	**14,770.00**

E. Participant/Trainee Support Costs		Funds Requested ($)*
1. Tuition/Fees/Health Insurance		0.00
2. Stipends		0.00
3. Travel		0.00
4. Subsistence		0.00
5. Other:		
0 Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	0.00
2. Publication Costs	0.00
3. Consultant Services	23,793.00
4. ADP/Computer Services	0.00
5. Subawards/Consortium/Contractual Costs	14,555.00
6. Equipment or Facility Rental/User Fees	0.00
7. Alterations and Renovations	0.00
8. Printing/Artwork	2,678.00
Total Other Direct Costs	**41,026.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**400,717.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Federal Primate Center Rate	78.6	397,031.00	312,066.00
		Total Indirect Costs	**312,066.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): HHS Representative: Shon Turner- 214-767-3261

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**712,783.00**

J. Fee	Funds Requested ($)*
	0.00

K. Budget Justification* File Name: BUDGET JUSTIFICATIION_2-26-15.pdf
(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

BUDGET JUSTIFICATIION

Director's Office

A number of significant changes have occurred in the leadership of SNPRC during the past year. The President of the host institute, Texas Biomedical Research Institute, changed this year from Excluded by Requester to Dr. Robert Gracy. The Principal Investigator of the SNPRC base grant was changed to Dr. Gracy. Personal Info as the Director in March of 2014 and Excluded by Requester was selected as the new Director. In September, Personal Info as the Deputy Director of SNPRC to assume a position with the newly formed University of Texas Rio Grande Valley. Excluded by Requester was recruited as the Associate Director of Research to replace Excluded by Requester the Assistant Director of SNPRC Administration also moved to the University of Texas Rio Grande Valley. Exc luded by Requester was previously the Administrative Manager and was selected as the new Assistant Director of SNPRC Administration. SNPRC is seeking a new candidate as Administrative Manager.

RESEARCH & RELATED BUDGET - SECTION A & B FINAL

ORGANIZATIONAL DUNS*: 8007721620000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: The University of Texas Health Science Center at San Antonio

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Excluded by Requester				Project Lead	Institutional Base Salary	EFFORT			7,727.00	2,009.00	9,736.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **9,736.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**					**Total Other Personnel**	**0.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**9,736.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E

ORGANIZATIONAL DUNS*: 8007721620000
Budget Type*: ❍ Project ● Subaward/Consortium
Enter name of Organization: The University of Texas Health Science Center at San Antonio

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	**0.00**
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	0.00
2. Foreign Travel Costs	0.00
Total Travel Cost	**0.00**

E. Participant/Trainee Support Costs		Funds Requested ($)*
1. Tuition/Fees/Health Insurance		0.00
2. Stipends		0.00
3. Travel		0.00
4. Subsistence		0.00
5. Other:		
0 Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K

ORGANIZATIONAL DUNS*: 8007721620000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: The University of Texas Health Science Center at San Antonio

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	0.00
2. Publication Costs	0.00
3. Consultant Services	0.00
4. ADP/Computer Services	0.00
5. Subawards/Consortium/Contractual Costs	0.00
6. Equipment or Facility Rental/User Fees	0.00
7. Alterations and Renovations	0.00
Total Other Direct Costs	**0.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**9,736.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Federal	49.5	9,736.00	4,819.00
		Total Indirect Costs	**4,819.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**14,555.00**

J. Fee	Funds Requested ($)*
	0.00

K. Budget Justification* File Name:
(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

A. COMPONENT COVER PAGE

Project Title: Baboon Colony

Component Project Lead Information:

Excluded by Requester

B. COMPONENT ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

Specific Aim 1:-- To maintain the Baboon Colony at a steady-state of approximately 1,500 pedigreed baboons.
Specific Aim 2:--To adopt management strategies that make it possible to meet the needs of biomedical researchers across the country.
Specific Aim 3:--To provide opportunities to develop the baboon as an animal model in new research areas.

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

File uploaded: baboon_colony_B2.pdf

B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

Not Applicable

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

NOTHING TO REPORT

B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

NOTHING TO REPORT

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

We will continue to adjust the baboon census to balance supply to requests. At the same time we will focus on maintaining genetic diversity and providing genetically characterized baboons for research use. We will continue to test for STLV-1 and sequester the negative baboons to support the use of these animals in research. The colony will be tested every 6 months for endoparasites and treated, if needed.

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

In response to requests and demand for animals, the Baboon Colony has been further reduced to 1,400 animals. The number of breeding females was reduced from 225 to 125 to maintain a continued decrease in the census. The number of baboons from the pedigree 1 and 2 are increasing while the number of baboons in pedigree group 3 is being reduced.

In March, 2014, we convened the Expert Panel on Infectious Disease Surveillance (EPIDS) at the SNPRC for a two day workshop. The members included nationally recognized experts on non human primates and infectious disease Excluded by Requester, Excluded by Requester, Excluded by Requester, Excluded by Requester, Excluded by Requester and Excluded by Requester. EPIDS recommended that the SNPRC pursue the eradication of STLV-1 positive baboons in the colony. We obtained funding from the host institution and initiated screening in June, 2014. Negative result baboons are grouped housed in areas with only other negative baboons and retested every six months. We also initiated breeding with STLV-1 negative females. Furthermore, in response to the review of the base grant and the recommendations of the EPIDS, we initiated screening for endoparasites. The semi-annual health checks are being expanded to include complete physical examinations, TB tests, and fecal sampling for detection of endoparasites. If pathogenic organisms are present in a cohort, the entire group will be treated. This colony wide testing for internal parasites began in the baboons housed in small group caging in August, 2014.

We used 934 baboons in research projects. We sold 67 baboons for use off-site. There were 179 births in the production colony.

C. COMPONENT PRODUCTS

C.1 PUBLICATIONS

Not Applicable

C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)

Not Applicable

C.3 TECHNOLOGIES OR TECHNIQUES

NOTHING TO REPORT

C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES

Not Applicable

C.5 OTHER PRODUCTS AND RESOURCE SHARING

C.5.a Other products

NOTHING TO REPORT

C.5.b Resource sharing

NOTHING TO REPORT

D. COMPONENT PARTICIPANTS

Not Applicable

E. COMPONENT IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES?

Not Applicable

E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE?

Not Applicable

E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER?

NOTHING TO REPORT

E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)?

Not Applicable

F. COMPONENT CHANGES

F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE

Not Applicable

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

NOTHING TO REPORT

F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS

F.3.a Human Subjects

No Change

F.3.b Vertebrate Animals

No Change

F.3.c Biohazards

No Change

F.3.d Select Agents

No Change

G. COMPONENT SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

Not Applicable

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

G.4.a Does the project involve human subjects?

No

G.4.b Inclusion Enrollment Data

Not Applicable

G.4.c ClinicalTrials.gov

Not Applicable

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

Not Applicable

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Not Applicable

G.8 PROJECT/PERFORMANCE SITES

Not Applicable

G.9 FOREIGN COMPONENT

Not Applicable

G.10 ESTIMATED UNOBLIGATED BALANCE

Not Applicable

G.11 PROGRAM INCOME

Not Applicable

G.12 F&A COSTS

Not Applicable

RESEARCH & RELATED BUDGET - SECTION A & B FINAL

ORGANIZATIONAL DUNS*: 007936834

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Excluded by Requester				Project Lead	Institutional Base Salary	EFFORT			15,275.00	4,323.00	19,598.00
2.						Veterinarian					5,202.00	1,472.00	6,674.00
3.						Associate Veterinarian					7,190.00	2,035.00	9,225.00
4.						Staff Scientist III					2,191.00	620.00	2,811.00
5.		To Be		Appointed		Assistant Veterinarian		0.59			5,113.00	1,447.00	6,560.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **44,868.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
31	Veterinary Care Staff	46.0			147,333.00	41,692.00	189,025.00
31	**Total Number Other Personnel**					**Total Other Personnel**	**189,025.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**233,893.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	**0.00**
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	0.00
2. Foreign Travel Costs	0.00
Total Travel Cost	**0.00**

E. Participant/Trainee Support Costs		Funds Requested ($)*
1. Tuition/Fees/Health Insurance		0.00
2. Stipends		0.00
3. Travel		0.00
4. Subsistence		0.00
5. Other:		
0 Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	120,383.00
2. Publication Costs	0.00
3. Consultant Services	0.00
4. ADP/Computer Services	0.00
5. Subawards/Consortium/Contractual Costs	0.00
6. Equipment or Facility Rental/User Fees	0.00
7. Alterations and Renovations	0.00
8. Pathology	36,911.00
9. T. cruzi Testing	3,948.00
10. Telecommunications, Freight, Overtime and Other Services	12,606.00
Total Other Direct Costs	**173,848.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**407,741.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Federal Primate Center Rate	78.6	407,741.00	320,484.00
		Total Indirect Costs	**320,484.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**728,225.00**

J. Fee	Funds Requested ($)*
	0.00

K. Budget Justification* File Name:
(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

A. COMPONENT COVER PAGE

Project Title: Behavioral Services

Component Project Lead Information:

Excluded by Requester

B. COMPONENT ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

a.Providing appropriate environmental enrichment to nonhuman primate species.
b.Determining the efficacy of management strategies targeting specific procedures and behavioral issues.
c.Characterizing the extent of abnormal behavior in singly-housed animals and identifying potential risk factors.
d.Refining a method for assessing alopecia, evaluating the extent of alopecia in the primate populations, and identifying potential variables associated with alopecia.
e.Implementing and refining procedures for identifying potential partners and for forming compatible pairs of macaque monkeys.
f.Increasing the effectiveness of management, husbandry, and research practices through positive reinforcement training.
g.Conducting relevant research to increase the effectiveness of the Behavioral Services program.
h.To consult with investigators during project formation, design, implementation, and evaluation by providing a resource for behavioral data collection, promoting the welfare of research subjects, and identifying training methods to facilitate the procedures.
i.To educate the staff by presenting workshops on primate behavior, enrichment, and animal training and to perform outreach programs to the local community.
j.To participate in the Behavioral Management Consortium

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

File uploaded: Behavioral_Services_B2.pdf

B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

Not Applicable

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

File uploaded: Behavioral_Services_B4.pdf

B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

Tours of the primate center are routinely led by Behavioral Services personnel. In 2014, 68 tours were given, including one to a local reporter, two to facility interns, two to local teachers, 23 to visiting scientists, 23 to local high school and college classes, and four to visiting veterinarians or vet students. In addition, a presentation covering environmental enrichment and animal training was presented to local middle and high school teachers at UTHSCA.

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

We plan to continue providing exceptional care to the nonhuman primates housed at SNPRC and to strive to improve and refine our behavioral management procedures.

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

Behavioral Services staff members provide routine specialty enrichment to the indoor caged monkeys and to the chimpanzees. In 2014, an average of 1,059 enrichment items per week was provided to the monkeys and 1,094 items per week provided to the chimpanzees. New Reel-N-Feed feeders were constructed and hung on the chimpanzee enclosures for the provisioning of produce. Approximately 500 pumpkins donated by local churches were provided to the animals as a seasonal activity. Additional televisions were purchased and placed in the animal areas for a sensory enrichment activity.

We are currently conducting a study to assess the use of manipulable devices that we provide to the animals. Five types of toys used at SNPRC are being assessed. To date, 16 animals have been videotaped totaling 80 hours of video; 21 hours of the video have been scored for toy usage and all 80 hours have been scored for behavior. We also evaluated four types of nesting material to be used for chimpanzee enrichment.

Animals are observed daily by animal care, veterinary technician, and/or enrichment staffs. In addition to these daily observations, routine behavioral assessments have been initiated in the chimpanzee colony to evaluate chimpanzee time budgets and space use in the enclosures. A total of 534 behavioral observations were conducted. Quarterly Behavioral Assessments are also routinely conducted to assess the behavior of singly housed animals at SNPRC. In 2014, 529 behavioral assessments were conducted, averaging 132 observations per quarter. At any time, animals exhibiting behaviors of concern are reported to the Behavioral Intervention Program (BIP) for further assessment and intervention, if necessary. The BIP received 315 notifications on 142 animals with potential behavior problems. Assessments were conducted on 64 of these animals, and interventions were implemented in 29 of those cases.

In an effort to better address alopecia in the animal colonies, a formalized process for assessing, documenting, and treating alopecia was established. A Primate Center-wide training session was held to familiarize staff with the new procedures, and flow-charts outlining those procedures were posted in all areas. Formal routine alopecia assessments have been initiated in the chimpanzee colony. In 2014, 135 alopecia scores were recorded.

To improve socialization, 48 pairing attempts were made with macaques with a 96% success rate. Nineteen introductions were conducted with the chimpanzees with a 100% success rate. In addition to socializations, observations are routinely conducted to ensure group compatibility and to address incompatibilities. A total of 326 observations were conducted on baboon and 190 observations on macaque social groups to address any concerns. To keep track of singly housed animals, a monthly Single Housing Report has been developed and is provided to the AV and the IACUC for review and approval.

Animal training is an important program in both the monkey and the chimpanzee populations. A new training program was initiated to train the baboons housed in the corral to shift inside for their routine physicals. In addition, 1058 sessions were conducted with monkeys for behavioral interventions and 457 sessions were conducted for chute training. Fourteen shifting cases were maintained/ trained with the chimpanzees and 2,630 training sessions were conducted to train chimpanzees for voluntary sedation.

To further improve behavioral management, a number of research projects have been conducted: a study on the effects of a feeding schedule change and the provision of forage on hair eating in baboons, a study on risk factors for abnormal behavior in baboons, a study on alopecia in group-housed baboons, and a study on risk factors for alopecia in rhesus monkeys. The Director of Behavioral Services also served as a consultant for two PI's applying for pilot study grants and assisted them with the behavioral portion of their study design.

All staff members who work with or around awake nonhuman primates are required to attend seven workshops presented by Behavioral Services which include presentations on the natural history and behavior of chimpanzees, baboons, macaque monkeys, marmosets, and on animal training, environmental enrichment, and abnormal behavior. An average of 26 employees attended each class, totaling 179 attendees. Six staff members completed all seven classes and received a certificate. In addition to these general classes, specific area classes have been developed, including a chute training class for baboon personnel, cooperative feeding classes for new chimpanzee personnel, and a chimpanzee escape training class for personnel who work with or around chimpanzees.

The Director of Behavioral Services is a member of the Behavioral Management Consortium. The Consortium has monthly phone webinars and an annual in-person meeting. The Consortium has standardized terminology and assessment tools with the development of a "Self-Injurious Behavior Scale" and an "Abnormal Behavior Ethogram."

B.4 (Behavioral_Services_B4.pdf)

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

We hosted two student volunteers to learn about and assist with the provisioning of enrichment to the nonhuman primates. The Director of Behavioral Services is also a member of the dissertation committee for a graduate student in the Psychology, Cognition and Brain Science Program at Georgia Tech.

C. COMPONENT PRODUCTS

C.1 PUBLICATIONS

Not Applicable

C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)

Not Applicable

C.3 TECHNOLOGIES OR TECHNIQUES

NOTHING TO REPORT

C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES

Not Applicable

C.5 OTHER PRODUCTS AND RESOURCE SHARING

C.5.a Other products

NOTHING TO REPORT

C.5.b Resource sharing

File uploaded: behavior_C5b.pdf

Publications:

Excluded by Requester 2014. Abnormal behavior and associated risk factors in captive baboons (*Papio hamadryas spp.*). American Journal of Primatology 76:355-361.

Excluded by Requester 2014. Hair loss and hypothalamic-pituitary-adrenocortical (HPA) axis activity in captive rhesus macaques (*Macaca mulatta*). JAALAS 53:261-266.

Excluded by Requester Stereotypic behavior in nonhuman primates as a model for the human condition. 2014. ILAR 55:284-296.

In Press

Published Abstracts:

Excluded by Requester 2014. The correlation of alopecia and anxiety behavior in rhesus macaques (*Macaca mulatta*). American Journal of Primatology 76(S1):67.

Excluded by Requester 2014. Hair cortisol phenotype predicts rhesus monkey (*Macaca mulatta*) behavior during the human intruder test. American Journal of Primatology 76(S1):68.

Excluded by Requester 2014. Risk factors for alopecia and hair cortisol in rhesus macaques (*Macaca mulatta*): Preliminary findings. American Journal of Primatology 76(S1):66.

Excluded by Requester

Excluded by Requester Hair loss and hair cortisol concentrations in rhesus monkeys (*Macaca mulatta*) remain stable across time and environmental condition. American Journal of Primatology 76(S1):86.

D. COMPONENT PARTICIPANTS

Not Applicable

E. COMPONENT IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES?

Not Applicable

E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE?

Not Applicable

E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER?

NOTHING TO REPORT

E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)?

Not Applicable

F. COMPONENT CHANGES

F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE

Not Applicable

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

NOTHING TO REPORT

F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS

F.3.a Human Subjects

No Change

F.3.b Vertebrate Animals

No Change

F.3.c Biohazards

No Change

F.3.d Select Agents

No Change

G. COMPONENT SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

Not Applicable

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

G.4.a Does the project involve human subjects?

No

G.4.b Inclusion Enrollment Data

Not Applicable

G.4.c ClinicalTrials.gov

Not Applicable

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

Not Applicable

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Not Applicable

G.8 PROJECT/PERFORMANCE SITES

Not Applicable

G.9 FOREIGN COMPONENT

Not Applicable

G.10 ESTIMATED UNOBLIGATED BALANCE

Not Applicable

G.11 PROGRAM INCOME

Not Applicable

G.12 F&A COSTS

Not Applicable

RESEARCH & RELATED BUDGET - SECTION A & B FINAL

ORGANIZATIONAL DUNS*: 007936834

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Excluded by Requester				Project Lead	Institutional Base Salary	EFFORT			82,152.00	23,249.00	105,401.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **105,401.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
6	Research Assistant/Sr. Research Associate	17.4			63,869.00	18,075.00	81,944.00
6	**Total Number Other Personnel**					**Total Other Personnel**	**81,944.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**187,345.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	**0.00**
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	0.00
2. Foreign Travel Costs	0.00
Total Travel Cost	**0.00**

E. Participant/Trainee Support Costs		Funds Requested ($)*
1. Tuition/Fees/Health Insurance		0.00
2. Stipends		0.00
3. Travel		0.00
4. Subsistence		0.00
5. Other:		
0 Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	381.00
2. Publication Costs	0.00
3. Consultant Services	0.00
4. ADP/Computer Services	0.00
5. Subawards/Consortium/Contractual Costs	0.00
6. Equipment or Facility Rental/User Fees	0.00
7. Alterations and Renovations	0.00
Total Other Direct Costs	**381.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**187,726.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Federal Primate Center Rate	78.6	187,726.00	147,552.00
		Total Indirect Costs	**147,552.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**335,278.00**

J. Fee	Funds Requested ($)*
	0.00

K. Budget Justification* File Name:
(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

A. COMPONENT COVER PAGE

Project Title: Biocontainment

Component Project Lead Information:

Excluded by Requester

B. COMPONENT ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

Specific Aim 1.--To provide a safe working environment for advanced research into vaccines, therapeutics, and novel infectious disease models for high consequence pathogens.
Specific Aim 2.--To provide training to expand and maintain a research team composed of scientists and veterinary staff with knowledge of and experience with viral hemorrhagic fevers and other high consequence pathogens.
Specific Aim 3.--To provide challenge models for the characterization of infectious disease processes and the evaluation of diagnostics, therapeutics, or vaccines for Category A, B, and C agents.

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

File uploaded: BL4_progress_report.pdf

B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

Not Applicable

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

NOTHING TO REPORT

B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

NOTHING TO REPORT

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

The TBRI BL4 is fully booked with projects throughout 2015, many of which will involve nonhuman primates and most of which will examine vaccines for filoviruses or arenaviruses.

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

There were 8 studies in the SNPRC Veterinary Services Request list that were in progress or completed using nonhuman primates in maximum biocontainment during 2014. These studies were, for the most part, done under consortium arrangements with NIH, DOD, and FDA and most involved testing of filovirus vaccines. Five projects used cynomolgus macaques, two projects used common marmosets and one project used rhesus macaques.

C. COMPONENT PRODUCTS

C.1 PUBLICATIONS

Not Applicable

C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)

Not Applicable

C.3 TECHNOLOGIES OR TECHNIQUES

NOTHING TO REPORT

C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES

Not Applicable

C.5 OTHER PRODUCTS AND RESOURCE SHARING

C.5.a Other products

NOTHING TO REPORT

C.5.b Resource sharing

NOTHING TO REPORT

D. COMPONENT PARTICIPANTS

Not Applicable

E. COMPONENT IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES?

Not Applicable

E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE?

Not Applicable

E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER?

NOTHING TO REPORT

E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)?

Not Applicable

F. COMPONENT CHANGES

F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE

Not Applicable

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

NOTHING TO REPORT

F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS

F.3.a Human Subjects

No Change

F.3.b Vertebrate Animals

No Change

F.3.c Biohazards

No Change

F.3.d Select Agents

No Change

G. COMPONENT SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

Not Applicable

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

G.4.a Does the project involve human subjects?

No

G.4.b Inclusion Enrollment Data

Not Applicable

G.4.c ClinicalTrials.gov

Not Applicable

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

Not Applicable

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Not Applicable

G.8 PROJECT/PERFORMANCE SITES

Not Applicable

G.9 FOREIGN COMPONENT

Not Applicable

G.10 ESTIMATED UNOBLIGATED BALANCE

Not Applicable

G.11 PROGRAM INCOME

Not Applicable

G.12 F&A COSTS

Not Applicable

RPPR - Core-7329

RESEARCH & RELATED BUDGET - SECTION A & B FINAL

ORGANIZATIONAL DUNS*: 007936834

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Excluded by Requester				Project Lead	Institutional Base Salary	EFFORT			8,028.00	2,272.00	10,300.00
2.						Veterinarian					25,791.00	7,299.00	33,090.00
3.						Veterinarian					2,721.00	770.00	3,491.00
4.						Associate Director of Research					16,497.00	4,669.00	21,166.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **68,047.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
5	Veterinary Care Staff	6.0			9,715.00	2,750.00	12,465.00
5	**Total Number Other Personnel**					**Total Other Personnel**	**12,465.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**80,512.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	**0.00**
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	0.00
2. Foreign Travel Costs	0.00
Total Travel Cost	**0.00**

E. Participant/Trainee Support Costs		Funds Requested ($)*
1. Tuition/Fees/Health Insurance		0.00
2. Stipends		0.00
3. Travel		0.00
4. Subsistence		0.00
5. Other:		
0 Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	0.00
2. Publication Costs	0.00
3. Consultant Services	0.00
4. ADP/Computer Services	0.00
5. Subawards/Consortium/Contractual Costs	0.00
6. Equipment or Facility Rental/User Fees	0.00
7. Alterations and Renovations	0.00
Total Other Direct Costs	**0.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**80,512.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Federal Primate Center Rate	78.6	80,512.00	63,283.00
		Total Indirect Costs	**63,283.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**143,795.00**

J. Fee	Funds Requested ($)*
	0.00

K. Budget Justification* File Name:
(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

A. COMPONENT COVER PAGE

Project Title: Biomaterial Services

Component Project Lead Information:

Excluded by Requester

B. COMPONENT ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

Specific Aim 1:--To collect, store, and distribute tissues from experimental and diagnostic necropsies, and from animals sedated for other purposes.

Specific Aim 2:--To maintain a database of requests for and uses of tissues as well as transfer to Freezerworks inventory software.

Specific Aim 3:--To expand the routine collection and develop a specialized collection of chimpanzee tissues collected at necropsy.

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

File uploaded: Biomaterials_Services_B2.pdf

B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

Not Applicable

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

NOTHING TO REPORT

B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

NOTHING TO REPORT

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

For Specific Aim's 1 and 3, we plan to continue collecting and distributing tissues to qualified investigators in the research community. Regarding Specific Aim 2, we plan to expand the information entered into Freezerworks so a sample can be tracked from the animal to the investigator. Moreover, relevant data on the samples will be searchable with the other SNPRC primary databases (i.e., CAMP, the animal colony management data, pathology reports, etc.) by using the newly acquired "Labkey" database management software.

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

Under Specific Aim 1, Biomaterial Services has distributed 2726 samples of blood and tissues (including 209 samples of hair) to 43 investigators (12 affiliates, 7 cores and 24 other) from 25 institutions from January 1, 2014 through January 31, 2014. Biomaterial services also prepared 214 shipments of biologicals in 2014.
Under Specific Aim 2, transfer of 88,000 aliquot data from the Repository to the LIMS inventory management software, *Freezerworks*, was completed in 2014. New samples and their final distribution are now routinely entered into the database.
Under Specific Aim 3, in addition to specific investigator requests, we collect the same tissues that are collected by pathology during a diagnostic necropsy of naïve chimps so that we can store a frozen aliquot and have a formalin fixed paraffin embedded block for slides available for future researchers.

C. COMPONENT PRODUCTS

C.1 PUBLICATIONS

Not Applicable

C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)

Not Applicable

C.3 TECHNOLOGIES OR TECHNIQUES

NOTHING TO REPORT

C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES

Not Applicable

C.5 OTHER PRODUCTS AND RESOURCE SHARING

C.5.a Other products

NOTHING TO REPORT

C.5.b Resource sharing

NOTHING TO REPORT

D. COMPONENT PARTICIPANTS

Not Applicable

E. COMPONENT IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES?

Not Applicable

E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE?

Not Applicable

E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER?

NOTHING TO REPORT

E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)?

Not Applicable

F. COMPONENT CHANGES

F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE

Not Applicable

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

NOTHING TO REPORT

F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS

F.3.a Human Subjects

No Change

F.3.b Vertebrate Animals

No Change

F.3.c Biohazards

No Change

F.3.d Select Agents

No Change

G. COMPONENT SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

Not Applicable

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

G.4.a Does the project involve human subjects?

No

G.4.b Inclusion Enrollment Data

Not Applicable

G.4.c ClinicalTrials.gov

Not Applicable

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

Not Applicable

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Not Applicable

G.8 PROJECT/PERFORMANCE SITES

Not Applicable

G.9 FOREIGN COMPONENT

Not Applicable

G.10 ESTIMATED UNOBLIGATED BALANCE

Not Applicable

G.11 PROGRAM INCOME

Not Applicable

G.12 F&A COSTS

Not Applicable

RESEARCH & RELATED BUDGET - SECTION A & B FINAL

ORGANIZATIONAL DUNS*: 007936834

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Excluded by Requester				Project Lead	Institutional Base Salary	EFFORT			7,332.00	2,075.00	9,407.00
2.						Staff Scientist I					38,226.00	10,818.00	49,044.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **58,451.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
2	Research Personnel	14.4			55,479.00	15,701.00	71,180.00
2	**Total Number Other Personnel**					**Total Other Personnel**	**71,180.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**129,631.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	**0.00**
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	0.00
2. Foreign Travel Costs	0.00
Total Travel Cost	**0.00**

E. Participant/Trainee Support Costs		Funds Requested ($)*
1. Tuition/Fees/Health Insurance		0.00
2. Stipends		0.00
3. Travel		0.00
4. Subsistence		0.00
5. Other:		
0 Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	10,202.00
2. Publication Costs	0.00
3. Consultant Services	0.00
4. ADP/Computer Services	0.00
5. Subawards/Consortium/Contractual Costs	0.00
6. Equipment or Facility Rental/User Fees	0.00
7. Alterations and Renovations	0.00
Total Other Direct Costs	**10,202.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**139,833.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Federal Primate Center Rate	78.6	139,833.00	109,909.00
		Total Indirect Costs	**109,909.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**249,742.00**

J. Fee	Funds Requested ($)*
	0.00

K. Budget Justification* File Name:
(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

A. COMPONENT COVER PAGE

Project Title: Chimpanzee Colony

Component Project Lead Information:

Excluded by Requester

B. COMPONENT ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

The primary objectives goals of this component are to maintain the SNPRC chimpanzee colony as a research resource to serve the national biomedical research needs and to manage the research projects that are conducted with chimpanzees at the SNPRC. The specific aims are as follows:
Specific Aim 1.--To maintain a healthy, well defined population of chimpanzees and to make them available for research to the extent that is permitted by NIH.
Specific Aim 2.--To maintain chimpanzees, with well-defined research histories, for future projects that require naive animals or animals previously exposed to human pathogens.
Specific Aim 3.--To maintain a cohort of well characterized chimpanzees persistently infected with HBV or HCV for basic research on pathophysiology of hepatitis B and C, mechanisms of host-viral interactions, and immune response to HBC or HCV; as well as for testing the safety and efficacy of new candidate therapeutics and preventives.
Specific Aim 4.--To provide high quality care and enrichment for those chimpanzees that NIH does not permit to be used for research until they die of natural causes or are euthanized for humane reasons.
Specific Aim 5.--To manage all chimpanzees assigned to experimental protocols at the SNPRC.

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

File uploaded: Chimp_Colony_B2.pdf

B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

Not Applicable

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

NOTHING TO REPORT

B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

NOTHING TO REPORT

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

We plan to renovate the primadome complex to meet the EAE recommendations. These renovations include the planting of grass, replacement of wooden climbing structures, painting of culverts, placement of a bridge to connect two outside primadomes and other improvements as the new committee makes such recommendations. We will also attempt to make some larger social groups of chimpanzees to place in this housing configuration. Additionally we will make a commitment to provide opportunities for nesting for all chimpanzees housed at the SNPRC. Additional improvements may also be implemented pending the committee's recommendations.

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

We continue to maintain a healthy well-defined population of chimpanzees and to make them available for research that is permitted by NIH. SNPRC responded to a Request for Information (RFI): Ethologically appropriate environments (EAE) and facilities that house and maintain chimpanzees used in NIH-supported research on June 2,2014. This response detailed how the SNPRC would fulfill the IOM criteria for ethologically appropriate housing for chimpanzees selected by NIH to become part of the 50 chimpanzees designated for use for CRUP approved research. This resulted in a site visit conducted by OLAW on behalf of the NIH Division of Program Coordination, Planning and Strategic Initiatives on January 22, 2014. A report from Dr. Excluded by Requester Director of the Division of Compliance Oversight for OLAW concluded that the requirements for ng EAE are already in place or can be met with minimal additional effort and OLAW supports ongoing efforts for improvements to be made in this area. There also is a new SNPRC committee established to work on these ongoing efforts to improve the facilities and provide more ethologically appropriate environments for all chimpanzees housed at SNPRC. We continue to maintain chimpanzees with well-defined research histories and maintain the cohort of well characterized chimpanzees persistently infected with HBV or HCV. We continue to provide high quality care and enrichment for those chimpanzees that NIH does not permit to be used for research. We will continue to manage all chimpanzees assigned to experimental protocols until such time when such research will require a permit from the Fish and Wildlife Service.

C. COMPONENT PRODUCTS

C.1 PUBLICATIONS

Not Applicable

C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)

Not Applicable

C.3 TECHNOLOGIES OR TECHNIQUES

NOTHING TO REPORT

C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES

Not Applicable

C.5 OTHER PRODUCTS AND RESOURCE SHARING

C.5.a Other products

NOTHING TO REPORT

C.5.b Resource sharing

NOTHING TO REPORT

D. COMPONENT PARTICIPANTS

Not Applicable

E. COMPONENT IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES?

Not Applicable

E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE?

Not Applicable

E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER?

NOTHING TO REPORT

E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)?

Not Applicable

F. COMPONENT CHANGES

F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE

Not Applicable

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

NOTHING TO REPORT

F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS

F.3.a Human Subjects

No Change

F.3.b Vertebrate Animals

No Change

F.3.c Biohazards

No Change

F.3.d Select Agents

No Change

G. COMPONENT SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

Not Applicable

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

G.4.a Does the project involve human subjects?

No

G.4.b Inclusion Enrollment Data

Not Applicable

G.4.c ClinicalTrials.gov

Not Applicable

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

Not Applicable

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Not Applicable

G.8 PROJECT/PERFORMANCE SITES

Not Applicable

G.9 FOREIGN COMPONENT

Not Applicable

G.10 ESTIMATED UNOBLIGATED BALANCE

Not Applicable

G.11 PROGRAM INCOME

Not Applicable

G.12 F&A COSTS

Not Applicable

RESEARCH & RELATED BUDGET - SECTION A & B FINAL

ORGANIZATIONAL DUNS*: 007936834

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Excluded by Requester				Project Lead	Institutional Base Salary	EFFORT			28,423.00	8,044.00	36,467.00
2.						Associate Veterinarian					19,241.00	5,445.00	24,686.00
3.						Staff Scientist III					3,469.00	982.00	4,451.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **65,604.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
16	Veterinary Care Staff	102.0			354,223.00	100,247.00	454,470.00
16	**Total Number Other Personnel**					**Total Other Personnel**	**454,470.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**520,074.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	**0.00**
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	0.00
2. Foreign Travel Costs	0.00
Total Travel Cost	**0.00**

E. Participant/Trainee Support Costs		Funds Requested ($)*
1. Tuition/Fees/Health Insurance		0.00
2. Stipends		0.00
3. Travel		0.00
4. Subsistence		0.00
5. Other:		
0 Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	214,277.00
2. Publication Costs	0.00
3. Consultant Services	0.00
4. ADP/Computer Services	0.00
5. Subawards/Consortium/Contractual Costs	0.00
6. Equipment or Facility Rental/User Fees	0.00
7. Alterations and Renovations	0.00
8. Pathology	29,316.00
9. T. cruzi Testing, Other Services	4,868.00
10. Telecommunications, Freight, Overtime	12,250.00
Total Other Direct Costs	**260,711.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**780,785.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Federal Primate Center Rate	78.6	780,785.00	613,697.00
		Total Indirect Costs	**613,697.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**1,394,482.00**

J. Fee	Funds Requested ($)*
	0.00

K. Budget Justification* File Name:
(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

A. COMPONENT COVER PAGE

Project Title: Clinical and Anatomic Pathology

Component Project Lead Information:

Excluded by Requester

B. COMPONENT ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

Specific Aim 1: To provide outstanding Anatomic Pathology Services through comprehensive anatomic pathology services, including gross examination at necropsy, supplemented by histology, cytopathology, immunopathology, cryopathology, special stains and other specialized techniques.
Specific Aim 2: To provide outstanding Clinical Pathology Services through comprehensive clinical pathology services, including analysis of blood, urine, feces, cerebrospinal fluid, and other bodily fluids by chemical, hematologic, and microbiologic methods.
Specific Aim 3: To provide outstanding Clinical and Research Support by assisting clinical veterinarians and investigators in interpreting pathologic data and recording the findings for future reference, and by organizing results of anatomic and clinical pathology assessments to improve the characterization of primates for research and possibly identify new models of human disease.
Specific Aim 4: To provide outstanding Tissue Share Services by working closely with Biomaterials Services to ensure efficient procurement of nonhuman primate tissues for investigators within and outside the SNPRC and to ensure the collection and storage of unique pathological tissues.
Specific Aim 5: To provide outstanding Teaching and Education by educating interested individuals in pathology and laboratory animal medicine, pursuing collaborative research, and publishing results in the scientific literature.

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

File uploaded: clin_anat_path_B2.pdf

B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

Not Applicable

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

NOTHING TO REPORT

B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

NOTHING TO REPORT

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

Continue to provide colony and research anatomic and clinical pathology support, tissue share support, publication preparation, and training for interns, externs, and other professional or technical personnel.

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

Anatomic Pathology evaluated 685 necropsy and biopsy cases, generated 7321 histologic slides, and collected 1145 tissue samples for the biomaterials program during 2014. Clinical Pathology performed 39,633 assays during 2014. Anatomic and Clinical Pathology hosted 6 visiting students, veterinarians and scientists, as well as 3 guests from other institutions during 2014.

C. COMPONENT PRODUCTS

C.1 PUBLICATIONS

Not Applicable

C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)

Not Applicable

C.3 TECHNOLOGIES OR TECHNIQUES

NOTHING TO REPORT

C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES

Not Applicable

C.5 OTHER PRODUCTS AND RESOURCE SHARING

C.5.a Other products

NOTHING TO REPORT

C.5.b Resource sharing

NOTHING TO REPORT

D. COMPONENT PARTICIPANTS

Not Applicable

E. COMPONENT IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES?

Not Applicable

E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE?

Not Applicable

E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER?

NOTHING TO REPORT

E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)?

Not Applicable

F. COMPONENT CHANGES

F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE

Not Applicable

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

NOTHING TO REPORT

F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS

F.3.a Human Subjects

No Change

F.3.b Vertebrate Animals

No Change

F.3.c Biohazards

No Change

F.3.d Select Agents

No Change

G. COMPONENT SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

Not Applicable

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

G.4.a Does the project involve human subjects?

No

G.4.b Inclusion Enrollment Data

Not Applicable

G.4.c ClinicalTrials.gov

Not Applicable

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

Not Applicable

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Not Applicable

G.8 PROJECT/PERFORMANCE SITES

Not Applicable

G.9 FOREIGN COMPONENT

Not Applicable

G.10 ESTIMATED UNOBLIGATED BALANCE

Not Applicable

G.11 PROGRAM INCOME

Not Applicable

G.12 F&A COSTS

Not Applicable

RESEARCH & RELATED BUDGET - SECTION A & B FINAL

ORGANIZATIONAL DUNS*: 007936834

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Excluded by Requester				Project Lead	Institutional Base Salary	EFFORT			29,328.00	8,300.00	37,628.00
2.						Associate Veterinarian					23,306.00	6,596.00	29,902.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **67,530.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
6	Laboratory Personnel	23.52			97,349.00	27,550.00	124,899.00
6	**Total Number Other Personnel**					**Total Other Personnel**	**124,899.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**192,429.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	**0.00**
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	0.00
2. Foreign Travel Costs	0.00
Total Travel Cost	**0.00**

E. Participant/Trainee Support Costs		Funds Requested ($)*
1. Tuition/Fees/Health Insurance		0.00
2. Stipends		0.00
3. Travel		0.00
4. Subsistence		0.00
5. Other:		
0 Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	50,090.00
2. Publication Costs	0.00
3. Consultant Services	0.00
4. ADP/Computer Services	0.00
5. Subawards/Consortium/Contractual Costs	0.00
6. Equipment or Facility Rental/User Fees	0.00
7. Alterations and Renovations	0.00
8. Laboratory Services	16,454.00
9. Other Services	1,884.00
10. Freight	3,130.00
Total Other Direct Costs	**71,558.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**263,987.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Federal Primate Center Rate	78.6	263,989.00	207,495.00
		Total Indirect Costs	**207,495.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**471,482.00**

J. Fee	Funds Requested ($)*
	0.00

K. Budget Justification* File Name:
(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

A. COMPONENT COVER PAGE

Project Title: DNA and Tissue Repository
Component Project Lead Information:
Excluded by Requester

B. COMPONENT ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

The Southwest National Primate Research Center maintains a DNA and Tissue Repository for Comparative Biology and Genomics as a service to the scientific community. Biological samples are collected from all nonhuman primate (NHP) species maintained at the SNPRC and can be associated with available phenotypic and genetic information for the animals. The goal of this unique resource is to facilitate a broad range of research projects by investigators from around the country.

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

File uploaded: Repository_B2.pdf

B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

Not Applicable

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

NOTHING TO REPORT

B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

NOTHING TO REPORT

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

We will continue activities as described in section B2.

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

Specific Aim 1: To collect and store NHP tissue samples and blood products, including serum, plasma, peripheral blood mononuclear cells (PBMC) and clot samples, in a long-term repository.

Table 1 lists samples archived in the Repository in 2014.

Tissue Type	Baboon	Chimp	Marmoset	Rhesus	Total
Clot	391	120	0	199	710
Plasma	0	60	0	0	60
Serum	391	120	0	199	710
WBC	392	67	0	199	658
Brain, Cerebellum	29	2	0	1	32
Brain, Cerebral Cortex	29	2	0	1	32
Fat, Abdominal	33	2	2	1	38
Heart, Left Ventricle	33	2	2	1	38
Kidney, Cortex & Medulla	21	1	0	0	22
Kidney, Cortex	12	0	2	1	15
Kidney, Medulla	12	0	2	1	15
Kidney, Wedge	12	0	2	1	15
Liver	36	2	3	2	43
Muscle, Skeletal	34	2	2	1	39
Total	**1425**	**380**	**15**	**607**	**2427**

Specific Aim 2: To maintain an archive of NHP serum, plasma, PBMC, clot, tissue and DNA samples which can be accessed by investigators engaged in research on comparative biology and genomics.

Table 2 lists samples provided to investigators from Repository requests in 2014.

Sample Type	Baboon	Chimp	Cyno	Marmoset	Rhesus	Tamarin	Total
Brain, Hind	6				6		12
Brain, C. Cortex	6						6
Heart, L.Ven.	6						6
Kidney	6				6		12
Liver	20	14	10	14	20	2	80
Skeletal Muscle	6				6		12
DNA		8					8
Serum	38				6		44
WBCs	6				6		12
Total	**94**	**22**	**10**	**14**	**50**	**2**	**192**

Specific Aim 3: To maintain a fully auditable database for all archived SNPRC NHP serum, plasma, PBMC, clot, tissue and DNA samples in a long-term repository.

Two major activities for this Aim have been 1) implementation of FreezerWorks unlimited database for maintenance of a detailed inventory, and 2) detailed inventory of all samples in the Repository.

1) Implementation of FreezerWorks unlimited database. We moved our repository electronic records from the basic version of FreezerWorks database to the unlimited version. The unlimited version allows more flexibility for information content and organization in the user interface. This flexibility includes flexibility in template design for export of data, which is relevant to use of our Pedsys database as an independent backup for the Repository inventory and eventual interface of the Repository inventory with LabKey.

2) Detailed inventory of all samples in the Repository. The locations of existing samples in the Repository inventory include freezer, rack and box location but do not include location within the box. Inclusion of box row and column location for each sample dramatically reduces sample retrieval time for sample requests and

allows a more rapid re-inventory of samples. We are currently updating our inventory to include within box location of samples. In addition, in April 2014 we began adding barcodes to labels on tubes. All samples with barcodes can be tracked using a barcode reader allowing semi-automated tracking of samples that are added to and removed from the Repository.

C. COMPONENT PRODUCTS

C.1 PUBLICATIONS

Not Applicable

C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)

Not Applicable

C.3 TECHNOLOGIES OR TECHNIQUES

NOTHING TO REPORT

C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES

Not Applicable

C.5 OTHER PRODUCTS AND RESOURCE SHARING

C.5.a Other products

NOTHING TO REPORT

C.5.b Resource sharing

File uploaded: Repository_resource_sharing_C5b.pdf

SNPRC Repository resources are made available via requests throught the SNPRC website: http://www.txbiomed.org/primate-research-center/contact/biological-materials-request.

D. COMPONENT PARTICIPANTS

Not Applicable

E. COMPONENT IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES?

Not Applicable

E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE?

Not Applicable

E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER?

NOTHING TO REPORT

E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)?

Not Applicable

F. COMPONENT CHANGES

F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE

Not Applicable

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

There may be changes to our electronic inventory process once LabKey is implemented. Until LabKey is implemented we won't' know the nature of these changes.

F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS

F.3.a Human Subjects

No Change

F.3.b Vertebrate Animals

No Change

F.3.c Biohazards

No Change

F.3.d Select Agents

No Change

G. COMPONENT SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

Not Applicable

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

G.4.a Does the project involve human subjects?

No

G.4.b Inclusion Enrollment Data

Not Applicable

G.4.c ClinicalTrials.gov

Not Applicable

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

Not Applicable

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Not Applicable

G.8 PROJECT/PERFORMANCE SITES

Not Applicable

G.9 FOREIGN COMPONENT

Not Applicable

G.10 ESTIMATED UNOBLIGATED BALANCE

Not Applicable

G.11 PROGRAM INCOME

Not Applicable

G.12 F&A COSTS

Not Applicable

RESEARCH & RELATED BUDGET - SECTION A & B FINAL

ORGANIZATIONAL DUNS*: 007936834

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Excluded by Requester				Project Lead	Institutional Base Salary		EFFORT		8,249.00	2,334.00	10,583.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **10,583.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
4	Sr. Research Assistant/Associates	17.7			81,873.00	23,170.00	105,043.00
4	**Total Number Other Personnel**					**Total Other Personnel**	**105,043.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**115,626.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	**0.00**
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	0.00
2. Foreign Travel Costs	0.00
Total Travel Cost	**0.00**

E. Participant/Trainee Support Costs		Funds Requested ($)*
1. Tuition/Fees/Health Insurance		0.00
2. Stipends		0.00
3. Travel		0.00
4. Subsistence		0.00
5. Other:		
0 Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	9,746.00
2. Publication Costs	0.00
3. Consultant Services	0.00
4. ADP/Computer Services	0.00
5. Subawards/Consortium/Contractual Costs	0.00
6. Equipment or Facility Rental/User Fees	0.00
7. Alterations and Renovations	0.00
8. Pathology	1,627.00
Total Other Direct Costs	**11,373.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**126,999.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Federal Primate Center Rate	78.6	126,999.00	99,821.00
		Total Indirect Costs	**99,821.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**226,820.00**

J. Fee	Funds Requested ($)*
	0.00

K. Budget Justification* File Name:
(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

A. COMPONENT COVER PAGE

Project Title: Immunology Core Laboratory

Component Project Lead Information:

Excluded by Requester

B. COMPONENT ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

The Immunology Core Laboratory (ICL) is a Core Science Service component of the Southwest National Primate Research Center. As a Core, the ICL provides services in support of nonhuman primate research to investigators at the SNPRC and Texas Biomed, and to scientists from around the country. The ICL provides services in the areas of Flow Cytometry for cell sorting and phenotyping, immunological assays based on Luminex technology, and serological surveillance for a number of viral agents relevant for NHP colony management and research.
The specific aims of the ICL are:
Specific Aim 1.--To provide assays based in flow cytometry for the characterization of blood cell subsets and the determination of cell mediated activity in nonhuman primate species, including cell sorting at BSL-3 level.
Specific Aim 2.--To provide methodologies for the simultaneous determination of multiple cytokines in biological fluids derived from nonhuman primate species.
Specific Aim 3.--To provide serological viral surveillance for the SNPRC SPF Indian rhesus macaque and baboon breeding colonies.

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

File uploaded: ICL_B2.pdf

B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

Not Applicable

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

NOTHING TO REPORT

B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

Services provided by the ICL are advertised in the SNPRC website.

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

The ICL will continue to support research and breeding programs with the three Specific Aims stated in section B.1. We expect to perform more cell sorting of stem cells in the upcoming year, and start cytokines quantification in ABSL-4 containment. In order to provide viral screening assays for the two Indian rhesus macaque breeding colonies, and for the increased use of cell sorting, we are adding and training more personnel so that this increased usage of the Core does not affect the quality and timeliness of our operations.

B.2 (ICL_B2.pdf)

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

During 2014, the ICL performed 6,208 flow cytometry assays (with one tube considered as one assay), and 6,018 Luminex assays (with one well of a 96-well plate considered as one assay). The ICL also performed Luminex-based antiviral testing in 1,149 plasma samples from the SNPRC rhesus and baboon colonies. The ICL has participated in a total of seven of EQAPOL's External Proficiency programs for Luminex testing and in two proficiency programs for Flow Cytometry. The EQAPOL (External Quality Assurance Oversight Laboratory) at Duke University is supported by the Division of AIDS at NIAID, and its mission is to assess factors contributing to variability in flow cytometry and multiplex human cytokine assays. The ICL ranks in the top 10% of 40 international laboratories in each EP.

C. COMPONENT PRODUCTS

C.1 PUBLICATIONS

Not Applicable

C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)

Not Applicable

C.3 TECHNOLOGIES OR TECHNIQUES

We have developed a new technique for the identification of antibodies against numerous viral antigens in nonhuman primates using the Luminex technology. A manuscript is being finalized with such technique.

C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES

Not Applicable

C.5 OTHER PRODUCTS AND RESOURCE SHARING

C.5.a Other products

File uploaded: immunology_C5a.pdf

C.5.b Resource sharing

NOTHING TO REPORT

We have tested and validated two commercially available NHP cytokine detection kits against molecules from seven Old World Monkey and two New World Monkey species. We demonstrated that some of the components of these kits do not work for most of these species.

D. COMPONENT PARTICIPANTS

Not Applicable

E. COMPONENT IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES?

Not Applicable

E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE?

Not Applicable

E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER?

As explained in C.5.a, we have tested and validated two commercially available NHP cytokine detection kits against molecules from seven Old World Monkey and two New World Monkey species. We demonstrated that some of the components of these kits do not work for most of these species. These results will allow these companies to promote their product with more accuracy.

E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)?

Not Applicable

F. COMPONENT CHANGES

F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE

Not Applicable

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

NOTHING TO REPORT

F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS

F.3.a Human Subjects

No Change

F.3.b Vertebrate Animals

No Change

F.3.c Biohazards

File uploaded: immunology_F3c.pdf

F.3.d Select Agents

No Change

Cell sorting of cells from nonhuman primate origin is a potential biohazard due to the formation of aerosols during the sorting process. In order to eliminate this biohazard potential, the FACS Aria cell sorter has been placed inside a class II biosafety cabinet (BioProtect IV), and this cabinet is also placed inside a Biosafety Level 3 laboratory. The ICL has developed an SOP for verification that there is no aerosol escape from the instrument during operation, and the SOP has been approved by the institutional office of Environmental Health & Safety.

G. COMPONENT SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

Not Applicable

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

G.4.a Does the project involve human subjects?

No

G.4.b Inclusion Enrollment Data

Not Applicable

G.4.c ClinicalTrials.gov

Not Applicable

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

Not Applicable

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Not Applicable

G.8 PROJECT/PERFORMANCE SITES

Not Applicable

G.9 FOREIGN COMPONENT

Not Applicable

G.10 ESTIMATED UNOBLIGATED BALANCE

Not Applicable

G.11 PROGRAM INCOME

Not Applicable

G.12 F&A COSTS

Not Applicable

RESEARCH & RELATED BUDGET - SECTION A & B FINAL

ORGANIZATIONAL DUNS*: 007936834

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Excluded by Requester				Project Lead	Institutional Base Salary	EFFORT			27,495.00	7,781.00	35,276.00
2.						Staff Scientst					23,534.00	6,660.00	30,194.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **65,470.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Research Technician	9.0			44,585.00	12,618.00	57,203.00
1	**Total Number Other Personnel**					**Total Other Personnel**	**57,203.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**122,673.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	**0.00**
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	0.00
2. Foreign Travel Costs	0.00
Total Travel Cost	**0.00**

E. Participant/Trainee Support Costs		Funds Requested ($)*
1. Tuition/Fees/Health Insurance		0.00
2. Stipends		0.00
3. Travel		0.00
4. Subsistence		0.00
5. Other:		
0 Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	36,450.00
2. Publication Costs	0.00
3. Consultant Services	0.00
4. ADP/Computer Services	0.00
5. Subawards/Consortium/Contractual Costs	0.00
6. Equipment or Facility Rental/User Fees	0.00
7. Alterations and Renovations	0.00
Total Other Direct Costs	**36,450.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**159,123.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Federal Primate Center Rate	78.6	159,123.00	125,071.00
		Total Indirect Costs	**125,071.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**284,194.00**

J. Fee	Funds Requested ($)*
	0.00

K. Budget Justification* File Name:
(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

A. COMPONENT COVER PAGE

Project Title: Improvement and Modernization

Component Project Lead Information:

Excluded by Requester

B. COMPONENT ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

The aim of this component is to continue to develop the SNPRC infrastructure through improvements and modernization of primate facilities, laboratories, and offices, in order to support the efficient and safe conduct of biomedical research with nonhuman primates. The primary goal is to address the most critical needs of the SNPRC. The single aim addressed by this component is to upgrade facilities assigned to the SNPRC. Acquisition, replacement, renovation and improvement plans include the following projects to be completed during the reporting period for the grant period.
1.Renovation of the Main Surgery Suite in Specific Animal Location
2.Installation of New Cage Storage Area Adjacent to Specific Animal Location
3.Renovation of Rhesus U42-supported Colony Cage Floor

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

File uploaded: Improvement_and_Modernization_B2.pdf

B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

Not Applicable

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

NOTHING TO REPORT

B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

NOTHING TO REPORT

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

The renovation of the Main Surgery Suite in Specific Animal will require further assessment to determine appropriate scope and applicability. The acquisition of the New England Primate Research Center Macaque and Marmoset colonies has the potential to increase our study load and utilization of the building. It will remain as a modernization goal for the next funding year. Installation of the area adjacent to Specific Animal Location will be transformed into a Cage Storage area once the SNPRC maintenance shop has been completely relocated. In the next year (2015-2016) renovation of Specific Animal be done to meet the increasing demands of our growing SPF macaque and HIV work. Another project proposed is the resurfacing of floors in Specific Animal Location The replacement of existing chain link fabric in Specific Animal is another goal of next year's improvements and modernization. A major renovation will be accomplished in Specific Animal Location renovation is supported by at G20 but will require some host funding as well. This building will house the expansion of the NEPR macaque colony.

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

The renovation of the Main Surgery Suite in Specific Animal Location continues to be a priority for the SNPRC clinical and research surgical program. The scope of this effort has expanded to include consideration of its use in other primate species by means of expanding the surgical lab's use. Therefore, it is under reevaluation and redesign based the feasibility of expanding its use. This is an ongoing assessment influenced by increased procedures anticipated in the SPF rhesus and the marmoset.

The installation of the Cage Storage Area Adjacent to Specific Animal Location is a phase of a master plan to centralize all SNPRC cage maintenance, repair and fabrication, storage of repaired and in-service caging. In close proximity to the proposed Specific Animal storage area is a large service building being repurposed for the SNPRC cage maintenance shop. Upon completion of this effort the proposed storage area will proceed to accommodate appropriate caging. As a prelude to the installation of the storage area adjacent Specific Animal Location all the bulk of caging likely to remain in service has been segregated from the out of service cages. Therefore priority will be given to this subset of cages as well as those put into circulation after repair or fabrication.

The Renovation of the U42-supported rhesus colony cage floors began in late funding year 15 and the effort was carried through into year 16 (2014-2015). The renovation of the cage flooring required the woven wire (hog wire) in Specific Animal Location be replaced. This entailed modification of Specific Animal Location The successful completion of this project has increased the access animals have to feed and decreased the incidence of injuries related to a raised flooring system previously in existence.

During the current year SNPRC performed extensive renovation of two areas Specific Animal Location was renovated partly with funds from a G20 grant, but a large amount of the funding came from Texas Biomed. This renovated building will house the NEPRC rhesus macaque colony. The second major renovation Specific Animal Location This was accomplished with a supplement to the base grant and was also supported by Texas Biomed. As discussed in the original budget justification, most of the funds for renovation come from the host or from G20 or C06 grants. This component does not have sufficient budget to fund major renovations.

C. COMPONENT PRODUCTS

C.1 PUBLICATIONS

Not Applicable

C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)

Not Applicable

C.3 TECHNOLOGIES OR TECHNIQUES

NOTHING TO REPORT

C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES

Not Applicable

C.5 OTHER PRODUCTS AND RESOURCE SHARING

C.5.a Other products

NOTHING TO REPORT

C.5.b Resource sharing

NOTHING TO REPORT

D. COMPONENT PARTICIPANTS

Not Applicable

E. COMPONENT IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES?

Not Applicable

E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE?

Not Applicable

E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER?

NOTHING TO REPORT

E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)?

Not Applicable

F. COMPONENT CHANGES

F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE

Not Applicable

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

NOTHING TO REPORT

F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS

F.3.a Human Subjects

No Change

F.3.b Vertebrate Animals

No Change

F.3.c Biohazards

No Change

F.3.d Select Agents

No Change

G. COMPONENT SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

Not Applicable

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

G.4.a Does the project involve human subjects?

No

G.4.b Inclusion Enrollment Data

Not Applicable

G.4.c ClinicalTrials.gov

Not Applicable

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

Not Applicable

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Not Applicable

G.8 PROJECT/PERFORMANCE SITES

Not Applicable

G.9 FOREIGN COMPONENT

Not Applicable

G.10 ESTIMATED UNOBLIGATED BALANCE

Not Applicable

G.11 PROGRAM INCOME

Not Applicable

G.12 F&A COSTS

Not Applicable

RESEARCH & RELATED BUDGET - SECTION A & B FINAL

ORGANIZATIONAL DUNS*: 007936834

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Excluded by Requester				Project Lead	Institutional Base Salary		EFFORT		9,165.00	2,594.00	11,759.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **11,759.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**					**Total Other Personnel**	**0.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**11,759.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	**0.00**
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	0.00
2. Foreign Travel Costs	0.00
Total Travel Cost	**0.00**

E. Participant/Trainee Support Costs		Funds Requested ($)*
1. Tuition/Fees/Health Insurance		0.00
2. Stipends		0.00
3. Travel		0.00
4. Subsistence		0.00
5. Other:		
0 Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	0.00
2. Publication Costs	0.00
3. Consultant Services	0.00
4. ADP/Computer Services	0.00
5. Subawards/Consortium/Contractual Costs	0.00
6. Equipment or Facility Rental/User Fees	0.00
7. Alterations and Renovations	56,454.00
Total Other Direct Costs	**56,454.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**68,213.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Federal Primate Center Rate	78.6	11,759.00	9,243.00
		Total Indirect Costs	**9,243.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**77,456.00**

J. Fee	Funds Requested ($)*
	0.00

K. Budget Justification*	File Name: BUDGET JUSTIFICATIION_2-26-15.pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

BUDGET JUSTIFICATIION

Improvement and Modernization

The Leader of this Component has changed. Excluded by Requester the previous leader, retired last year and Excluded by Requester, the Associate Director of Veterinary Resources and Research Support, is the new Leader.

A. COMPONENT COVER PAGE

Project Title: Macaque Colony

Component Project Lead Information:

Excluded by Requester

B. COMPONENT ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

The goal of this project is to increase the nation's capacity to produce Indian-origin rhesus monkeys (Macaca mulatta) that are specific pathogen-free (SPF) for herpes B virus, SIV, SRV, and STLV-1. The colony will continue to produce high quality genetically characterized animals for use in AIDS-related research by NIH grantees based at SNPRC and at other research institutions. Most of the founding stock of the SNPRC Colony 1 was obtained through acquisition of an existing SPF colony from the U.S. Air Force (USAF). The breeding colony enables an annual production of 70 animals per year for AIDS-related research. This program has been expanded to include a new SPF colony, SNPRC Colony 2.

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

File uploaded: macaque_accomplishments_B2.pdf

B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

Not Applicable

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

NOTHING TO REPORT

B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

NOTHING TO REPORT

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

During the next reporting period, the remaining macaques for Colony 2 will be received from NEPRC, processed through quarantine and acclimated to the newly renovated building that will house them. Colony 2 will not provide animals for research during the next year, since the colony is comprised of breeding harems and one year old off spring. The colony will be expanded and research animals will become available in the next 2-3 years. Colony 1 (the existing SNPRC colony) will provide approximately 75 animals for research. Many of these animals will be used in the studies of Excluded by including a new vaccine study supported by Private Source Excluded by Requester has new studies initiating on a novel HIV vaccine as well. All animals will be screened for the SPF agents twice during the year. We expect to genotype over 200 animals for MHC haplotype with Wisconsin NPRC and to initiate the new initiative of high throughput sequencing of total genomes for macaques.

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

This year, we will receive approximately 260 macaques from NEPRC to form a new colony, SNPRC Colony 2. A building was renovated to house the new colony. These animals will be maintained genetically and physically separate from SNPRC Colony 1. This colony will be expanded to provide 55 new animals per year for research. From Colony 1, we recorded 81 live births in 2014, and 156 animals were used by investigators. A major use of animals this year was a new Private Source funded vaccine trial conducted by Excluded by Requester Excluded by Requester We continue to outsource MHC typing to Wisconsin NPRC. Typing was performed on 180 ani ve instituted the new NIH guidelines for SPF verification. As in the past, the initial screening will be for serology using the Luminex technology. Confirmatory screening by western blot and PCR will be outsourced to California NPRC and the National B virus laboratory. Consistent with the new guidelines, we will add PCR screening for SRV for the entire colony in the coming year. We have begun a new initiative to genotype by high throughput total genome sequencing. High throughput sequencing will provide the genetic markers to ensure Indian origin and pedigree, but will also increase our capacity for genetic management of the colony and the ability to provide animals with greater genetic characterization to investigators.

C. COMPONENT PRODUCTS

C.1 PUBLICATIONS

Not Applicable

C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)

Not Applicable

C.3 TECHNOLOGIES OR TECHNIQUES

NOTHING TO REPORT

C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES

Not Applicable

C.5 OTHER PRODUCTS AND RESOURCE SHARING

C.5.a Other products

NOTHING TO REPORT

C.5.b Resource sharing

NOTHING TO REPORT

D. COMPONENT PARTICIPANTS

Not Applicable

E. COMPONENT IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES?

Not Applicable

E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE?

Not Applicable

E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER?

NOTHING TO REPORT

E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)?

Not Applicable

F. COMPONENT CHANGES

F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE

Not Applicable

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

NOTHING TO REPORT

F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS

F.3.a Human Subjects

No Change

F.3.b Vertebrate Animals

No Change

F.3.c Biohazards

No Change

F.3.d Select Agents

No Change

G. COMPONENT SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

Not Applicable

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

G.4.a Does the project involve human subjects?

No

G.4.b Inclusion Enrollment Data

Not Applicable

G.4.c ClinicalTrials.gov

Not Applicable

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

Not Applicable

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Not Applicable

G.8 PROJECT/PERFORMANCE SITES

Not Applicable

G.9 FOREIGN COMPONENT

Not Applicable

G.10 ESTIMATED UNOBLIGATED BALANCE

Not Applicable

G.11 PROGRAM INCOME

Not Applicable

G.12 F&A COSTS

Not Applicable

RPPR - Core-7337

RESEARCH & RELATED BUDGET - SECTION A & B FINAL

ORGANIZATIONAL DUNS*: 007936834

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Excluded by Requester				Project Lead	Institutional Base Salary	EFFORT			4,583.00	1,297.00	5,880.00
2.						Veterinarian					650.00	184.00	834.00
3.						Associate Veterinarian					1,706.00	483.00	2,189.00
4.						Staff Scientist III					548.00	155.00	703.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **9,606.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
28	Veterinary Care Staff	12.81			37,032.00	10,482.00	47,514.00
28	**Total Number Other Personnel**					**Total Other Personnel**	**47,514.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**57,120.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	**0.00**
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	0.00
2. Foreign Travel Costs	0.00
Total Travel Cost	**0.00**

E. Participant/Trainee Support Costs		Funds Requested ($)*
1. Tuition/Fees/Health Insurance		0.00
2. Stipends		0.00
3. Travel		0.00
4. Subsistence		0.00
5. Other:		
0 Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	18,017.00
2. Publication Costs	0.00
3. Consultant Services	0.00
4. ADP/Computer Services	0.00
5. Subawards/Consortium/Contractual Costs	0.00
6. Equipment or Facility Rental/User Fees	0.00
7. Alterations and Renovations	0.00
8. Pathology, T cruzi Testing	4,246.00
9. Viral Testing	684.00
10. Other Services, Freight, Overtime	2,071.00
Total Other Direct Costs	**25,018.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**82,138.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Federal Primate Center Rate	78.6	82,138.00	64,560.00
		Total Indirect Costs	**64,560.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**146,698.00**

J. Fee	Funds Requested ($)*
	0.00

K. Budget Justification* File Name: BUDGET JUSTIFICATIION_2-26-15.pdf
(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

BUDGET JUSTIFICATIION

Macaque Colony

The Leader of this Component has changed. Excluded by Requester became the Leader upon the Personal Info last year. Excluded by Requester also became the PI of the recently renewed U42 grant that supports the SPF macaque colony.

A. COMPONENT COVER PAGE

Project Title: Marmoset Colony

Component Project Lead Information:

Excluded by Requester

B. COMPONENT ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

The Southwest National Primate Research Center has an active and growing program to develop and supply the common marmoset (Callithrix jacchus) as a biomedical research resource. We propose to further enhance this SNPRC resource through the inclusion of a segment of the marmoset colony from the New England Primate Research Center. This revised proposal requests support for this activity.
The overall aims of the marmoset colony in the last competitive renewal were:

Aim 1: To continue production of marmosets for use in biomedical research.

Aim 2: To further consortium arrangements with Wisconsin NPRC, New England PRC and the NIH Intra-mural program. Two specific goals within this aim are to have a defined, accepted profile of a marmoset diet and a SNP panel that can be used as a tool to define best animal use and animal breeding.

Aim 3: To continue comparison of the SPF, barrier-maintained marmoset colony with the conventionally housed colonies, in order to identify those aspects of research use (e.g., healthy longevity) which will specifically benefit from this SPF, barrier approach to colony management and animal production.

The following revised additional aims are proposed with the addition of the NEPRC marmosets to the SNPRC:

Aim 1: To continue production of marmosets for use in biomedical research with the NEPRC marmosets contributing to that continued production. The NEPRC marmosets will be maintained as a separate population, with husbandry and diet maintained as closely as possible to the original NEPRC protocols. The increased size of the total colony will greatly enhance our ability to meet the needs of NIH-funded investigators, some of which currently use the marmoset model at NEPRC.

Aim 2: To conduct planned comparisons of factors that represent important sources underlying phenotypic variation within and among marmoset populations. These comparisons will provide a means to identify best practices as regards to husbandry and best methods for assigning subjects to studies or breeding in relation to genetic variation. This aim will be conducted in collaboration with the Wisconsin NPRC.

Aim 3: To establish a specific resource of geriatric marmosets to be used in studies of aging and chronic disease.

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

File uploaded: Marmoset_Colony_B2.pdf

B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

Not Applicable

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

NOTHING TO REPORT

B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

NOTHING TO REPORT

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

The primary aim of the coming grant period continues to be to produce marmosets and provide them to NIH-supported investigators. Colony 1 was minimally able to meet the present SNPRC need and was not able to support any growth in projects or any sales to outside investigators. The addition of the colony 2 more than doubles the SNPRC marmoset population – from 146 to 327 animals. More specifically, it increases the SNPRC marmoset population available for use or breeding in 2015 by 60% - from 97 to 148 animals. After assessing the age/sex structure of each population, and the anticipated need for on-site projects in 2015 and 2016, we plan to provide some marmosets to at least 3-4 of the investigators who have unmet requests, with preference given to those investigators who will be using the animals in NIH-funded projects.

Production
Between the two marmoset colonies, the present breeding population is 21 breeding pairs – marmosets are routinely housed as mated male x female pairs plus up to 6-7 of their offspring, reflecting their social structure in the wild and ensuring that non-breeding individuals gain experience in cooperative infant care, increasing their value as future breeders (18). Our historic data on production of weaned offspring per pair per year indicates that an estimate of 2.2 young per pair per year is a conservative target. We propose to produce 70 weaned young per year, plus 10 replacement breeders, requiring a breeding population of 36 pairs for 2015. Therefore, we will be retaining 30 animals (15 males and 15 females) as new breeding stock, for a total of 18 breeding groups in each colony.

Genetic Management
While maintaining the SNPRC and NEPRC populations as separate entities, we will design and implement plans to define the genetic diversity in the two populations. Based upon these findings, we will structure a long-term management plan to most effectively maintain the diversity present in the populations.

The major goals of our breeding program are to maintain the genetic diversity present in each colony and, in the future be able to enrich for genetic variants of interest to investigators using these animals for biomedical research. The SNPRC Genomics Core will begin sequencing both Colony 1 and Colony 2 with the ultimate goal for the marmosets will be to identify >50,000 SNPs that will provide information for genetic management, as well as determine the genetic differences in the two colonies that will benefit research scientists.

Nutritional Management
We also intend to design and implement plans to determine effects of dietary change upon health in these two marmoset populations, ultimately defining the best diet for continued use. The development of these studies will be undertaken as part of colony development in collaboration with Wisconsin NPRC but ultimately the projects are proposed to be supported by an R24 grant from ORIP. Pending Support

Pending Support

Geriatric Resource Development
We plan to establish a specific resource of geriatric marmosets to be used in studies of aging and chronic disease. With its small size and short life span, the marmoset presents unique opportunities for aging studies. The collaboration between the Barshop Institute for Longevity & Aging Studies (UTHSCSA) and the SNPRC – two, geographically close institutions with established expertise in marmoset research resource development and aging research - will allow us to parlay the strengths of each institution, to further aging research and ensure a stable base of support for the required resources. With the addition of colony 2, the SNPRC has one of the largest marmoset research populations in the U.S. and the only large (>70) population of aged (> 10 years) marmosets in the country, while the Barshop Institute has the only specially designed barrier facility for long-term housing and research use of marmosets.

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

Colony 2 Relocation

We successfully relocated 90 marmosets from NEPRC to SNPRC in November, 2014 and an additional 90 animals in January, 2015 – hereafter referred to as Colony 2. The animals were shipped in intact social units as much as is possible given limitations of transport crate size. We set up the marmosets in caging configurations that, as closely as possible, mirrored their configuration at NEPRC, in terms of identity of neighboring groups. The November shipment completed quarantine with no mortality. Five breeder females were believed to be pregnant at the time of shipment. Four out of 5 appear to have retained their pregnancies and two deliveries of viable offspring occurred during the quarantine period. The Colony 2 marmosets are maintained in a building that is physically separate from the buildings housing Colony 1 and that contains no other nonhuman primates. Specific Animal Location underwent renovation prior to the arrival of the first shipment. Renovations included the addition of drain trench grating to allow for cage rolling; installation of a dishwasher and a water softener; repair of the roof skylights; the placement of a concrete slab at the exterior yard and the addition of Specific Animal Location for cage movement and storage.

Projects Supported by the Marmoset Component

Table 1 lists new marmoset projects begun at SNPRC during 2014.

Table 1

Principal Investigator & Institution	Project Title	Sponsor	Period Of Support	Animal Use	On-Site Research Use
Excluded by Requester Private Source	***Cognitive dysfunction in the marmoset EAE model***	***SNPRC Pilot Grant***	***9/4/13 – 8/30/14***	***Animals***	***X***
Excluded by Private Source ***Univ***	***Gastrin-releasing peptide and pulmonary fibrosis***	***SNPRC Pilot Grant***	***9/24/13 – 8/30/14***	***Animals***	***X***
Excluded by Requester ***Univ Illinois Chicago***	***Transgenerational programming of reproductive development & health in the common marmoset***	***5R01HD076018***	***4/30/14 – 4/30/2018***	***Animals***	***X***
Excluded by Requester Excluded ***SNPRC & UTHSCSA***	***Parkinson's Disease: autologous cell therapy in the marmoset***	***TBRI.*** Private Source Private Source ***CTSA/IIMS Pilot Grant***	***8/12/14 -***	***Animals***	***X***
Excluded by Requester ***Univ Louisville***	***Development of new bivalent cross-protective arenaviral vaccines***	***5R01AI093450***	***4/1/11-3/31/16***	***Animals***	***X***
Excluded by Requester Excluded by Private Source ***Univ & U Washington***	***A metabolomics model of aging in the common marmoset***	***5R01AG038746***	***1/4/15-5/31/16***	***Animals***	***X***
Excluded by Requester ***UTHSCSA***	***A nonhuman primate model of nontuberculous mycobacterial (NTM) lung disease***	***UTHSCSA***	***1/16-14 -***	***Animals***	***X***
Excluded by Requester ***Texas Biomed***	***Antibody therapy in marmoset Ebola model***	***FDA contract***	***1/1/2015-***	***Animals***	***X***

Table 2 provides a list of investigators who have requested to purchase marmosets since 2014 whose requests remain active. From 2013-2014, we were unable to meet most requests for marmoset purchases as animals were not available. All save two of the investigators who contacted us in 2014 asked to remain in the queue for possible animals available in 2015, as they were unable to locate marmosets to meet their needs through other sources.

Table 2

Proprietary Info

C. COMPONENT PRODUCTS

C.1 PUBLICATIONS

Not Applicable

C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)

Not Applicable

C.3 TECHNOLOGIES OR TECHNIQUES

NOTHING TO REPORT

C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES

Not Applicable

C.5 OTHER PRODUCTS AND RESOURCE SHARING

C.5.a Other products

NOTHING TO REPORT

C.5.b Resource sharing

NOTHING TO REPORT

D. COMPONENT PARTICIPANTS

Not Applicable

E. COMPONENT IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES?

Not Applicable

E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE?

Not Applicable

E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER?

NOTHING TO REPORT

E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)?

Not Applicable

F. COMPONENT CHANGES

F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE

Not Applicable

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

NOTHING TO REPORT

F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS

F.3.a Human Subjects

No Change

F.3.b Vertebrate Animals

No Change

F.3.c Biohazards

No Change

F.3.d Select Agents

No Change

G. COMPONENT SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

Not Applicable

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

G.4.a Does the project involve human subjects?

No

G.4.b Inclusion Enrollment Data

Not Applicable

G.4.c ClinicalTrials.gov

Not Applicable

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

Not Applicable

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Not Applicable

G.8 PROJECT/PERFORMANCE SITES

Not Applicable

G.9 FOREIGN COMPONENT

Not Applicable

G.10 ESTIMATED UNOBLIGATED BALANCE

Not Applicable

G.11 PROGRAM INCOME

Not Applicable

G.12 F&A COSTS

Not Applicable

RESEARCH & RELATED BUDGET - SECTION A & B FINAL

ORGANIZATIONAL DUNS*: 007936834

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Excluded by Requester				Project Lead	Institutional Base Salary	EFFORT			4,583.00	1,297.00	5,880.00
2.						Director					1,222.00	346.00	1,568.00
3.						Staff Scientist III					548.00	155.00	703.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **8,151.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
5	Veterinary Care Staff	8.82			27,709.00	7,843.00	35,552.00
5	**Total Number Other Personnel**					**Total Other Personnel**	**35,552.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**43,703.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	**0.00**
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	0.00
2. Foreign Travel Costs	0.00
Total Travel Cost	**0.00**

E. Participant/Trainee Support Costs		Funds Requested ($)*
1. Tuition/Fees/Health Insurance		0.00
2. Stipends		0.00
3. Travel		0.00
4. Subsistence		0.00
5. Other:		
0 Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	12,810.00
2. Publication Costs	0.00
3. Consultant Services	0.00
4. ADP/Computer Services	0.00
5. Subawards/Consortium/Contractual Costs	0.00
6. Equipment or Facility Rental/User Fees	0.00
7. Alterations and Renovations	0.00
8. Pathology	4,528.00
9. Overtime, Other Services	796.00
10. Freight	419.00
Total Other Direct Costs	**18,553.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**62,256.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Federal Primate Center Rate	78.6	62,256.00	48,934.00
		Total Indirect Costs	**48,934.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**111,190.00**

J. Fee	Funds Requested ($)*
	0.00

K. Budget Justification* File Name: BUDGET JUSTIFICATIION_2-26-15.pdf
(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

BUDGET JUSTIFICATIION

Marmoset Colony

The Leader of this Component is Excluded by Requester was previously supported as the Leader of this Component through a subcontract from SNPRC to University of Texas Health Science Center at San Antonio Excluded by Requester recently moved to SNPRC to become the new Associate Director of Research (see Director's Office) and her effort is now covered directly by this Component rather than through a subcontract with the UTHSCSA.

A. COMPONENT COVER PAGE

Project Title: NPRC Consortium Activities

Component Project Lead Information:

Excluded by Requester

B. COMPONENT ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

Consortium activities are important for exchanging information among the different NPRCS, expanding access to capabilities and resources, and leveraging the unique strengths of each of the Centers. The Southwest National Primate Research Center is an active participant in a variety of consortium activities. Scientists, veterinarians, and support service directors participate in a variety of Working Groups. The SNPRC has representatives serving on the Genetics and Genomics Working Group, the Breeding Colony Management Consortium, the Data Access Guidelines Group, the Behavioral Management Consortium, the Pathology Working Group, the Training Consortium, the Education Outreach Working Group, and the Occupational Health and Safety Working Group.

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

File uploaded: Consortium_B2.pdf

B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

Not Applicable

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

NOTHING TO REPORT

B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

NOTHING TO REPORT

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

The Consortium groups will continue to meet to expand resources.

NPRC CONSORTIUM ACTIVITIES

GENETICS & GENOMICS WORKING GROUP (GGWG) CONSORTIUM

SNPRC Representative: Excluded by Requester

The purpose of the Genetics & Genomics Working Group (GGWG) is to provide researchers and colony managers working with nonhuman primates (NHPs) information systems and genomic resources to support their activities. In order to accomplish this, the GGWG is currently focused on four activities: development of genetics and genomics tools for the NHPRC Consortium website; development of a Single Nucleotide Polymorphism (SNP) portal for NHPs; development of NHP genetics and genomics tools and workflows; and training and evaluation. Each of these activities leverages the Consortium's BIRN infrastructure for data management, data integration, data security and implementation of the developed software tools.

Excluded by Requester joined the GGWG in 2010. As a member of the GGWG Excluded by Requester participates in biweekly conference calls and annual meetings of the GGWG. Progress generated by consortium activities includes the development of the GGWG portion of the consortium website, creation of a SNP portal for analysis and management of NHP SNP data, evaluation of SNP data management standards currently being used in genetics research and incorporation of these standards into the SNP portal analysis tools, linkage of existing genetic analysis tools (e.g. UCSC genome browser) through the GGWG portion of the NPRC website, and evaluation of SNP portal tools for improvement and refinement. In addition, the GGWG has developed a rhesus ancestry and parentage SNP chip to standardize rhesus genotyping among the NPRC colonies.

Usefulness of involvement: I've had the greatest contributions in discussions of linking existing genetic analysis tools (e.g. UCSC genome browser) through the GGWG portion of the NPRC website. In addition, our plans at the SNPRC to use a Genotype-by-Sequencing approach for genetic characterization of our NHP colonies is of interest to GGWG members at the other NPRCs with the possibility of implementing this approach at multiple NPRCs.

DATA ACCESS GUIDELINES GROUP

SNPRC representative: Excluded by Requester

The Data Access Guidelines Group (DAGG) reviews content and permissions for the Nonhuman Primate Research Center Consortium website. We did not receive any material for review during 2014.

BREEDING COLONY MANAGEMENT CONSORTIUM

SNPRC representative: Excluded by Requester

The goal of the Breeding Colony Management Consortium (BCMC) is to improve and maximize use of the resource. During 2014, the SNPRC representatives met with the other NPRCs representatives during eight teleconferences and a two-day face to face meeting. The focus of the conference calls and meeting were:

- *Multicenter Measles Vaccination Safety and Efficacy Study* was completed and the final draft of paper sent for review.
- The *Colony Health Benchmarks* (CHB) phase 1 data has been analyzed and phase 2 initiated to promote direct capture of essential data from each center.
- The development of *Genetic Health Benchmarks* is a joint effort between Genetics and Genomics Working Group and BCMC. A white paper on genetic management was produced with specific plans and procedures to manage nonhuman primate breeding to enhance genetic diversity. Tools to determine ancestry and parentage were demonstrated during the face to face meeting.
- A multicenter cross-consortium group created *viral testing best practices* in several white papers that provided recommendations on viral testing algorithms, standardized definitions, and disposition of non-negative animals.
- *Disaster Recovery Plans* were discussed to determine how the NPRCs can assist each other in recovery from a major disaster or significant disruption to primate center operations.

- The results of *Extreme Phenotype Survey* were discussed and action items developed for expanding information about these phenotypes, collating information across centers, and other tasks necessary to fully exploit the information acquired through the initial survey.
- *Tuberculosis Testing* methods were surveyed and found that most practices are fairly uniform, but there are some differences among centers on quarantine and New World monkey practices.

BEHAVIORAL MANAGEMENT CONSORTIUM

SNPRC representative Excluded by Requester

In 2014, Excluded by Requester participated in monthly Behavioral Management Consortium webinars and an annual face to face meeting which was held at YNPRC in September. She participated in current behavioral management discussions and planning, including an alopecia scoring and reliability checking initiative, a comparison of social introduction procedures and standardization of socialization records, and the development of an abnormal behavior ethogram.

PRIMATE PATHOLOGY WORKING GROUP

SNPRC representatives: Excluded by Requester

Both Excluded by Requester attended and presented at the monthly online virtual slide conferences of the Excluded by Requester Pathology Working Group. Excluded by Requester also attended and presented a case at the Primate Pathology Workshop in November at Atlanta (held in conjunction with the American College of Veterinary Pathologist's Annual Meeting).

EDUCATION OUTREACH WORKING GROUP

SNPRC representatives: Excluded by Requester

Three Outreach Working Group members manned an exhibitor display at the Society for Neuroscience in November of 2014, the USA Science and Engineering Festival in April 2014 , and participated in NHP AIDS community outreach at the 3rd annual Outreach Working Group meeting in Oregon 11/12/14. Working group members produced outreach materials for marketing and promotion and collaboratively developed and wrote articles for the NPRC website.

In the summer of 2014, 50 science teachers were hosted at "Science Teachers Day at Texas Biomed" which is the host institution for the SNPRC. The Texas Biomed Forum Group, Teachers Enrichment Initiative of the University of Texas Health Sciences Center in San Antonio, Voelker Biosciences Teacher Academy and the PEER Texas A&M veterinary students participated by presenting free resources and programs available for the teachers.

The 2014 SNPRC summer intern program had five students who were awarded internships for 8 weeks and several veterinary student-externs participated in weekly, biweekly or monthly training. SNPRC summer intern students attended Science Teachers Day events and interacted with the science teachers in animal research discussions.

Texas Biomed conducted outreach efforts with the help of the TxBiomed forum group for 11 high school groups (410 students and teachers) with half day sessions of scientist talks, tours of the BSL4 suit room, and the animal colonies tour. A number of community groups and individuals totaling 160 people also had briefings and tours as part of the outreach effort. Lectures for laypersons known as Fireside Chats took place at an affiliated club and were attended by 189 people.

C. COMPONENT PRODUCTS

C.1 PUBLICATIONS

Not Applicable

C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)

Not Applicable

C.3 TECHNOLOGIES OR TECHNIQUES

NOTHING TO REPORT

C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES

Not Applicable

C.5 OTHER PRODUCTS AND RESOURCE SHARING

C.5.a Other products

NOTHING TO REPORT

C.5.b Resource sharing

NOTHING TO REPORT

D. COMPONENT PARTICIPANTS

Not Applicable

E. COMPONENT IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES?

Not Applicable

E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE?

Not Applicable

E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER?

NOTHING TO REPORT

E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)?

Not Applicable

F. COMPONENT CHANGES

F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE

Not Applicable

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

NOTHING TO REPORT

F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS

F.3.a Human Subjects

No Change

F.3.b Vertebrate Animals

No Change

F.3.c Biohazards

No Change

F.3.d Select Agents

No Change

G. COMPONENT SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

Not Applicable

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

G.4.a Does the project involve human subjects?

No

G.4.b Inclusion Enrollment Data

Not Applicable

G.4.c ClinicalTrials.gov

Not Applicable

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

Not Applicable

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Not Applicable

G.8 PROJECT/PERFORMANCE SITES

Not Applicable

G.9 FOREIGN COMPONENT

Not Applicable

G.10 ESTIMATED UNOBLIGATED BALANCE

Not Applicable

G.11 PROGRAM INCOME

Not Applicable

G.12 F&A COSTS

Not Applicable

RESEARCH & RELATED BUDGET - SECTION A & B FINAL

ORGANIZATIONAL DUNS*: 007936834

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Excluded by Requester				Project Lead	Institutional Base Salary		EFFORT		0.00	0.00	0.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **0.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**					**Total Other Personnel**	**0.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**0.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	**0.00**
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	10,000.00
2. Foreign Travel Costs	0.00
Total Travel Cost	**10,000.00**

E. Participant/Trainee Support Costs		Funds Requested ($)*
1. Tuition/Fees/Health Insurance		0.00
2. Stipends		0.00
3. Travel		0.00
4. Subsistence		0.00
5. Other:		
0 Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	0.00
2. Publication Costs	0.00
3. Consultant Services	0.00
4. ADP/Computer Services	0.00
5. Subawards/Consortium/Contractual Costs	0.00
6. Equipment or Facility Rental/User Fees	0.00
7. Alterations and Renovations	0.00
Total Other Direct Costs	**0.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**10,000.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Federal Primate Center Rate	78.6	10,000.00	7,860.00
		Total Indirect Costs	**7,860.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**17,860.00**

J. Fee	Funds Requested ($)*
	0.00

K. Budget Justification*	File Name: BUDGET JUSTIFICATIION_2-26-15.pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

BUDGET JUSTIFICATIION

Consortium Activities

The Leader of this Component has changed, Personal Info and Excluded by Requester assumed the leadership role for Consortium Activities.

A. COMPONENT COVER PAGE

Project Title: Pilot Research Program

Component Project Lead Information:

Excluded by Requester

B. COMPONENT ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

The specific aim of the program is to support pilot studies that advance biomedical research through the use of nonhuman primates and that are likely to be leveraged into major programs and funding that are consistent with the mission of the NIH.

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

File uploaded: Pilot_Research_Program_B2.pdf

B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

Not Applicable

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

NOTHING TO REPORT

B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

NOTHING TO REPORT

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

The Pilot Research Program will continue to advertise funding opportunities and review applications that advance biomedical research through the use of nonhuman primates.

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

The last competitive renewal reported on progress in the SNPRC Pilot Program through 2012. Table 1 provides comparative data on the applications reviewed and funded during 2013-14, compared with those reviewed and funded for the previous grant periods of 2008-2012. Submissions by investigators outside of the host institution increased dramatically – doubling the submission rate seen over previous years. The funding rate for applications from investigators outside the institution (30%) continues to be approximately the same as that for individuals within the institution (28.6%).

Table 1

Period	Applications from Host Institution		Applications from Other Institutions	
	Received per year	Funded per year	Received per year	Funded per year
2008-2012	4.2	1.4	5.6	1.4
2013-2014	3.5	1.0	11.5	3.5

Table 2 provides a list of those investigators with pilot projects that became active during 2014.

Table 2

Review Year	Investigator	Institution	Title
2013	Excluded by Requester	TBRI	Marmoset model of CCHFV disease
		Univ Texas Health Science Center	Stem cell therapy in the marmoset: Preliminary trial of intranasal delivery
		TBRI	Development of a baboon model of hind limb ischemia
		Private Source	Gastrin-releasing peptide mediates pulmonary fibrosis
			Cognitive dysfunction in the marmoset EAE model
2014		Univ Texas Health Science Center	Contribution of epigenetic and metabolic changes to monocyte priming and early atherogenesis in non-human primates
		Univ Texas at San Antonio	Culture and transplantation of baboon spermatogonial stem cells
		Oregon NPRC	Targeting oviductal epithelium with magnetic nanoparticles
		Univ Texas Health Science Center	Cardiac microlesion formation during invasive pneumococcal disease

C. COMPONENT PRODUCTS

C.1 PUBLICATIONS

Not Applicable

C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)

Not Applicable

C.3 TECHNOLOGIES OR TECHNIQUES

NOTHING TO REPORT

C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES

Not Applicable

C.5 OTHER PRODUCTS AND RESOURCE SHARING

C.5.a Other products

NOTHING TO REPORT

C.5.b Resource sharing

NOTHING TO REPORT

D. COMPONENT PARTICIPANTS

Not Applicable

E. COMPONENT IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES?

Not Applicable

E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE?

Not Applicable

E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER?

NOTHING TO REPORT

E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)?

Not Applicable

F. COMPONENT CHANGES

F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE

Not Applicable

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

NOTHING TO REPORT

F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS

F.3.a Human Subjects

No Change

F.3.b Vertebrate Animals

No Change

F.3.c Biohazards

No Change

F.3.d Select Agents

No Change

G. COMPONENT SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

Not Applicable

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

G.4.a Does the project involve human subjects?

No

G.4.b Inclusion Enrollment Data

Not Applicable

G.4.c ClinicalTrials.gov

Not Applicable

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

Not Applicable

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Not Applicable

G.8 PROJECT/PERFORMANCE SITES

Not Applicable

G.9 FOREIGN COMPONENT

Not Applicable

G.10 ESTIMATED UNOBLIGATED BALANCE

Not Applicable

G.11 PROGRAM INCOME

Not Applicable

G.12 F&A COSTS

Not Applicable

RESEARCH & RELATED BUDGET - SECTION A & B FINAL

ORGANIZATIONAL DUNS*: 007936834

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Excluded by Requester				Project Lead	Institutional Base Salary	EFFORT			37,118.00	10,504.00	47,622.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **47,622.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**					**Total Other Personnel**	**0.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**47,622.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	**0.00**
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	0.00
2. Foreign Travel Costs	0.00
Total Travel Cost	**0.00**

E. Participant/Trainee Support Costs		Funds Requested ($)*
1. Tuition/Fees/Health Insurance		0.00
2. Stipends		0.00
3. Travel		0.00
4. Subsistence		0.00
5. Other:		
0 Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	0.00
2. Publication Costs	0.00
3. Consultant Services	0.00
4. ADP/Computer Services	0.00
5. Subawards/Consortium/Contractual Costs	0.00
6. Equipment or Facility Rental/User Fees	0.00
7. Alterations and Renovations	0.00
8. Pilot Studies	400,000.00
Total Other Direct Costs	**400,000.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**447,622.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Federal Primate Center Rate	78.6	447,622.00	351,831.00
		Total Indirect Costs	**351,831.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**799,453.00**

J. Fee	Funds Requested ($)*
	0.00

K. Budget Justification*	File Name: BUDGET JUSTIFICATIION_2-26-15.pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

BUDGET JUSTIFICATIION

Pilot Studies

The Leader of this Component has changed! Excluded by Requester has assumed the leadership role and replaces Excluded by Requester the previous Leader, who accepted a position with the University of Texas Rio Grande Valley. Excluded by Requester was hired to fill the position of Associate Director of Research (see Director's Office).

A. COMPONENT COVER PAGE

Project Title: Research Coordination

Component Project Lead Information:

Excluded by Requester

B. COMPONENT ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

Specific Aim 1.--To provide efficient service to investigators who want to access or are accessing Center resources so that projects are initiated quickly, executed smoothly, and completed on schedule.

Specific Aim 2.--To coordinate the efforts of investigators, veterinarians and veterinary technical staff, internal regulatory committees (e.g., IACUC), and Core Scientist collaborators in order to achieve maximal efficiency.

Specific Aim 3.--To monitor procedures and costs accurately and efficiently so that charge-backs can be applied quickly to recover funds for Primate Center operations. Procedures are also monitored to compare the documentation of performed procedures against procedures approved by the IACUC.

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

File uploaded: research_coordination_B2.pdf

B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

Not Applicable

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

NOTHING TO REPORT

B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

NOTHING TO REPORT

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

We continue to make changes in the process to initiate research projects and purchase primates. The online request forms have been modified to simplify the responses needed while acquiring essential details required to proceed.

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

During the report period we received a total of 97 requests to use primate resources. Table 1 provides details on these requests by species and project or purchase.

Table 1. Requests received and processed by the Research Coordination Group during 2014.

Request	Baboon	Chimpanzee	Marmoset	Macaque	Other Primates
Project	42	5	8	21	2
Purchase	7	0	10	2	0
Total	49	5	18	23	2

C. COMPONENT PRODUCTS

C.1 PUBLICATIONS

Not Applicable

C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)

Not Applicable

C.3 TECHNOLOGIES OR TECHNIQUES

NOTHING TO REPORT

C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES

Not Applicable

C.5 OTHER PRODUCTS AND RESOURCE SHARING

C.5.a Other products

NOTHING TO REPORT

C.5.b Resource sharing

NOTHING TO REPORT

D. COMPONENT PARTICIPANTS

Not Applicable

E. COMPONENT IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES?

Not Applicable

E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE?

Not Applicable

E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER?

NOTHING TO REPORT

E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)?

Not Applicable

F. COMPONENT CHANGES

F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE

Not Applicable

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

NOTHING TO REPORT

F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS

F.3.a Human Subjects

No Change

F.3.b Vertebrate Animals

No Change

F.3.c Biohazards

No Change

F.3.d Select Agents

No Change

G. COMPONENT SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

Not Applicable

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

G.4.a Does the project involve human subjects?

No

G.4.b Inclusion Enrollment Data

Not Applicable

G.4.c ClinicalTrials.gov

Not Applicable

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

Not Applicable

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Not Applicable

G.8 PROJECT/PERFORMANCE SITES

Not Applicable

G.9 FOREIGN COMPONENT

Not Applicable

G.10 ESTIMATED UNOBLIGATED BALANCE

Not Applicable

G.11 PROGRAM INCOME

Not Applicable

G.12 F&A COSTS

Not Applicable

RESEARCH & RELATED BUDGET - SECTION A & B FINAL

ORGANIZATIONAL DUNS*: 007936834

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Excluded by Requester				Project Lead	Institutional Base Salary	EFFORT			25,714.00	7,277.00	32,991.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **32,991.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
6	Research Coordinators	28.0			120,909.00	34,217.00	155,126.00
6	**Total Number Other Personnel**					**Total Other Personnel**	**155,126.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**188,117.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	**0.00**
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	0.00
2. Foreign Travel Costs	0.00
Total Travel Cost	**0.00**

E. Participant/Trainee Support Costs		Funds Requested ($)*
1. Tuition/Fees/Health Insurance		0.00
2. Stipends		0.00
3. Travel		0.00
4. Subsistence		0.00
5. Other:		
0 Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	0.00
2. Publication Costs	0.00
3. Consultant Services	0.00
4. ADP/Computer Services	0.00
5. Subawards/Consortium/Contractual Costs	0.00
6. Equipment or Facility Rental/User Fees	0.00
7. Alterations and Renovations	0.00
Total Other Direct Costs	**0.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**188,117.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Federal Primate Center Rate	78.6	188,117.00	147,860.00
		Total Indirect Costs	**147,860.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**335,977.00**

J. Fee	Funds Requested ($)*
	0.00

K. Budget Justification* File Name:
(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

A. COMPONENT COVER PAGE

Project Title: Summer Intern Program

Component Project Lead Information:

Excluded by Requester

B. COMPONENT ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

The long-term objective of the Summer Intern Program is to foster an interest in career development in biomedical research with nonhuman primates. It is expected that some of the students will, at a later time, become veterinarians, postdoctoral scientists and even scientists at nonhuman primate research facilities. The program strives to provide students with an appreciation for and an understanding of the important role of nonhuman primates in biomedical research. One specific aim is addressed in the process of achieving the objective of the program.

Specific Aim: To provide summer research training opportunities in biomedical research and veterinary medicine with nonhuman primates to undergraduate, graduate, and veterinary students enrolled at accredited academic institutions.

Applicants will choose preferred mentors whose research programs are described on the SNPCR external website. A maximum of six internships will be awarded each summer, after review and ranking of the applicants by the Selection Committee. Selected interns will then conduct a research project at the SNPRC under the guidance of his or her mentors. At the conclusion of the internship, each student will present a brief seminar concerning their work. Those interns who obtain results worthy of publication will be encouraged to continue the work with their mentors as they develop a contribution for the scientific literature.

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

File uploaded: Summer_Intern_Program_B2.pdf

B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

Not Applicable

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

NOTHING TO REPORT

B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

NOTHING TO REPORT

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

We activated announcements for the 2015 summer program earlier than in 2014. This effort has successfully resulted in submission of 25 applications (or twice as many) for the summer of 2015. We also plan to examine various systems for evaluating the success of the program.

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

In 2014, the program was activated by the previous administration later than usual, but we had 12 applications. We awarded the internship to 5 students (2 graduate (1 male and 1 female) and 3 female undergraduates). Excluded by Requester students were from [redacted] one Excluded by Requester and one from Excluded by Requester [redacted] ents gave a presentation of their results at the end of the internship period to a mixed audience of mentors and collaborators.

NAME	LEVEL	INSTITUTION	MENTORS	TITLE OF PROJECT
Excluded by Requester	Undergrad	Excluded by Requester		*Histoplasma capsulatum var. duboisii* in baboons
	Grad			Skeletal epigenetics in the baboon
	Undergrad			Characterization of antibodies present in rhesus macaques protected from SHIV-C by vaccination
	Undergrad			Generation of a plasmid-based reverse genetics system for engineering recombinant SUDV
	Grad			Measurement of plasma viral loads by qRT-PRC using QB bacteriophage as internal control

C. COMPONENT PRODUCTS

C.1 PUBLICATIONS

Not Applicable

C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)

Not Applicable

C.3 TECHNOLOGIES OR TECHNIQUES

NOTHING TO REPORT

C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES

Not Applicable

C.5 OTHER PRODUCTS AND RESOURCE SHARING

C.5.a Other products

NOTHING TO REPORT

C.5.b Resource sharing

NOTHING TO REPORT

D. COMPONENT PARTICIPANTS

Not Applicable

E. COMPONENT IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES?

Not Applicable

E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE?

Not Applicable

E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER?

NOTHING TO REPORT

E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)?

Not Applicable

F. COMPONENT CHANGES

F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE

Not Applicable

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

NOTHING TO REPORT

F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS

F.3.a Human Subjects

No Change

F.3.b Vertebrate Animals

No Change

F.3.c Biohazards

No Change

F.3.d Select Agents

No Change

G. COMPONENT SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

Not Applicable

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

G.4.a Does the project involve human subjects?

No

G.4.b Inclusion Enrollment Data

Not Applicable

G.4.c ClinicalTrials.gov

Not Applicable

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

Not Applicable

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Not Applicable

G.8 PROJECT/PERFORMANCE SITES

Not Applicable

G.9 FOREIGN COMPONENT

Not Applicable

G.10 ESTIMATED UNOBLIGATED BALANCE

Not Applicable

G.11 PROGRAM INCOME

Not Applicable

G.12 F&A COSTS

Not Applicable

RESEARCH & RELATED BUDGET - SECTION A & B FINAL

ORGANIZATIONAL DUNS*: 007936834

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Excluded by Requester				Project Lead	Institutional Base Salary	EFFORT			9,165.00	2,594.00	11,759.00
2.						Co-Lead					23,891.00	6,761.00	30,652.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **42,411.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
4	Graduate Students	8.0			22,995.00	6,508.00	29,503.00
	Undergraduate Students						
	Secretarial/Clerical						
4	**Total Number Other Personnel**					**Total Other Personnel**	**29,503.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**71,914.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	**0.00**
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	0.00
2. Foreign Travel Costs	0.00
Total Travel Cost	**0.00**

E. Participant/Trainee Support Costs		Funds Requested ($)*
1. Tuition/Fees/Health Insurance		0.00
2. Stipends		0.00
3. Travel		0.00
4. Subsistence		0.00
5. Other:		
0 Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	6,018.00
2. Publication Costs	0.00
3. Consultant Services	0.00
4. ADP/Computer Services	0.00
5. Subawards/Consortium/Contractual Costs	0.00
6. Equipment or Facility Rental/User Fees	0.00
7. Alterations and Renovations	0.00
8. Freight	309.00
9. Printing	309.00
Total Other Direct Costs	**6,636.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**78,550.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Federal Primate Center Rate	78.6	78,550.00	61,741.00
		Total Indirect Costs	**61,741.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**140,291.00**

J. Fee	Funds Requested ($)*
	0.00

K. Budget Justification* File Name:
(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

A. COMPONENT COVER PAGE

Project Title: Veterinary Technical Services	
Component Project Lead Information:	
Excluded by Requester	

B. COMPONENT ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

Specific Aim 1: To develop new techniques and procedures to meet the needs of investigators and research projects. We will continue to provide research support by utilizing veterinary and technical resources to meet specific study needs. We are currently planning to develop Laser Doppler imaging techniques and surgical models for endometriosis, and Laser Doppler imaging for assessing blood flow in the hind limb ischemia model.
Specific Aim 2: To develop new techniques and procedures to meet emerging clinical care needs.
Specific Aim 3: To develop research teams with clearly defined roles for team members in order to improve ease of project implementation. We are currently assessing research support team functions and improving the delineation of roles and responsibilities. Through this process, we are working to decrease duplication of effort and improve efficiencies in clinical and research applications.
Specific Aim 4: To work closely with the training component to provide technical staff with specific training required in order to meet the specialized needs of the research programs at the SNPRC and to facilitate career development for the technical staff.

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

File uploaded: Vet_Tech_Services_B2.pdf

B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

Not Applicable

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

NOTHING TO REPORT

B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

NOTHING TO REPORT

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

The development of techniques in support of the Clinical and Research program will continue in the next reporting period. Progress in technique development will be tracked in our biweekly study progress meetings. Annual budgets developed and submitted to the host institution for funding will include equipment to support both the clinical medicine and research program. These new techniques will maintain a progressive clinical medicine and research program and will allow for advancement of science in the primate center.
The SNPRC study process manual is a document which outlines all of the steps the SNPRC uses to develop and perform a study. This manual will track and update our study processes and capture project team function updates. The SNPRC will continue to develop the project team, always seeking opportunities to improve the processes which develop and schedule studies. In an increasing study load, the need to improve efficiencies and improve timelines will be at the forefront of the project development process. An area we will focus on is improved management of the study timeline, central management of space, back up staffing at all levels, resource management and project administration.
The Technical Training Program will continue to be developed with an aim at supporting career paths for staff, and to allow staff new learning opportunities. New opportunities for training will come in the form of new equipment use, studies requiring new techniques to be performed and advanced skills identified for each level. Another aspect of the training program is to assess the effectiveness of training modules and assess how staff is performing at each respective technical level skill. Through this effort, training methods will be evaluated, competency standards modified to maintain alignment with each technical level, and the appropriateness of application of skills required for each level may be determined.

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

Specific Aim 1 Accomplishments

The development of new techniques is critical to the advancement of research done at the SNPRC. Development of these techniques includes refinement of existing techniques aimed at specific projects, application of equipment to support new techniques and novel approaches aimed at providing a mechanism to accomplish a specific research objective. We successfully developed the Laser Doppler imaging technique to measure blood flow in the hind limb ischemia model. We were also successful in developing the surgical model for inducing endometriosis in the baboon. The following are other research related procedures developed in this reporting period.

Date	New Study Procedures
1/9/2014	Visceral Fat Liquification for obesity reduction
1/23/2014	Vas deferens injection for male contraception
3/20/2014	Alert nasogastric dosing twice a day for drug delivery
5/1/2014	Vaginal wash for detection of sperm
10/2/2014	Reversal of vas deferens contraception
10/16/2014	Remote logon for temperature and EKG data collection and monitoring
12/11/2014	Fetal intracardiac injection (abortifacient)
11/13/2014	Testicle Injection (spermatogonial stem cells)

Specific Aim 2 Accomplishments

The development of clinical techniques is essential to the development of a progressive clinical medicine and supports a healthy research program model at the SNPRC. Development of these techniques include; refinement of existing techniques aimed at improving the veterinary care program, application of equipment to support new techniques in therapeutics, diagnostic medicine and surgery, and novel approaches aimed at providing a mechanism for drug administration, surgical techniques, treatment of disease, management of pain, distress and convalescent care. The following are clinical procedures developed in this reporting period.

Date	New Clinical Procedures
3/20/2014	Twice a day nasogastric dosing in alert macaques
5/29/2014	Using lasers for clinical wound therapy
5/29/2014	Chemical castration

Specific Aim 3 Accomplishments

Functionality and efficiency are key components of project execution and equally important to adhering to project funding constraints. Each member of the research project team has defined roles in study execution. The primary research project team at the SNPRC is made up of the veterinarian, research coordinator, technical supervisor, veterinary technician and animal care technician. The project team is focused on the needs of the Principal Investigator and their study. Efforts have proven effective to provide seamless communication with the PI regarding all aspects of study preparation, study execution, and through project completion, a hallmark of the SNPRC research team.

We have made considerable strides in Aim 3 as a result of ongoing assessments of the research team. This assessment has focused on the following:

- Professional training/experience and the person's role on the project. This has resulted in projects supported by an SNPRC team who have expertise in a particular research focus (e.g. Reproduction, Neurodegenerative Diseases, Metabolic Diseases, Biocontainment studies).
- What are the interrelationships of job function within the project team? By focusing on these interrelationships, study and schedule preparation can be more streamlined to meet project timelines. Pre-study meetings with the entire research team work through the details where project milestones are stated and individual roles in the study are defined as well as the tasks associated with project execution.
- What means may be employed to decrease dependence on others in the team in order to fulfill milestones and improve functionality throughout project completion. Because there are a series of parallel processes occurring at any given time for a project it is important that team members are able to function independently to achieve the milestones set forth in the project timeline. Examples of these processes include;

project timeline and calendar placement, animal selection, resource management (animal housing and procedure rooms), technical team formation, training of staff, equipment procurement, and administrative responsibilities (pre-study meetings, IACUC protocol development and submittal, data management, post approval monitoring, communication with PI). We continue to evaluate how interdependencies impact workflow and efficiencies.

Specific Aim 4 Accomplishments

Technical Training is an essential element to the successful completion of tasks required to support a study. Technical development is supported by the SNPRC Technical Training Program. In the last reporting period this comprehensive program has provided skilled training for each animal care and veterinary technical level, implemented competency requirements, provided training milestones and percentages for each technical level and provided a mechanism of monitoring a technician's technical career advancement status. Each technician's level has a specific set of technical skills associated with it. There are continual developments in the technical training program which include: a defined set of technical skills required to advance, AALAS training and technical certifications to advance animal care and technical staff to the next career level and monetary compensation for AALAS certification and technical level advancement.
Percentage of P51 support:

C. COMPONENT PRODUCTS

C.1 PUBLICATIONS

Not Applicable

C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)

Not Applicable

C.3 TECHNOLOGIES OR TECHNIQUES

NOTHING TO REPORT

C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES

Not Applicable

C.5 OTHER PRODUCTS AND RESOURCE SHARING

C.5.a Other products

NOTHING TO REPORT

C.5.b Resource sharing

NOTHING TO REPORT

D. COMPONENT PARTICIPANTS

Not Applicable

E. COMPONENT IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES?

Not Applicable

E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE?

Not Applicable

E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER?

NOTHING TO REPORT

E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)?

Not Applicable

F. COMPONENT CHANGES

F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE

Not Applicable

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

NOTHING TO REPORT

F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS

F.3.a Human Subjects

No Change

F.3.b Vertebrate Animals

No Change

F.3.c Biohazards

No Change

F.3.d Select Agents

No Change

G. COMPONENT SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

Not Applicable

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

G.4.a Does the project involve human subjects?

No

G.4.b Inclusion Enrollment Data

Not Applicable

G.4.c ClinicalTrials.gov

Not Applicable

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

Not Applicable

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Not Applicable

G.8 PROJECT/PERFORMANCE SITES

Not Applicable

G.9 FOREIGN COMPONENT

Not Applicable

G.10 ESTIMATED UNOBLIGATED BALANCE

Not Applicable

G.11 PROGRAM INCOME

Not Applicable

G.12 F&A COSTS

Not Applicable

RPPR - Core-7343

RESEARCH & RELATED BUDGET - SECTION A & B FINAL

ORGANIZATIONAL DUNS*: 007936834

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Excluded by Requester				Project Lead	Institutional Base Salary	EFFORT			5,499.00	1,556.00	7,055.00
2.						Veterinarian					32,510.00	9,200.00	41,710.00
3.						Associate Veterinarian					15,842.00	4,483.00	20,325.00
4.		To Be		Appointed		Veterinary Resources Vet		1.5			22,913.00	6,484.00	29,397.00
5.		To Be		Appointed		Assistant Veterinarian		1.6			13,867.00	3,924.00	17,791.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **116,278.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
26	Veterinary Care Staff	81.6			349,123.00	98,803.00	447,926.00
26	**Total Number Other Personnel**					**Total Other Personnel**	**447,926.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**564,204.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	**0.00**
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	0.00
2. Foreign Travel Costs	0.00
Total Travel Cost	**0.00**

E. Participant/Trainee Support Costs		Funds Requested ($)*
1. Tuition/Fees/Health Insurance		0.00
2. Stipends		0.00
3. Travel		0.00
4. Subsistence		0.00
5. Other:		
0 Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K

ORGANIZATIONAL DUNS*: 007936834
Budget Type*: ● Project ❍ Subaward/Consortium
Enter name of Organization: TEXAS BIOMEDICAL RESEARCH INSTITUTE

Start Date*: 05-01-2015 **End Date*:** 04-30-2016

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	84,733.00
2. Publication Costs	0.00
3. Consultant Services	0.00
4. ADP/Computer Services	0.00
5. Subawards/Consortium/Contractual Costs	0.00
6. Equipment or Facility Rental/User Fees	0.00
7. Alterations and Renovations	0.00
8. Overtime	13,788.00
9. Other Services	3,051.00
10. Freight	1,462.00
Total Other Direct Costs	**103,034.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**667,238.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Federal Primate Center Rate	78.6	667,238.00	524,449.00
		Total Indirect Costs	**524,449.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**1,191,687.00**

J. Fee	Funds Requested ($)*
	0.00

K. Budget Justification* File Name:
(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)