Notice of Award

BIOLOGICAL MATERIALS RESOURCE GRANTS **Federal Award Date:** 04/30/2020
Department of Health and Human Services
National Institutes of Health

OFFICE OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH

Grant Number: 5P40OD010965-15 REVISED
FAIN: P40OD010965

Principal Investigator(s):
Matthew Jorgensen, PHD

Project Title: Vervet Research Colony as a Biomedical Resource

Angela Horton
WAKE FOREST UNIVERSITY HEALTH SCIENCES
GRANTS & CONTRACTS ADMINISTRATOR 1
MEDICAL CENTER BLVD
OFFICE OF RESEARCH
Winston-Salem, NC 27157

Award e-mailed to: awards@wakehealth.edu

Period Of Performance:
Budget Period: 04/01/2019 – 04/30/2020
Project Period: 07/01/2004 – 04/30/2020

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 WAKE FOREST UNIVERSITY HEALTH SCIENCES 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 P40OD010965. 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 – 5P40OD010965-15 REVISED

Award Calculation (U.S. Dollars)

Salaries and Wages	$203,835
Fringe Benefits	$56,223
Personnel Costs (Subtotal)	$260,058
Other	$184,693
Federal Direct Costs	$444,751
Federal F&A Costs	$244,613
Approved Budget	$689,364
Total Amount of Federal Funds Obligated (Federal Share)	$689,364
TOTAL FEDERAL AWARD AMOUNT	$689,364
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTAL FEDERAL AWARD AMOUNT YEAR (15)	
GRANT NUMBER	**TOTAL FEDERAL AWARD AMOUNT**
5P40OD010965-15	$689,364
3P40OD010965-15S1	$340,332
TOTAL	**$1,029,696**

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
15	$689,364	$1,029,696

Fiscal Information:

CFDA Name:	Research Infrastructure Programs
CFDA Number:	93.351
EIN:	1223849199A1
Document Number:	POD010965D
PMS Account Type:	P (Subaccount)
Fiscal Year:	2019

IC	CAN	2019
OD	8014500	$689,364

NIH Administrative Data:
PCC: CMR03 / **OC**: 41025 / **Released**: eRA Commons User /21/2020
Award Processed: 04/30/2020 12:00:02 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5P40OD010965-15 REVISED

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 – 5P40OD010965-15 REVISED

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 System for Award Management (SAM). 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) P40OD010965. 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 period of performance end 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, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience.*

NIH strongly encourages electronic submission of 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 invention statement may be e-mailed as PDF attachments to: NIHCloseoutCenter@mail.nih.gov.

Hard copy: Paper submissions of 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 RPPR 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.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – OD Special Terms and Conditions – 5P40OD010965-15 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REVISION:

This award has been revised to change project and budget end dates due to the funding of a competing continuation grant application.

All previous terms and conditions remain in effect.

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SUBJECT FOA
This award is subject to the conditions set forth in PAR-14-005, "Animal and Biological Material Resource Centers (P40)," 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-14-005.html

ORIP FUNDING PLAN FOR FY2019
This non-competing award reflects the NIH Fiscal Policy for Grant Awards for FY2019 (see NIH Guide Notice NOT-19-031) and the implementation of the ORIP FY2019 grants funding policy: https://orip.nih.gov/funding/awards-funding-policy

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

Redacted by agreement

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.

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 Part II Chapter 8 the NIH Grants Policy Statement for the activities and/or expenditures that require NIH approval at http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf

GENOMIC DATA SHARING:
Dissemination of study data will be in accordance with the grantee's accepted genomic data sharing plan as approved. Failure to adhere to the sharing plan as mutually agreed upon by the Recipient and the NIH/ORIP) may result in Enforcement Actions as described in the NIH Grants Policy Statement.

COMMUNICATIONS/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 https://orip.nih.gov/

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: Stephanie Blackford
Email: stephanie.page@nih.gov **Phone**: 301-402-6737

Program Official: Harold L. Watson
Email: watsonh@mail.nih.gov **Phone**: 301-435-0884 **Fax**: 301-480-3819

SPREADSHEET SUMMARY
GRANT NUMBER: 5P40OD010965-15 REVISED

INSTITUTION: WAKE FOREST UNIVERSITY HEALTH SCIENCES

Budget	Year 15
Salaries and Wages	$203,835
Fringe Benefits	$56,223
Personnel Costs (Subtotal)	$260,058
Other	$184,693
TOTAL FEDERAL DC	$444,751
TOTAL FEDERAL F&A	$244,613
TOTAL COST	$689,364

Facilities and Administrative Costs	Year 15
F&A Cost Rate 1	55%
F&A Cost Base 1	$444,751
F&A Costs 1	$244,613

A. COVER PAGE

Project Title: Vervet Research Colony as a Biomedical Resource	
Grant Number: 5P40OD010965-15	**Project/Grant Period:** 07/01/2004 - 03/31/2020
Reporting Period: 04/01/2018 - 03/31/2019	**Requested Budget Period:** 04/01/2019 - 03/31/2020
Report Term Frequency: Annual	**Date Submitted:** 01/28/2019
Program Director/Principal Investigator Information: MATTHEW JORGENSEN , BS MS PHD **Phone number:** 336-716-6935 **Email:** mjorgens@wakehealth.edu	**Recipient Organization:** WAKE FOREST UNIVERSITY HEALTH SCIENCES MEDICAL CENTER BLVD WINSTON-SALEM, NC 271570001 **DUNS:** 937727907 **EIN:** 1223849199A1 **RECIPIENT ID:**
Change of Contact PD/PI: N/A	
Administrative Official: Redacted by agreement Medical Center Boulevard Winston-Salem, NC 27104 **Phone number:** Redacted by agreement **Email:** nihawards@wakehealth.edu	**Signing Official:** Redacted by agreement MEDICAL CENTER BLVD WINSTON-SALEM, NC 27157 **Phone numbe** Redacted by agreement **Email:** Redacted wakehealth.edu
Human Subjects: No	**Vertebrate Animals:** Yes
hESC: No	**Inventions/Patents:** No

B. ACCOMPLISHMENTS

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

The goals of this project are:

1) To ensure an annual supply of approximately 70-85 pedigreed, pathogen-free Caribbean-origin vervet/African green monkeys (Chlorocebus aethiops sabaeus) to meet projected research demands and to provide the accompanying research resources required to facilitate a systems biology approach to human disease;

In addition, we intend to engage in the following three activities: 1)maintain extensive multisystem clinical phenotyping, tissue collections, and data repositories to aid researchers in monkey selection, data generation, and use; 2) continue genomic sequencing and related resource collections to enable genetic/epigenetic investigations; and 3) support investigators by ensuring access to genetic and statistical tools, providing expertise in NHP models and their translational relevance, and enabling on- or off-site options for monkey purchase/lease including pilot, interventional, or observational investigations.

2) To continue providing the VRC as a platform for training veterinarians and other professionals in biomedical research, husbandry, clinical care, and the management of animal resources; and

3) To increase the VRC's translational value by developing data and tissue repositories from repeated assessments while consuming 'Western' vs. usual laboratory chow diets, thereby providing a relevant nutritional context for studying chronic disease risk and facilitating 'omic' approaches to the study of females across the life span and juveniles of both sexes (applied research component).

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: P40 Progress Report 2019 SectionB2 Goals 2019-01-11.pdf

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?

No

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

File uploaded: B.4.pdf

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

Proprietary Info

Proprietary Info

Outreach to the lay community included 15 visits by middle school, high school and college student groups, including a total of 293 guests. These visits included faculty presentations and tours of the facilities along with question-and-answer periods. We also participated in a Medical Center open house for the Clarkson Campus, which included 76 visitors from across the center.

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

During the next reporting period, we plan to continue the collection and banking of samples and data for the VRC biorepository. These collections will include blood (plasma, serum, whole blood) and cerebral spinal fluid (CSF). Phenotypic data will include cardiometabolic and lipid assays, complete blood counts and blood chemistries, morphometric measures and ultrasounds. We have added the collection of feces, blood pressure and hemoglobin A1c to our annual assessments to be responsive to changing requests from the research community. We also plan to continue providing animals, samples, tissues and data for translational biomedical research, while also maintaining our core breeding colony.

In addition, as part of the applied research component of our grant, we will complete any remaining assays that were part of a year-long dietary challenge. This dietary challenge should continue to increase the VRC's translational value by providing investigators with data and tissue repositories from repeated assessments under both Western and laboratory chow diets. This will provide a relevant nutritional context for studying chronic disease risk in this valuable nonhuman primate model.

We also plan to assess the impact of the 10 imported males on breeding and infant survivorship within the colony. The new males are currently housed in 7 of the 16 breeding groups.

Finally, we will continue to support an array of commercial sponsors. This work will continue to focus on vaccine development, metabolic disease and other research areas.

B.2 What was accomplished under these goals?

There has been significant progress made on all three of the major goals of this project, including the maintenance and utilization of the Vervet Research Colony (VRC), training and the research component.

Aim 1. Resource Maintenance and Utilization

As of 1-Jan-2018, the VRC consisted of 311 total animals. Of those, 254 were housed in 16 matrilineal social groups, 20 males were housed in 2 all-male groups and 37 animals (25 females and 12 males) were housed indoors in pairs or individually. At the end of 2018, all 16 of the social groups were actively breeding in order to maintain sufficient numbers of animals for colony maintenance and for use in future studies. In 2018, the VRC produced 29 new animals, compared to 35-47 animals/year from 2014-2017. This reduction was largely due to 1) the previous restriction of breeding in 7 pens in order to accommodate a large industry-funded study, 2) the reduction in the number of breeding-age females to accommodate on-going studies and 3) the removal of some breeding males in advance of the addition of new males in the fall of 2018. While the number of infants has gone down in recent years, the survivorship of infants has increased every year since 2015 (48.9% in 2015 to 67.4% in 2018).

A major change in 2018 involved the importation of 10 new young adult males from Proprietary Info in order to help avoid/reduce inbreeding. These males represent the first importation of new animals to the VRC since the initial founders of the colony in the mid-1980's. The males cleared quarantine, were briefly housed in an all-male group to acclimate to the facilities and were introduced into 7 of the 16 breeding groups (1-2/group) in the fall of 2018. Genotype-by-sequencing analysis was also performed on the males to confirm that they were sufficiently unrelated to the existing colony and would introduce new genetic material to the colony.

Between 2014 and 2018, the VRC provided 257 animals to 18 different investigators and 618 animals were used for short-term studies by 28 different investigators. The areas of research included immunology and vaccine development, neuroscience, ophthalmology, aging and Alzheimer's disease, cardiovascular disease, diabetes, drug abuse and oncology. In addition, during that same time period, a total of **1641 biological samples were provided to 39 different investigators and 4938 data records were provided to 16 different investigators.** Biological samples included blood, feces, fat, muscle, skin and other tissues for studies ranging from immunology, microbiome, aging, metabolism, ophthalmology, endometriosis, cancer and obesity. Data records included morphometric, behavioral, insulin, glucose, lipids, reproductive, veterinary and CT imaging data. **Consultations were provided to 21 different investigators** regarding the use of vervets/AGMs for biomedical research. This included providing information regarding behavioral management, husbandry, enrichment, sampling collections, anesthesia and clinical conditions. See table below for a list of colony requests and utilization during the current reporting period.

In 2018 we supported multiple NIH-funded research projects. These included 1) a study of urinary tract infections (R21-AI135645, PI: Sarguruanathan Subashchandrabose), 2) a study focused on the development and validation of novel PET radioligands (R21-MH112037, PI: Jaya Prabhakaran), 3) a study of RSV-infection in neonates Private Source , 4) the continued evaluation of a cohort of elderly animals for the Wake Forest Alzheimer's Research Center (P30- AG049638) and 5) the continued integration of the VRC and the Wake Forest Clinical and Translational Science Institute to help facilitate multi-categorical pilot studies using nonhuman primate models (UL1-TR001420, PI: Donanld McClain).

In 2018, we continued to provide animals, study oversight, screening data and technical assistance for two major studies with industry sponsors. First, we provided 22 animals for a study to assess the pharmacological effects of microRNA mimics against measures of obesity. This study was conducted in collaboration with Proprietary Info Proprietary Info group. This study required animals with pre-diabetic symptoms, which necessitated the examination of archived glucose, insulin, hemoglobin A1c and lipid data during the selection process. Second, we continued a pre-clinical study intended to test the efficacy of a respiratory syncytial virus (RSV) vaccine. This study was also done in collaboration with Proprietar and was focused on Proprietary Info The original study required the use of 45

Proprietary Info

The collection and banking of samples and data for inclusion in the VRC biorepository was continued during the reporting period. In 2018, primarily as part of final collections for our applied research component (see below), sample collections included blood (plasma, n=849 aliquots; serum, n=451 aliquots; buffy coat, n=59 aliquots), CSF (n=10), hair (n=10), fecal (n=110), muscle (n=10) and fat biopsies (n=10). Phenotypic data collections included complete blood counts and blood chemistry (n=226), glucose/insulin (n=89), lipids (n=88), hemoglobin A1c (n=96), morphometric measures (weight, n=1059; length, waist circumference; n=488) and pregnancy ultrasounds (n=524).

Aim 2. Training

Training remains a critical component of the VRC mission. During the reporting period, undergraduates, medical students, veterinary students, graduate students, veterinary residents, post-doctoral fellows and new faculty all utilized the VRC resource as part of their education. See section B.4 for details on our training activities.

Aim 3. Applied Research Component

The sample and data collections for our applied research component were completed in 2018. The collections included blood samples, fecal samples, hair samples, cerebral spinal fluid (CSF) samples, health screening (CBC/blood chemistry), morphometric measurements, blood pressure measurements (BP), hemoglobin A1c measurements, muscle and fat biopsies and dual-energy x-ray absorptiometry (DXA) assessments. The dietary challenge was initiated in April 2017, with three different experimental conditions:

- USA-TRF: Animals in 2 social groups fed a western diet (LabDiet 5L3K) on a time-restricted schedule in which food is provided once per day for only 4-6 hours.
- USA-Adlib: Animals in 2 social groups fed a western diet (LabDiet 5L3K) ad libitum.
- Chow-Adlib: Animals in 2 social groups fed a standard monkey chow diet (LabDiet 5038) ad libitum.

By the end of the study there were n=52 adult females that completed all sample collections (n=14-16 in each of the 3 experimental conditions), along with n=30 immature animals. All archived samples and data will be made available to the scientific community. The sampling time points were:

- Baseline 1: 3-months prior to diet change.
  Morphometric, blood, CSF, BP, fecal
- Baseline 2: 1-month prior to diet change.
  Muscle, fat, dual-energy x-ray absorptiometry (DEXA)
- Post1: 2-months post-diet change
  Morphometric, blood, A1c, fecal, hair, muscle, fat
- Post2: 6-months post-diet change
  Morphometric, blood BP, fecal
- Post3: 8-months post-diet change
  Blood, fecal, DEXA
- Post4: 11-months post-diet change
  Morphometric, blood, A1c, BP, fecal
- Post5: 11.5-months post-diet change
  CSF, hair, muscle, fat

Blood samples have been assayed for glucose, insulin, lipids (total cholesterol, HDL and non-HDL) and triglycerides. Annual CBC and blood chemistry were also measured in older adults as part of routine veterinary care prior to the start of the diet study and at the 6-month time period.

Table of Use

The following table includes a list of completed requests utilizing the VRC resource during the reporting period.

Animals/Samples/Data	Funding	Research Area	Institution	Date
Consultation on coagulation/venipuncture	---	Veterinary	Private Source	Jan-18
Continued use of 15 mother-infant dyads for milk, fecal, blood samples	NCATS	Development		Jan-18
Consultation on actigraphy	Institutional	Behavior		Jan-18
Proprietary Info 42 animals Proprietary Info	Proprietary Info	Vaccines		Jan-18
Proprietary Info 15 animals		Immunology		Jan-18
Proprietary Info Proprietary Info		Physiology		Jan-18
Metabolomic and pedigree data from 13 animals	Institutional	Metabolism		Feb-18
Consultation on dental tissue	---	Dental		Feb-18
Use of 22 animals for diabetes study	Proprietary Info	Diabetes		Feb-18
Consultation on possible reproductive study	---	Reproduction		Mar-18
Consultation on possible genetic study	---	Genetics		Mar-18
Plasma from 9 aniamls	Institutional	Cardiology		Mar-18
Proprietary Info	Proprietary Info	Toxicology		Mar-18
Blood samples from 2 animals	Institutional	Genetics		Apr-18
Use of 2 animals for PET imaging	NIDA	Neuroimaging		Apr-18
Use of 23 elderly animals for MRI, blood, CSF, behavior	NIA	Alzheimer's		Apr-18
Blood pressure and pedigree data from 370 animals	Institutional	Genetics		Apr-18
Consultation on vervet behavior/management	---	Management		Apr-18
Blood samples from 6 animals	Institutional	Diabetes		May-18
Use and MRI/PET imaging of 6 animals	NCATS	Metabolism		Jun-18
Consultation	---	Cardiology		Jun-18
Plasma samples from 144 animals	NIH ORIP	Metabolism		Jul-18
Blood samples and blood pressure from 5 animals	NIH ORIP	Metabolism		Jul-18
Blood and urine samples from 3 animals	NCATS	Hypertension	Private Source	Jul-18
Amniotic fluid samples from 20 animals	NIH ORIP			Jul-18
Use of 17 animals for UTI study	NIAID	Immunology		Jul-18
Follow-up consultation on use of vervets for neural recording	---	Neuroscience		Aug-18
CT scan data from 2 animals	Institutional	Pulmonary		Aug-18
Use of 7 Proprietary Info study	NIH/Proprietary Info	Vaccines		Sep-18
Use of 3 pregnant females and 3 offspring	Institutional	Vaccines		Sep-18
200 fecal samples	NCATS	Microbiome		Sep-18
Demographic and pedigree data from 884 animals	Institutional	Genetics		Sep-18
Serum samples from 20 animals, adult and elderly	Institutional	Metabolism		Sep-18
Bronchoalveolar lavage samples from 10 animals	NAIDS	HIV/AIDS		Sep-18
Blood, CBC/chemistry data from 10 animals	NCATS	Alzheimer's		Sep-18
Age, CBC, chemistry data on 43 animals	NIAID	Immunology		Sep-18
Consultation on virology study	---	Virology		Sep-18
Consultation and site visit	---	Aging		Oct-18
Blood samples from 6 animals	NIAID	Transplantation		Oct-18

Blood samples from 3 animals	Institutional	Vaccines	Private Source	Oct-18
Consultation on use of vervets for obstetric research	---	Obstetrics		Oct-18
Consultation	---	Aging		Oct-18
Consultation on age equivalence	---	Genetics		Oct-18
Use of 12 animals peanut allergy study	NCATS	Allergy		Nov-18
Use of 3 Proprietary Info	Proprietary Info	Pharmacology		Nov-18
Consultation	---	Respiratory		Nov-18
Reproductive data from 24 animals	---	Reproduction		Dec-18
Use of 17 animals fo Proprietary Info Proprietary Info	Proprietary Info	Diabetes		Dec-18
Pending Support: Private Source				Pending
				Pending
				Pending
				Pending
				Pending
				Pending

B.4 What opportunities for training and professional development has the project provided.

The VRC continues to provide a rich and varied platform for training young scientists. This includes undergraduates, medical students, veterinary students, graduate students, veterinary residents, post-doctoral fellows and new faculty. Trainees supported by Wake Forest training grants (T32-OD010957, PI: J. Mark Cline; T35-OD010946, PI: Kylie Kavanagh) and the recipients of pilot grants funded by the Wake Forest CTSA (UL1TR001240) have all benefited from experiences working with the VRC resource.

For any trainee involved with the Proprietary Info and the VRC, there is exposure and learning opportunities through attendance at weekly Grand Rounds and Pathology Rounds. These are conducted on Fridays and directed by the board-certified faculty who hold joint appointments with the Wake Forest Animal Resources Program and the Department of Pathology. Trainees also attend and present at the weekly journal club and research strategy sessions, which often includes work involving and/or pertaining to the VRC.

Laboratory Animal Residents additionally spend between 6-12 months at the Proprietary Info providing primary care to the VRC animals. Pathology Residents additionally support the gross and histopathologic assessment of pre- and post-mortem samples during their 2-3 year training period. The VRC has also contributed to professional development and enabled successful placement of recent trainees in primate-centric positions at other research institutions.

The current reporting period represents the sixth year in which the VRC has hosted month-long internships for undergraduate biology majors at Proprietary Info This program has included 11 students since its inception in 2013 and gives students a unique experience and opportunity to learn about translational science using nonhuman primate models.

C. 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
Complete	Chen JA, Fears SC, Jasinska AJ, Huang A, Al-Sharif NB, Scheibel KE, Dyer TD, Fagan AM, Blangero J, Woods R, Jorgensen MJ, Kaplan JR, Freimer NB, Coppola G. Neurodegenerative disease biomarkers Aβ₁₋₄₀, Aβ₁₋₄₂, tau, and p-tau₁₈₁ in the vervet monkey cerebrospinal fluid: Relation to normal aging, genetic influences, and cerebral amyloid angiopathy. Brain and behavior. 2018 February;8(2):e00903. PubMed PMID: 29484263; PubMed Central PMCID: PMC5822592.
Complete	Westcott MM, Smedberg J, Jorgensen MJ, Puckett S, Lyles DS. Immunogenicity in African Green Monkeys of M Protein Mutant Vesicular Stomatitis Virus Vectors and Contribution of Vector-Encoded Flagellin. Vaccines. 2018 March 19;6(1). PubMed PMID: 29562688; PubMed Central PMCID: PMC5874657.
Complete	Schmitt CA, Service SK, Jasinska AJ, Dyer TD, Jorgensen MJ, Cantor RM, Weinstock GM, Blangero J, Kaplan JR, Freimer NB. Obesity and obesogenic growth are both highly heritable and modified by diet in a nonhuman primate model, the African green monkey (Chlorocebus aethiops sabaeus). International journal of obesity (2005). 2018 April;42(4):765-774. PubMed PMID: 29211707; PubMed Central PMCID: PMC5984074.
Complete	Wilson QN, Wells M, Davis AT, Sherrill C, Tsilimigras MCB, Jones RB, Fodor AA, Kavanagh K. Greater Microbial Translocation and Vulnerability to Metabolic Disease in Healthy Aged Female Monkeys. Scientific reports. 2018 July 27;8(1):11373. PubMed PMID: 30054517; PubMed Central PMCID: PMC6063974.
In Process at NIHMS	Latimer CS, Shively CA, Keene CD, Jorgensen MJ, Andrews RN, Register TC, Montine TJ, Wilson AM, Neth BJ, Mintz A, Maldjian JA, Whitlow CT, Kaplan JR, Craft S. A nonhuman primate model of early Alzheimer's disease pathologic change: Implications for disease pathogenesis. Alzheimer's & dementia : the journal of the Alzheimer's Association. 2019 January;15(1):93-105. PubMed PMID: 30467082.

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

Category	Explanation
Other	•Wake Forest School of Medicine, Clarkson Campus Resources: https://school.wakehealth.edu/About-the-School/Facilities-and-Environment/Campuses/Clarkson-Campus/Clarkson-Campus-Our-Research-and-Resources •Wake Forest Innovations, Nonhuman Primates & Large Animal Research: https://www.wakeforestinnovations.com/research-collaboration/research-services/technical-services/nonhuman-primates-large-animal-research/ •VRC raw whole genome sequencing data: (reads): http://www.ncbi.nlm.nih.gov/bioproject/?term=PRJNA240242 •Chlorocebus aethiops sabaeus (vervet) Sequence Assembly: https://www.ncbi.nlm.nih.gov/assembly/GCF_000409795.2 •Transcriptomic resource of African green monkey (Chlorocebus aethiops sabaeus): https://www.ncbi.nlm.nih.gov/bioproject/?term=PRJNA219198 •VRC genotype data: http://www.ebi.ac.uk/eva/?eva-study=PRJEB7923 •Genome Data Viewer for Chlorocebus sabaeus: https://www.ncbi.nlm.nih.gov/genome/gdv/?acc=GCF_000409795.2&context=genome •Federation of American Societies for Experimental Biology (FASEB) Database of US Providers of Research Organisms:

	http://www.faseb.org/Science-Policy-and-Advocacy/Science-Policy-and-Research-Issues/Shared-Research-Resources/Stock-Center-Database.aspx

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

If yes, has this information been previously provided to the PHS or to the official responsible for patent matters at the grantee organization?

C.5 OTHER PRODUCTS AND RESOURCE SHARING

Nothing to report

D. PARTICIPANTS

D.1 WHAT INDIVIDUALS HAVE WORKED ON THE PROJECT?

Commons ID	S/K	Name	Degree(s)	Role	Cal	Aca	Sum	Foreign Org	Country	SS
eRA Commons User Name	Y	Jorgensen, Matthew	BS,MS,PHD	PD/PI	EFFORT	EFFORT				NA
	N	Redacted by agreement	Redacted by agreement	Redacted by agreement	EFFORT					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

File uploaded: Combined Other Support D.2.2019.pdf

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?

No

PHS 2590/RPPR OTHER SUPPORT

Jorgensen, Matthew J.
ACTIVE

P40 OD010965 (Matthew Jorgensen-PI) 04/01/15-03/31/20 EFFORT Calendar
NIH/OD $444,927
Vervet Research Colony as a Biomedical Resource
This grant supports the vervet research colony as an Animal and Biological Materials Resource colony. To enrich the VRC as a resources through a research component designed to determine the biological relationships between neurobehavioral and cardiometabolic phenotypes.
Role on Project: Principal Investigator

UL1 TR004120 (McClain-PI) 08/13/15-03/31/19 EFFORT Calendar
WF Clinical and Translational Sci. Award $3,232,083

The major goals of this project are to establish a Clinical and Translational Science Award based on the Wake Forest Translational Science Institute. A Mentored Career Development Award Program (KL2 T001421;PI Kritchevsky) is part of this award.

P30 AG049638-01A1 (Craft-PI) 07/01/16-06/30/21 EFFORT Calendar
NIH $1,746,765
Wake Forest Alzheimer's Disease Core Center

The major goals of this project seek to establish a new Alzheimer's Disease Core Center (ADCC) at Wake Forest School of Medicine that will provide a comprehensive infrastructure for translational, interdisciplinary research on the pathophysiology, prevention, and treatment of AD and related disorders. Our ADCC will focus on the transition from normal aging to mild cognitive impairment and then to AD and other dementias, and understanding the contribution of metabolic and vascular factors to these transitions. The ADCC will enroll a diverse group of ~1,000 adults to facilitate the discovery of new biomarkers and promising targets for prevention and therapy. We will also utilize novel nonhuman primate models to promote pivotal mechanistic and translational research.

Private Source (Jorgensen-PI) Proprietary Info EFFORT Calendar
Private Source
Proprietary Info

INACTIVE: None

OVERLAP:None

Redacted by agreement

ACTIVE

Redacted by agreement

The major goals of this project is to seek to expose veterinary students to biomedical research through practical experience. Objectives are 1) To provide a structured summer research experience at [redacted] 2) to teach students in the program the basic elements of hypothesis-driven research, grant-writing, and data analysis; 3) to provide training in ethics and professionalism in research; and 4) to provide the students with experience in oral and written presentation of scientific findings.

P40 OD010965 (Jorgensen-PI)
NIH/OD 04/01/15-03/31/20 EFFORT
Vervet Research Colony as a Biomedical Resource $444,692
This grant supports the vervet research colony as an Animal and Biological Materials Resource colony. To enrich the VRC as a resources through a research component designed to determine the biological relationships between neurobehavioral and cardiometabolic phenotypes.
Role on Project: [redacted]

[redacted]

This project is to explore the clinically relevant observations of delayed effects of acute radiation exposure in a unique and priceless cohort of non-human primates, termed the Radiation Survivor Cohort. We have a history of exploring methods for mitigating the effects of radiation exposures that could occur through terrorist acts and medical radiation exposures.
Role on Project [redacted]

[redacted]

The major goals of this project establish a Clinical and Translational Science Award based on the [redacted] [redacted] A Mentored Career Development Award Program [redacted] [redacted] is part of this award.

[redacted]

[redacted]

Controversy exists regarding the metabolically healthy obese (MHO) classification, whether it is a transient state that precedes the development of cardiometabolic disease, or whether these individuals have preferred biological handling of excess adipose tissue (AT). We have documented the first spontaneous monkey model of MHO and unhealthy (MUO) obesity. Monkeys have near identical prevalence of MHO as humans and are an excellent model of cardiovascular disease (CVD) and diabetes.

Private Source

Private Source

Private Source

Private Source

OVERLAP: none

INACTIVE:

Redacted by agreement

Redacted by agreement

The major goal of this proposal is to study healthy, aging monkeys to establish a connection between gut motility and barrier function, and physical function which will support a new clinical paradigm for the treatment of frailty in older people.

Redacted by agreement

The major goals of this project is restoring tissue HSP90 levels post-irradiation to prevent T2DM as a delayed effect of radiation A newly recognized consequence of irradiation (IR) is the development of diabetes and metabolic disease. Type 2 diabetes (T2DM), has been recently documented in childhood and adult cancer survivors with T2DM hospitalization rates for survivors of childhood cancer 1.6 times greater than rates seen in age-matched cohorts.

Redacted by agreement

The major goals of this project are Urinary tract infection (UTI) is an extremely common infectious disease affecting ~11 million people annually in the United States. By elucidating the protective role of copper during UTI and bolstering copper response in the host to resolve UTI, the proposed research is expected to engender a significant public health benefit against UTI and is perfectly aligned with the NIH's mission of *'turning discovery into health'*.

E. 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?

The funding of the VRC P40 continues to have a substantial impact on the host institution. First, the VRC continues to be a critical component of the 'Primate Signature Program' of Wake Forest's Clinical and Translational Science Institute (CTSI, PI: Donald Mcclain, UL1-TR001240). The VRC and Primate Signature Program help provide infrastructure, expertise, monkeys, and feasibility funds in support of scientific outreach to the national consortium of CTSA hubs and the nation's broader community of translational investigators. In this grant year, the CTSI supported 3 additional pilot projects that involved use of VRC resources, with two Proprietary Info the Proprietary Info

Second, the VRC continues to be an essential component of the preclinical core for our institution's recently funded Alzheimer's Disease Core Center (PI: Suzanne Craft, P30-AG049638), the Sticht Center for Healthy Aging and Alzheimer's Prevention, and our Center for Diabetes and Metabolic Disorders. The VRC is able to provide known-age, adult and elderly animals as well as samples, tissues and data for use in studies focused on aging, Alzheimer's disease and diabetes. The VRC also maintains a small cohort of insulin-resistant and diabetic animals for use in metabolic research.

Third, in collaboration with Wake Forest Innovations, the VRC continues to provide the institution's largest cohort of nonhuman primates that can be made available to commercial sponsors for use in development of new therapies across a wide range of diseases. The attractiveness of the VRC to commercial sponsors is important to our ability broaden the sources of financial support for our research infrastructure, now that overall support of biomedical research by pharmaceutical and biotech companies equals or exceeds funding available from the NIH. In the past year, the VRC has supported three (3) industry-funded projects with a number of other projects currently in development.

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. 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. SPECIAL REPORTING REQUIREMENTS

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

NOTHING TO REPORT

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: Wake Forest University Health Sciences	937727907	NC-005	WAKE FOREST UNIVERSITY HEALTH SCIENCES Winston-Salem NC 271570001

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?

No

G.12 F&A COSTS

Is there a change in performance sites that will affect F&A costs?

No

RPPR

RESEARCH & RELATED BUDGET - SECTION A & B

FINAL

ORGANIZATIONAL DUNS*: 937727907

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: WAKE FOREST UNIVERSITY HEALTH SCIENCES

Start Date*: 04-01-2019 **End Date*:** 03-31-2020

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.		Matthew		Jorgensen		Project Lead	Institutional Base Salary	EFFORT			81,679.00	12,252.00	93,931.00
2.		Redacted by agreement									19,500.00	2,925.00	22,425.00

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

Additional Senior Key Persons: File Name:

Total Senior/Key Person **116,356.00**

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						
3	Technical staff	EFFORT			107,559.00	25,814.00	133,373.00
3	**Total Number Other Personnel**					**Total Other Personnel**	**133,373.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**249,729.00**

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

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

ORGANIZATIONAL DUNS*: 937727907
Budget Type*: ● Project ○ Subaward/Consortium
Enter name of Organization: WAKE FOREST UNIVERSITY HEALTH SCIENCES

Start Date*: 04-01-2019 **End Date*:** 03-31-2020

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*: 937727907
Budget Type*: ● Project ○ Subaward/Consortium
Enter name of Organization: WAKE FOREST UNIVERSITY HEALTH SCIENCES

Start Date*: 04-01-2019 **End Date*:** 03-31-2020

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	195,022.00
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	**195,022.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**444,751.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. MTDC	55.0	0.00	244,613.00
		Total Indirect Costs	**244,613.00**

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)	**689,364.00**

J. Fee	Funds Requested ($)*
	0.00

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

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

Budget Justification

Personnel

Matthew J. Jorgensen, Ph.D., Associate Professor of Pathology (Comparative Medicine) [EFFORT] Calendar Months Effort requested. As principal investigator and Director of the VRC, Dr. Jorgensen will be responsible for coordination of all activities involved in the resource. He will oversee all resource requests, sampling, and data collection. He will also provide quality control over the data and sample repository and provide training and consultation on the use of vervets in biomedical research.

Redacted by agreement

Redacted by agreement will serve as an Associate Director of the VRC. She will assist in the collection, analysis and interpretation of data pertaining to applied research component. She will also provide training and consultation on the use of vervets in biomedical research.

Redacted by agreement **B.A., Laboratory Technician IV** [EFFORT] Calendar Months Effort requested. Redacted by agreement is the senior VRC technician and will also assist Drs. Jorgensen and Redacted by Agreement with all sampling procedures and the disbursement of all biological, cardiometabolic, and viral screening samples. Additionally, she will help integrate of all of data into the VRC data repository and coordinate the storage of specimens in the tissue repository. She will also assist with all colony management tasks.

Redacted by agreement **Laboratory Technician II** [EFFORT] Calendar Months Effort requested. Redacted by agreement will assist Redacted by with scheduling of all colony procedures, coordination of sample collections, and the disbursement of all biological, cardiometabolic, and viral screening samples. He will integrate of all of data into the VRC data repository and will also assist with colony management tasks.

Redacted by agreement **B.A., Technical Services Manager** [EFFORT] Calendar Months Effort requested. Redacted by agreement has over 30 years of experience designing and maintaining the computer systems and programs necessary for the management and disbursement of research data, and will do so with the data collected in support of the proposed specific aims. She not coordinates the daily workload of the research specialists and developers, but actively participates in their assignments.

Supplies

Per diem. Funds are requested to cover a portion of the animal colony maintenance costs. Specifically, we are seeking support for 45 monkeys at $9.97/day. The costs for animals used in research at Wake Forest University Health Sciences are established in accordance with federal guidelines, and are included as part of the operational budget of the Institution's Animal Resources Program. We fully recognize that the proposed colony currently consists of over 300 animals. The remaining expenses will be offset by expected use and sales. Total costs requested $163,757.

Research Assays. Assays for genetic characterization and viral screening. Total costs requested $20,195.

Diet and General Lab Supplies. Funds are requested for supplies used for the collection and storage of biological samples. Total costs requested: $11,070.