



NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Grant Number: 5R01HL087103-10 REVISED
FAIN: R01HL087103

Principal Investigator(s):
Carol A. Shively, PHD

Project Title: Dietary Mitigation of Psychosocial Stress Effects on CVD Risk

Means, Paula
Assistant Dean for Research
Wake Forest University Health Sciences
Office of Research - Grants Administration
Medical Center Boulevard
Winston-Salem, NC 27157

Award e-mailed to: nihawards@wakehealth.edu

Period Of Performance:

Budget Period: 04/01/2017 – 03/31/2020

Project Period: 07/01/2007 – 03/31/2020

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 National Heart, Lung, And Blood Institute of the National Institutes of Health under Award Number R01HL087103. 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,

Erin A Davis
Grants Management Officer
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Additional information follows

SECTION I – AWARD DATA – 5R01HL087103-10 REVISED**Award Calculation (U.S. Dollars)**

Salaries and Wages	\$290,939
Fringe Benefits	\$84,998
Personnel Costs (Subtotal)	\$375,937
Consultant Services	\$1,200
Materials & Supplies	\$90,560
Travel	\$3,000
Other	\$1,400

Federal Direct Costs	\$472,097
Federal F&A Costs	\$226,607
Approved Budget	\$698,704
Total Amount of Federal Funds Obligated (Federal Share)	\$698,704
TOTAL FEDERAL AWARD AMOUNT	\$698,704

AMOUNT OF THIS ACTION (FEDERAL SHARE)	\$0
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SUMMARY TOTALS FOR ALL YEARS		
YR	THIS AWARD	CUMULATIVE TOTALS
10	\$698,704	\$698,704

Fiscal Information:

CFDA Name: Cardiovascular Diseases Research
CFDA Number: 93.837
EIN: 1223849199A1
Document Number: RHL087103C
PMS Account Type: P (Subaccount)
Fiscal Year: 2017

IC	CAN	2017
HL	8475146	\$698,704

NIH Administrative Data:

PCC: HHCG N / **OC:** 414E / **Released:** eRA Commons User Name 04/26/2019
Award Processed: 04/26/2019 07:01:19 PM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01HL087103-10 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 – 5R01HL087103-10 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:

- The grant program legislation and program regulation cited in this Notice of Award.
- Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- 45 CFR Part 75.
- 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.
- Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- 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).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

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) R01HL087103. 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 (FAPIS)). 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 – HL Special Terms and Conditions – 5R01HL087103-10 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 # 1 - EXTENSION WITHOUT FUNDS

The purpose of this revision is to change the performance period end dates from 3/31/2019 to 3/31/2020 in accordance with recipient's request dated 2/7/2019.

All terms and conditions listed below are still in effect.

SPECIAL FUNDING NOTICE

NIH is currently operating under a Continuing Resolution (See NIH Guide Notice NOT-OD-17-048: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-048.html>) and this award is being issued in accordance with the NHLBI FY 2017 Operating Guidelines which can be found at: <https://www.nhlbi.nih.gov/research/funding/general/current-operating-guidelines>

DELAYED AWARD

This grant award has been delayed due to late submission of an acceptable publications report was submitted April 5, 2017. According to NIH policy, if preaward costs are necessary, they may be approved by the authorized institution official(s).

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: Christina M Rinaldi
Email: christina.rinaldi@nih.gov **Phone:** 301-827-8287

Program Official: Catherine Stoney
Email: stoneyc@mail.nih.gov **Phone:** 301-435-6670 **Fax:** 301-480-1773

SPREADSHEET SUMMARY

GRANT NUMBER: 5R01HL087103-10 REVISED

INSTITUTION: WAKE FOREST UNIVERSITY HEALTH SCIENCES

Budget	Year 10
Salaries and Wages	\$290,939
Fringe Benefits	\$84,998
Personnel Costs (Subtotal)	\$375,937
Consultant Services	\$1,200
Materials & Supplies	\$90,560
Travel	\$3,000
Other	\$1,400
TOTAL FEDERAL DC	\$472,097
TOTAL FEDERAL F&A	\$226,607
TOTAL COST	\$698,704

Facilities and Administrative Costs	Year 10
F&A Cost Rate 1	48%
F&A Cost Base 1	\$472,097
F&A Costs 1	\$226,607

A. COVER PAGE

Project Title: Dietary Mitigation of Psychosocial Stress Effects on CVD Risk	
Grant Number: 5R01HL087103-10	Project/Grant Period: 12/01/2006 - 03/31/2018
Reporting Period: 04/01/2016 - 03/31/2017	Requested Budget Period: 04/01/2017 - 03/31/2018
Report Term Frequency: Annual	Date Submitted: 02/14/2017
Program Director/Principal Investigator Information: CAROL A SHIVELY , BA MA PHD Phone number: 336716-1524 Email: cshively@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: MEREDITH RENTZ Wake Forest University Health Sciences School of Medicine Controller's Office Winston Salem, NC 27103 Phone number: Email: nihawards@wakehealth.edu	Signing Official: ANGELA HORTON MEDICAL CENTER BLVD WINSTON-SALEM, NC 27157 Phone number: 336-716-1433 Email: ahorton@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?

To Determine:

1. Physiological responses to an acute psychological stressor (Acute Stress Test) in subordinate and dominant females. Hypothesis:

Proprietary Info

2. Physiological and behavioral indices of chronic stress and cardiovascular risk in subordinate and dominant females. Hypothesis:

Proprietary Info

3. Coronary (CAA) and carotid (CarAA) artery atherosclerosis and arterial gene expression in subordinate and dominant monkeys.

Hypothesis: Proprietary Info

Proprietary Info

4. Structural characteristics of neural regions involved in modulation of emotional behavior in subordinate and dominant monkeys.

Hypothesis: Proprietary Info

Proprietary Info

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: B.2 Accomplishments.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 Opportunities.pdf

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

Shively CA. Social Inequalities in Health: Modeling the CoMorbidity of Coronary Artery Disease and Depression in Primates. 12th Federation of American Societies for Experimental Biology (FASEB) Summer Research Conference "Neural Mechanisms in Cardiovascular Regulation". Saxons River, Vermont July 2016

Shively CA. Recognizing and managing depression-like behavior in macaques. National Centre for the Replacement Refinement & Reduction of Animal in Research Primate Welfare Meeting: "Cumulative Severity and Lifetime Experience of NHPs in Research". London, UK, October

Maldjian JA, Shively CA, Nader MA, Friedman DP, Whitlow CT. Multi-Atlas Library for Eliminating Normalization Failures in Non-Human Primates. Neuroinformatics. 2016 Apr; 14(2):183-90. PubMed PMID: 26643442.

Silverstein-Metzler MG2, Clarkson TB, Appt SE, Carr JJ, Shively CA, Register TC. Sertraline inhibits increases in body composition and carbohydrate dysregulation in adult female cynomolgus monkeys. Psychoneuroendocrinology. 2016 Jun; 68:29-38. Doi: 10.1016/j.psyneuen.2016.02.012. Epub 2016 Feb 21. PMID:26939086

Kavanagh K, Brown RN, Davis AT, Uberseder B, Floyd E, Pfisterer B, Shively CA. Microbial translocation and skeletal muscle in young and old vervet monkeys. Age (Dordr). 2016 Jun;38(3):58. PMID:21794407

Kalidindi A2, Kelly SD, Singleton KS, Guzman D, Merrill L, Willard SL2, Shively CA, Neigh GN. Reduced marker of vascularization in the anterior hippocampus in a female monkey model of depression. Physiol Behav. 2016 Jul 14. pii. S0031-9384(16)30530-3. Doi: 10.1016/j.physbeh.2016.07.007 [Epub ahead of print] review. PMID:27423324

Shively CA, Silverstein-Metzler M, Justice J, Willard SL. The impact of treatment with selective serotonin reuptake inhibitors on primate cardiovascular disease, behavior, and neuroanatomy. Neurosci Biobehav Rev. 2016 Aug 30. pii: S0149-7634(16)30111-7. doi:

10.1016/j.neubiorev.2016.08.037. [Epub ahead of print] Review. PubMed PMID: 27590831.

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

Proprietary Info

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

Progress Report: 4/1/15-3/31/16

B.2 Accomplishments (as of 2/10/17)

Proprietary Info

Proprietary Info These represent all goals for the project for this year, they were successfully met.

Proprietary Info

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

**B.4 Opportunities for training and professional development
Training**

Summer students

Redacted by agreement

Master's Student

Redacted by agreement

PhD Students

Redacted by agreement

Postdoctoral Fellows

Redacted by agreement

Professional Development

2016 iLEAD. Creating & Leading High Performing Teams. August WFBMC

2016 iLEAD. Giving & Receiving Feedback. August WFBMC

2016 iLEAD Leader's Guide to Employment Law & HR Policies October WFBMC

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
N/A: Not Journal	Developments in Primatology: Social Inequalities in Health in Nonhuman Primates: The Biology of the Gradient. Shively CA, Wilson ME, editors. Switzerland. Springer; 2016.
N/A: Not Journal	Dietary Modification of Physiological Responses to Chronic Psychosocial Stress: Implications for the Obesity Epidemic Developments in Primatology. Social Inequalities in Health in Nonhuman Primates: The Biology of the Gradient.. Shively CA, Fimmel A, editors. Switzerland. Springer; 2016. 159-178p.
N/A: Not Journal	Social status and the nonhuman primate brain: Developments in Primatology: Social Inequalities in Health in Nonhuman Primates: The Biology of the Gradient. Willard SL, Shively CA, editors. Switzerland. Springer; 2016. 117-140p.
Complete	Kavanagh K, Brown RN, Davis AT, Uberseder B, Floyd E, Pfisterer B, Shively CA. Microbial translocation and skeletal muscle in young and old vervet monkeys. Age (Dordrecht, Netherlands). 2016 June;38(3):58. PubMed PMID: 27194407; PubMed Central PMCID: PMC5005918.
Non-Compliant	Silverstein-Metzler MG, Shively CA, Clarkson TB, Appt SE, Carr JJ, Kritchevsky SB, Jones SR, Register TC. Sertraline inhibits increases in body fat and carbohydrate dysregulation in adult female cynomolgus monkeys. Psychoneuroendocrinology. 2016 June;68:29-38. PubMed PMID: 26939086.
Complete	Kalidindi A, Kelly SD, Singleton KS, Guzman D, Merrill L, Willard SL, Shively CA, Neigh GN. Reduced marker of vascularization in the anterior hippocampus in a female monkey model of depression. Physiology & behavior. 2016 July 14. PubMed PMID: 27423324; PubMed Central PMCID: PMC5237427.
N/A: Not Journal	Unpublished

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

Nothing to report

D. 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	Country	SS
eRA Commons User Name	Y	Shively, Carol A.	PII		BA,MA,PHD	PD/PI	EFFORT					NA
	N	Redacted by agreement				Technician						NA
	N					Technician						NA
	N					Technician						NA
	N					Technician						NA
	N		PII	PII	PHD,BS,BS	Co-Investigator						NA
	N				BS,DVM,OTH	Co-Investigator						NA
	N					Technician						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: C. Shively Other Support 2.17.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?

NA

CHANGES IN OTHER SUPPORT (D.2.c)**Carol A. Shively, Ph.D.**Active:

R21 AG049160 (Kavanagh-PI)	04/15/15-03/31/17	<div style="border: 1px solid black; padding: 2px;">EFFORT</div>	Months Effort
NIH/NIA	\$150,000		

Age-Related Changes in Intestinal Function and Sarcopenia in Monkeys
 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.
 Role: Co-Investigator

R01HL122393 (Register-Co-PI, Shively – Co-PI)	08/01/15-07/31/19	<div style="border: 1px solid black; padding: 2px;">EFFORT</div>	Months Effort
NIH	\$308,749		

Social Stress, Diet, and Primate Monocyte Programming in Cardiovascular Risk
 This project seeks to determine the effects of psychosocial stress on monocytes (cells that are important in inflammation and cardiovascular disease), and to evaluate whether a healthier diet can improve the hypothesized adverse effects of psychosocial stress on monocyte characteristics. We will conduct genomic and epigenomic studies of peripheral blood monocytes and examine their relationships to cardiovascular disease outcomes in female nonhuman primates. If successful, the proposed study could provide a widely applicable and cost-effective intervention on psychological stress, reducing the burden of cardiovascular disease in millions of Americans.
 Role on Project: Co-Principal Investigator

Active: on previous listed as pending

1P30 AG049638-01 A1 (Craft-PI)	09/01/16-06/30/21	<div style="border: 1px solid black; padding: 2px;">EFFORT</div>	Months Effort
NIH	\$1,153,710		

Wake Forest Alzheimer's Disease Core Center
 This application seeks to establish a new Alzheimer's Disease Core Cer (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. Finally, we will educate new investigators in translational research practices, and health professionals, afflicted adults, their families, and their communities about AD and strategies for reducing risk.
 Role on Project: Co-Investigator

Inactive: none

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?

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. 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 Medical Center Blvd 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?

Yes

Estimated unobligated balance: 240000

G.10.b Provide an explanation for unobligated balance:

The unobligated balance is due to the study running behind schedule due to 1) a three to four month initial delay in obtaining the monkeys, and 2) a subsequent three/four-month delay in starting the Experimental Phase because the Baseline Phase took longer than anticipated.

G.10.c If authorized to carryover the balance, provide a general description of how it is anticipated that the funds will be spent

Funds will be spent as planned and described in the original grant application. However, there will be a six-eight month delay in the timetable as stated above in G.10.b.

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