Recipient Information

1. Recipient Name

RECTOR & VISITORS OF THE UNIVERSITY OF VIRGINIA 1001 EMMET ST N CHARLOTTESVILLE, VA 22903

2. Congressional District of Recipient 05

3. Payment System Identifier (ID) 1546001796A1

4. Employer Identification Number (EIN) 546001796

5. Data Universal Numbering System (DUNS) 065391526

6. Recipient's Unique Entity Identifier JJG6HU8PA4S5

7. Project Director or Principal Investigator

Patricia Fiorella Rodriguez Lozano, MD

pr3gg@virginia.edu 434-982-4270

8. Authorized Official

Lauren Armstrong uva_som_ogc@virginia.edu 434-982-1852

Federal Agency Information

9. Awarding Agency Contact Information

FATU Kamara Grants Management Specialist NATIONAL HEART, LUNG, AND BLOOD INSTITUTE fatima.kamara@nih.gov 301-435-7916

10. Program Official Contact Information

Wayne C. Wang Program Official NATIONAL HEART, LUNG, AND BLOOD INSTITUTE wangwc@mail.nih.gov 301-435-0535

Federal Award Information

11. Award Number

1K01HL174889-01

12. Unique Federal Award Identification Number (FAIN)

K01HL174889

13. Statutory Authority

42 USC 241 42 CFR 52

14. Federal Award Project Title

Innovative Therapy to Treat Women with Angina with Nonobstructive CAD (ANOCA) and Coronary Microvascular Disease

15. Assistance Listing Number

93.837

16. Assistance Listing Program Title

Cardiovascular Diseases Research

17. Award Action Type

New Competing

18. Is the Award R&D?

Yes

Summary Federal Award Financial Information				
19. Budget Period Start Date 09/01/2024 - End Date 08/31/2025				
20. Total Amount of Federal Funds Obligated by this Action	\$162,000			
20 a. Direct Cost Amount	\$150,000			
20 b. Indirect Cost Amount	\$12,000			
21. Authorized Carryover				
22. Offset				
23. Total Amount of Federal Funds Obligated this budget period	\$162,000			
24. Total Approved Cost Sharing or Matching, where applicable	\$0			
25. Total Federal and Non-Federal Approved this Budget Period	\$162,000			
26. Project Period Start Date 09/01/2024 – End Date 08/31/2029				
27. Total Amount of the Federal Award including Approved Cost	\$162,000			
Sharing or Matching this Project Period				

28. Authorized Treatment of Program Income

Additional Costs

29. Grants Management Officer - Signature

CHANTAL DERA Falade

30. Remarks

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



RESEARCH SCIENTIST DEVELOPMENT AWARD Department of Health and Human Services National Institutes of Health



NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

SECTION I - AWARD DATA - 1K01HL174889-01

Principal Investigator(s):

Patricia Fiorella Rodriguez Lozano, MD

Award e-mailed to: osp-nih-noa@virginia.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of \$162,000 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to The Rector and Visitors of the University of Virginia 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 recipient when funds are drawn down or otherwise requested 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 K01HL174889. 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 direct questions to the Federal Agency contacts.

Sincerely yours,

CHANTAL DERA Falade Grants Management Officer NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Additional information follows

Salaries and Wages Fringe Benefits Personnel Costs (Subtotal) Other	\$100,000 \$28,200 \$128,200 \$21,800
Federal Direct Costs Federal F&A Costs Approved Budget Total Amount of Federal Funds Authorized (Federal Share) TOTAL FEDERAL AWARD AMOUNT	\$150,000 \$12,000 \$162,000 \$162,000 \$162,000
AMOUNT OF THIS ACTION (FEDERAL SHARE)	\$162,000

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)				
YR	THIS AWARD	CUMULATIVE TOTALS		
1	\$162,000	\$162,000		
2	\$162,000	\$162,000		
3	\$162,000	\$162,000		
4	\$162,000	\$162,000		
5	\$162,000	\$162,000		

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier:1546001796A1Document Number:KHL174889APMS Account Type:P (Subaccount)

Fiscal Year: 2024

IC	CAN	2024	2025	2026	2027	2028
HL	8475183	\$162,000	\$162,000	\$162,000	\$162,000	\$162,000

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:

PCC: HHVVBN / OC: 41033 / Released: 08/06/2024 Award Processed: 08/14/2024 12:20:27 AM

SECTION II - PAYMENT/HOTLINE INFORMATION - 1K01HL174889-01

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 - STANDARD TERMS AND CONDITIONS - 1K01HL174889-01

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.)

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).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

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

This grant is excluded from Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI 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) K01HL174889. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

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 provides support for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration System Information Website. NIH encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English
 proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure
 meaningful access to programs or activities by limited English proficient individuals,
 see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-quidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious

nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/religious-freedom/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

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 - HL SPECIFIC AWARD CONDITIONS - 1K01HL174889-01

Clinical Trial Indicator: Yes

This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

RESTRICTION: This award is issued subject to the following special condition: Only activities that do not directly involve human subjects (i.e., are clearly severable and independent from those

activities that do involve Human Subjects) may be conducted under this award until the following issue addressed in NHLBI Grants Management Specialist, Fatima Kamara's letter dated August 5, 2024 to University of Virginia's Authorized Organization Representative, Lauren Armstrong, have been addressed to the satisfaction of the NIH.

No funds may be drawn down from the payment system and no obligations may be made against Federal funds for any research involving human subjects prior to the NIH's notification to the recipient that the identified issues have been addressed and this restriction removed.

NHLBI FUNDING GUIDELINES

This award is being issued in accordance with the NHLBI FY 2024 Operating Guidelines which can be found at: https://www.nhlbi.nih.gov/current-operating-guidelines

SUBJECT FOA

This award is subject to the conditions set forth in PAR/RFA HL-22-010, "Mentored Career Development Award to Promote Faculty Diversity in Biomedical Research (K01 Independent Clinical Trial Required)," 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: https://grants.nih.gov/grants/guide/rfa-files/RFA-HL-22-010.html

MENTORED CAREER DEVELOPMENT AWARD

Mentored CDA recipients are required to devote a minimum commitment equivalent of 9 calendar <u>person months</u> (75% of their full-time appointment at the applicant institution) to the career development and research objectives of the program specified in FOA, the policy and additional details are found

here: https://grants.nih.gov/grants/policy/nihgps/HTML5/section 12/12.3.6 level of effort.htm. The recipient may supplement the NHLBI salary contribution with non-federal funds up to a level that is consistent with the institution's salary scale, the policy, including additional details and exceptions are found here:

https://grants.nih.gov/grants/policy/nihgps/HTML5/section_12/12.8.1_salaries_and_fringe_benefits.htm

MENTOR'S REPORT

Please note that a concise statement from the awardee's mentor must be included in the RPPR. The statement should address progress and performance, see Section 7.1 of the NIH RPPR Instruction Guide.

NHLBI-SPECIFIC Data Management and Sharing Policy

This award is being issued with the acceptance of the recipients DMS Plan dated: October 13, 2023. Grantees are required to adhere to the NIH DMS Policy in addition to NHLBI Supplement to the NIH Policy for Data Management and Sharing found at: https://www.nhlbi.nih.gov/grants-and-training/policies-and-guidelines/nhlbi-policy-for-data-sharing

CLINICAL TRIAL DISSEMINATION PLAN

The clinical trial(s) supported by this award is subject to the plan dated October 13, 2023 submitted to NIH and the NIH policy on *Dissemination of NIH-Funded Clinical Trial Information*. The plan states that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant and primary summary results reported in ClinicalTrials.gov, not later than one year after the completion date. The reporting of summary results is required by this term of award even if the primary completion date occurs after the period of performance.

This award is subject to additional certification requirements with each submission of the Annual, Interim, and Final Research Performance Progress Report (RPPR). The recipient must agree to the following annual certification when submitting each RPPR. By submitting the RPPR, the AOR signifies compliance, as follows:

In submitting this RPPR, the SO (or PD/PI with delegated authority), certifies to the best of his/her knowledge that, for all clinical trials funded under this NIH award, the recipient and all investigators conducting NIH-funded clinical trials are in compliance with the recipient's plan addressing compliance with the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information. Any clinical trial funded in whole or in part under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the completion date, even if the completion date occurs after the period of performance.

eConnect

The NHLBI utilizes a reporting system, eConnect, for both Clinical Trial Milestones and Participant Enrollment/Milestone Accrual. eConnect utilizes the existing Electronic Research Administration (eRA) logon system and current institutional accounts so no Authorized Organizational Representative or Principal Investigator will be required to create new accounts with the NHLBI. The system is designed to facilitate NHLBI monitoring traditionally accomplished through standard paper submissions for Quarterly/Annual Reporting of Patient Recruitment per the NHLBI Milestones Policy as well as the reporting of Clinical Trial Milestones negotiated and/or peer reviewed on this award. The NHLBI encourages the recipient to report when milestones are achieved through eConnect as well as report on a quarterly basis recruitment that has occurred under this award.

NON-COMPETING RENEWAL (NON-SNAP)

The NIH requires the use of the Research Performance Progress Report (RPPR) for all Type 5 progress reports. The RPPR and other documents applicable to this Non-SNAP Page 6 of 7

grant are due the first of the month preceding the month in which the budget period ends (e.g., if the budget period ends 11/30, the due date is 10/1). Please see http://grants.nih.gov/grants/rppr/index.htm for additional information on the RPPR.

PRIOR APPROVAL REQUEST

It is recommended that applicable prior approval requests be submitted via the eRA Commons Prior Approval Module (link: <u>prior_approval (nih.gov)</u>). Please refer to Part II Chapter 8 of 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

Data Management and Sharing Policy: Applicable

This project is expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing applies. The approved Data Management and Sharing (DMS) Plan is hereby incorporated as a term and condition of award, and the recipient shall manage and disseminate scientific data in accordance with the approved plan. Any significant changes to the DMS Plan (e.g., new scientific direction, a different data repository, or a timeline revision) require NIH prior approval. Failure to comply with the approved DMS plan may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

SPREADSHEET SUMMARY

AWARD NUMBER: 1K01HL174889-01

INSTITUTION: The Rector and Visitors of the University of Virginia

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	\$100,000	\$100,000	\$100,000	\$100,000	\$100,000
Fringe Benefits	\$28,200	\$28,200	\$28,200	\$28,200	\$28,200
Personnel Costs (Subtotal)	\$128,200	\$128,200	\$128,200	\$128,200	\$128,200
Other	\$21,800	\$21,800	\$21,800	\$21,800	\$21,800
TOTAL FEDERAL DC	\$150,000	\$150,000	\$150,000	\$150,000	\$150,000
TOTAL FEDERAL F&A	\$12,000	\$12,000	\$12,000	\$12,000	\$12,000
TOTAL COST	\$162,000	\$162,000	\$162,000	\$162,000	\$162,000

Facilities and Administrative	Year 1	Year 2	Year 3	Year 4	Year 5
Costs					
F&A Cost Rate 1	8%	8%	8%	8%	8%
F&A Cost Base 1	\$150,000	\$150,000	\$150,000	\$150,000	\$150,000
F&A Costs 1	\$12,000	\$12,000	\$12,000	\$12,000	\$12,000