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
Mete Civelek, PHD (Contact)
Assistant Professor
mc2wq@virginia.edu
143-424-3166

8. Authorized Official
Lauren B. Armstrong
uva_som_ogc@virginia.edu
434-924-8426

Federal Agency Information

9. Awarding Agency Contact Information
Eunica Haynes

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES
haynese@mail.nih.gov
301-827-4018

10. Program Official Contact Information
TERESA L Z JONES
Program Director
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES
jonest@extra.niddk.nih.gov
301-435-2996

Federal Award Information

11. Award Number
1U01DK142283-01

12. Unique Federal Award Identification Number (FAIN)
U01DK142283

13. Statutory Authority
42 USC 241 31 USC 6305 42 CFR 52

14. Federal Award Project Title
Molecular Drivers of Atherosclerosis in Diabetes

15. Assistance Listing Number
93.847

16. Assistance Listing Program Title
Diabetes, Digestive, and Kidney Diseases Extramural Research

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 09/18/2024 **– End Date** 06/30/2025	
20. Total Amount of Federal Funds Obligated by this Action	$962,975
20 a. Direct Cost Amount	$603,200
20 b. Indirect Cost Amount	$359,775
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$962,975
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$962,975
26. Project Period Start Date 09/18/2024 **– End Date** 06/30/2027	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$962,975

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
MARY K. ROSENBERG

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.

SECTION I – AWARD DATA – 1U01DK142283-01

Principal Investigator(s):
Mete Civelek (contact), PHD
Clint L Miller, PHD
Suna Onengut, PHD

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 $962,975 (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 31 USC 6305 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 Institute Of Diabetes And Digestive And Kidney Diseases of the National Institutes of Health under Award Number U01DK142283. 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,

MARY K. ROSENBERG
Grants Management Officer
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$275,191
Fringe Benefits	$83,868
Personnel Costs (Subtotal)	$359,059
Materials & Supplies	$175,000
Travel	$10,000
Other	$10,941
Subawards/Consortium/Contractual Costs	$43,200
Publication Costs	$5,000
Federal Direct Costs	$603,200
Federal F&A Costs	$359,775
Approved Budget	$962,975
Total Amount of Federal Funds Authorized (Federal Share)	$962,975
TOTAL FEDERAL AWARD AMOUNT	$962,975
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$962,975

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$962,975	$962,975
2	$947,600	$947,600
3	$947,600	$947,600

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

Fiscal Information:

Payment System Identifier:	1546001796A1
Document Number:	UDK142283A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2024

IC	CAN	2024	2025	2026
DK	8033711	$962,975	$947,600	$947,600

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

NIH Administrative Data:
PCC: DTJ CVTR / **OC**: 41026 / **Released**: 09/17/2024
Award Processed: 09/18/2024 12:30:55 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1U01DK142283-01

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 – 1U01DK142283-01

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.)

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).

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 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) U01DK142283. 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/.

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-guidance/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/conscience-protections/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 – DK SPECIFIC AWARD CONDITIONS – 1U01DK142283-01

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.

Budget Period Adjustment

Although the initial budget period for this award is 9/18/2024 to 6/30/2024, the award includes funds for 12 months of support. Future year budget periods will cycle each year on 7/1.

Key Personnel

In addition to the PI, Mete Civelek the following individuals are named as key personnel:

Sander van der Laan, Suna Onengut-Gumuscu, and Clint Miller

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.

Consortium Involvement

This award includes funds awarded for consortium activity with the University of Medical Center Utrecht. Consortiums are to be established and administered as described in the NIH Grants Policy Statement.

Other Support

NIDDK has received the updated other support information provided for all key personnel as identified by the applicant. Only other support information for the PD/PI(s) and any individual(s) named as key personnel on the Notice of Grant Award have been reviewed for overlap. It is the responsibility of the recipient to make sure no overlap of budget, effort, or aims exist for all personnel devoted to this grant.

Salary Cap

None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the current salary cap (Executive Level II). Therefore, this award and/or future years are adjusted accordingly, if applicable. See the Salary Cap Summary for the current and historical record of the salary cap, including effective dates.

Prior Approvals with Multiple PI's

In keeping with NOT-OD-11-118, as this grant has multiple Principal Investigators (PIs), although the signatures of the PIs are not required on prior approval requests submitted to the agency, the

grantee institution must secure and retain the signatures of all of the PIs within their own internal processes.

Cooperative Agreement Terms and Conditions of Award
The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 2 CFR Part 200, and other HHS, PHS, and NIH grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial NIH programmatic involvement with the Recipients is anticipated during the performance of the activities. Under the cooperative agreement, the NIH purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the Recipients for the project as a whole, although specific tasks and activities may be shared among the Recipients and the NIH as defined below.

The CARE-T1D Consortium consists of a Coordinating Center and Tissue Analysis Sites.

The PD(s)/PI(s) will have the primary responsibility for:

- Recipient(s) will be primarily responsible for defining the objectives and approaches, planning, conduct, analysis, and publication of results, interpretations, and conclusions of studies conducted under the terms and conditions of the cooperative agreement award.
- The Program Director/Principal Investigator (PD/PI) will assume responsibility and accountability to the applicant organization officials and to the NIH for the performance and proper conduct of the research supported under this Funding Opportunity Announcement (NOFO) in accordance with the terms and conditions of award, as well as all pertinent laws, regulations, and policies.
- Recipient(s) will retain custody of and have primary rights to the data and software developed under these awards, subject to Government policies regarding rights of access consistent with current DHHS, PHS, and NIH policies.
- Recipients are responsible for their staff in maintaining confidentiality of the information as developed by the network/consortium, including, without limitation, study protocols, data analysis, conclusions, etc. per policies approved by the Steering Committee (SC) as well as any confidential information received by third party collaborators.
- Recipients must analyze, publish and/or publicly release and disseminate results, data and other products of the study in a timely manner, concordant with the approved plan for making quality-assured data and materials available to the scientific community and the NIH, consistent with NIH policies and achieving the goals of the NOFO.
- Data Management and Sharing Plan: In accordance with the NIH Policy for Data Management and Sharing (NIH NOT-OD-21-013), the NIDDK approved plan will become a term and condition of award, be routinely monitored during the award period, and compliance may factor into future funding decisions. By the end of the funding or proprietary period, a recipient or study group may not continue to use or share study generated resources until those resources are available to the public via a NIDDK approved repository per the NIDDK approved plan.

- Recipient(s) will be required to participate in a cooperative and interactive manner with members of the network/consortium including designated NIH staff (e.g., Program Official, Project Scientist, Project Coordinator).

- Recipient(s) agree to establish agreements amongst themselves that address the following issues: (1) procedures for data sharing among network/consortium members and data sharing with industry partners; (2) procedures for safeguarding confidential information, including without limitation, any data generated by the network/consortium as well as information and/or data received from external collaborators; (3) procedures for addressing ownership of intellectual property that result from aggregate multi-party data; (4) procedures for sharing bio-specimens under an overarching Material Transfer Agreement (MTA) amongst network/consortium members that operationalizes material transfer in an efficient and expeditious manner; (5) procedures for reviewing publications, determining authorship, and industry access to publications.

- Any third-party collaboration (including but not limited to interactions with organizations from industry, academia, and nonprofit institutions) should be governed by a research collaboration agreement (e.g., Clinical Trial Agreement, Research Collaborative Agreement, etc.) or any third-party contract mechanism(s) with terms that ensure the collaboration is conducted in accordance with the Cooperative Agreement, applicable NIH/NIDDK policies and procedures, applicable network/consortium policies, and with written approval from NIDDK Program staff. Any relevant proposed third-party agreements related to the network/consortium studies between grantee and third-party will be provided to the NIDDK Program staff and NIDDK Technology Advancement Office for review, comment, and approval to assure compliance with NIH/NIDDK policies and network/consortium policies. Further, at the request of the NIDDK Program staff, any other network/consortium-relevant third-party agreements must be shared with NIDDK. Failure to comply with this term may prompt action in accordance with NIH Grants Policy Statement, Section 8.5 titled: “Special Award Conditions and Remedies for Noncompliance (Special Award Conditions and Enforcement Actions)”, and Section 8.5.2, titled: “Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding Support”, noncompliance with the terms and conditions of award will be considered by the funding IC for future funding and support decisions and may result in termination of the award.”

- Any involvement of a third-party (including but not limited to industry, academia, and nonprofit institutions) in the study and network/consortium activities that includes access to any network/consortium generated resources (i.e., data and biosamples), or study results that are not publicly available, or using the name of the network/consortium or study or the name of the NIH or NIDDK, is permitted only after written permission by the NIDDK Program staff who will consult with others at NIH and NIDDK Technology Advancement Office.

- Recipients must agree to comply with the processes and goals as delineated within the NOFO.

- Recipient(s) agree to the governance of the study through a Steering Committee:
    - The PD/PI or contact PD/PI in the case of multi-PD/PI awards, will serve as a voting member of the Steering Committee and will attend all meetings of the Steering Committee.
    - Each full member will have one vote.
    - The Recipient will be responsible for accepting and implementing the goals, priorities, procedures, protocols, and policies agreed upon by the Steering Committee and subcommittees.

- Recipients must serve on Subcommittees as needed. Subcommittees will report progress at Steering Committee Meetings and/or lead discussions at the Annual Investigator's Retreat.

- Recipients must share data, materials, models, methods, information and unique research resources that are generated by the projects in concordance with Network/Consortium policies in order to facilitate progress. When appropriate, and in accordance with NIH policies, as well as NIDDK policies, Recipients will be expected to collaborate; share novel reagents, biomaterials, methods and models and resources; and share both positive and negative results that would help guide the research activities of other members.

- Upon completion or termination of the research project(s), the Recipients are responsible for making all study materials and procedures broadly available (e.g., putting them into the public domain) or making them accessible to the research community according to the NIH-approved plan submitted for each project, for making all study materials and procedures available to the scientific community and the NIH for the conduct of research. The Data Management and Sharing Plan should include a plan to accomplish afore mentioned at the end of the study.

- Recipients may be asked to scientifically review applications for special opportunity pool funds, as it is deemed appropriate.

NIH staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

The NIDDK and the NIH will designate program staff, including a Program Official and a Grants Management Specialist to provide normal program stewardship and administrative oversight of the cooperative agreement. The Program Official and Grants Management Specialist will be named in the Notice of Grant Award (NOA).

An NIH IC Project Scientist will be substantially involved in this project above and beyond the normal stewardship of an NIH IC Program Official as follows:

1. Serve as the contact point for all facets of the scientific interaction with the recipient(s). As required for the coordination of activities and to expedite progress, NIDDK and NIH may designate additional NIDDK and NIH staff to provide advice to the recipient on specific scientific and/or analytic issues.

2. For multi-center studies, participate in the Steering Committee that oversees study conduct. The NIH Project Scientist will be a full participant and voting member of the Steering Committee and, if applicable, subcommittees.

3. Serve as a resource to study investigators with respect to other ongoing NIDDK and NIH activities that may be relevant to the study to facilitate compatibility with the NIDDK and NIH missions and avoid unnecessary duplication of effort.

4. Have substantial involvement assisting in the design and coordination of research activities for Recipients as elaborated below:

a. The NIH Project Scientist may coordinate activities among recipients by assisting in the design, development, and coordination of a common research or clinical protocol and statistical evaluations of data; in the preparation of questionnaires and other data recording forms; and in the publication of results.

b. Reviewing procedures for assessing data quality and study performance monitoring.

c. The NIH Project Scientist may be co-authors on study publications. In general, to warrant co-authorship, NIH staff must have contributed to the following areas: (a) design of the concepts or experiments being tested; (b)

performance of significant portions of the activity; (c) participation in analysis and interpretation of study results and (d) preparation and authorship of pertinent manuscripts.

The NIDDK Program Official identified in the Notice of Award will:

1. Interact with the Program Director(s)/Principal Investigator(s) on a regular basis to monitor study progress. Monitoring may include regular communications with the Program Director/Principal Investigator and staff, periodic site visits, observation of field data collection and management techniques, quality control, fiscal review, and other relevant matters; as well as attendance at Steering Committee, data safety and monitoring board, and related meetings. The NIDDK retains, as an option, periodic review of progress by researchers not involved with the study.
2. Review and approve protocols prior to implementation to ensure they are within the scope of peer review, for safety considerations, as required by federal regulations.
3. The NIDDK Program Official will monitor protocol progress, and may request that a protocol study be closed to accrual for reasons including: (a) accrual rate insufficient to complete study in a timely fashion; (b) accrual goals met early; (c) poor protocol performance; (d) participant safety and regulatory concerns; (e) study results that are already conclusive; (f) low likelihood of showing a benefit of the intervention (futility); and (g) emergence of new information that diminishes the scientific importance of the study question. The NIDDK will not permit further expenditures of NIDDK funds for a study after requesting closure except as specifically approved by the NIDDK.
4. Make recommendations for continued funding based on: a) overall study progress, including sufficient patient and/or data accrual; b) cooperation in carrying out the research (e.g., attendance at Steering Committee meetings, implementation of group decisions, compliance with the terms of award and reporting requirements); and/or c) maintenance of a high quality of research, which will allow pooling of data and comparisons across multiple cooperative agreement awards for common data elements.
5. Appoint an independent Data and Safety Monitoring Board (DSMB) as appropriate for Phase III clinical trials or other high-risk studies, or an Observational Study Monitoring Board (OSMB) for observational/epidemiologic studies; these Boards will review study progress, safety data, and interim results, as appropriate, and provide guidance to the NIDDK. The NIDDK Program Official or their Project Coordinator will serve as the Executive Secretary and/or NIDDK program representative on the DSMB/OSMB.

- The NIDDK and the NIH may invite External Consultants with relevant scientific expertise for the sole purpose of consultative advice on scientific developments and opportunities that may enhance the achievement of the study goals.
- The NIDDK Program Official will review and approve applications of the Special Opportunity Funds to ensure that they are within the scope of network/consortium research as described in the NOFO and NIH guidelines.

Areas of Joint Responsibility include:

Through the Recipient, Steering Committee and NIH staff, the study members will cooperatively develop and implement processes to submit information and data to the Coordinating Center (CC), determine criteria and processes for quality control of information and data to be posted for the research community, refine scientific objectives, and implement research advances to facilitate the goals of the study, consistent with NIH policies and achieving the goals of the program as described in the NOFO.

Executive Committee (EC)

- The EC will consist of: The Director of the Coordinating Center, the NIH Project Scientist(s) or Project Coordinator, and representative Principal Investigator(s) chosen among the Recipients; the EC is not a governing body and does not cast votes.
- The EC will review the progress of all NIH-funded special funding opportunity programs and make recommendations for improvement. Annual reports will be prepared for each special funding opportunity to coincide with one of the annual SC meetings.
- The EC will be responsible for organizing the yearly Scientific Retreat.
- The EC will have meetings that will be organized by the Director of the Coordinating Center. Any EC member may place items on the agenda. These should be communicated in advance of the meeting to the Project Scientist(s) who will distribute these to all members. The designated NIDDK Program Official(s) of CARE-T1D may be asked to participate in order to provide additional information and to summarize actions that are taken.

Steering Committee (SC)

- A Steering Committee organized by the study investigator(s) will be the main governing body of the study.
- The Steering Committee has primary responsibility to design research activities, establish priorities, develop common protocols and manuals, questionnaires and other data recording forms, establish and maintain quality control among recipients, review progress, monitor patient accrual, coordinate and standardize data management, and cooperate on the publication of results. Major scientific decisions regarding the core data will be determined by the Steering Committee. The Steering Committee will document progress in written reports to the NIDDK Program Official and will provide periodic supplementary reports upon request.
- The Steering Committee will be composed of all Program Director(s)/Principal Investigator(s), (including those of data coordinating/statistical centers, if any) and co-investigator(s) as deemed necessary, and the NIH Project Scientist. The final structure of the Steering Committee and voting procedures will be established at the first meeting. The NIH Project Scientist will have voting membership on the Steering Committee, and as appropriate, its subcommittees. The frequency of Steering Committee meetings will be dictated by a vote of the members of the Steering Committee. The NIDDK Program Official may serve as a non-voting member on the Steering Committee.
- A Chairperson of the Steering Committee will be selected and voted on by the Steering Committee members. The Chairperson provides leadership to the Committee by conducting the Steering Committee meetings and by interacting closely with the recipients during protocol development and implementation. The NIH Project Scientist may not serve as Chairperson. The NIDDK program official will review the Committee's selection for potential bias, conflicts of interest, or lack of required expertise. If the Program Official has concerns regarding selection of the Chairperson which are not satisfactorily resolved, the Program Official may withhold concurrence if approved by the Director, Division of Extramural Activities, NIDDK based on written justification. In cases where Program Official concurrence is withheld, the Steering Committee will be required to make another selection.

External Consultants

An independent panel of External Consultants may be established by the Steering Committee. The External Consultants may periodically review interim progress of the project(s) and provide reports to the Steering Committee. Members of the panel of External Consultants may be asked, on an *ad hoc* basis, to participate in the peer review of

applications for new research initiatives that utilize special “opportunity pool” funds. The NIDDK Program Official will review the Committee’s selections for potential bias, conflicts of interest, or lack of required expertise. If the NIDDK Program Official has concerns regarding selection of one or more External Consultants which are not satisfactorily resolved, the NIDDK Program Official may withhold concurrence if approved by the Director of NIDDK Division of Extramural Activities based on written justification. In cases where NIDDK Program Official concurrence is withheld, the Steering Committee will be required to make another selection.

Dispute Resolution:

Any disagreements that may arise in scientific or programmatic matters (within the scope of the award) between award recipients and the NIH may be brought to Dispute Resolution. A Dispute Resolution Panel composed of three members will be convened. It will have three members: a designee of the Steering Committee chosen without NIH staff voting, one NIH designee, and a third designee with expertise in the relevant area who is chosen by the other two; in the case of individual disagreement, the first member may be chosen by the individual Recipient. This special dispute resolution procedure does not alter the Recipient's right to appeal an adverse action that is otherwise appealable in accordance with PHS regulation 42 CFR Part 50, Subpart D and DHHS regulation 45 CFR Part 16.

3. Data Management and Sharing

Consistent with the 2023 NIH Policy for Data Management and Sharing, when data management and sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirements as outlined in the NIH Grants Policy Statement. Upon the approval of a Data Management and Sharing Plan, it is required for recipients to implement the plan as described.

All data generated from CaRe-T1D resources and other sources (animal studies and other human tissue banks) that were produced as part of the grant research will be placed in the CaRe-T1D database and made available to investigators within and outside the CaRe-T1D consortium through a timeline and procedure established by the CaRe-T1D Steering Committee.

4. Reporting

When multiple years are involved, recipients will be required to submit the Research Performance Progress Report (RPPR) annually and financial statements as required in the NIH Grants Policy Statement.

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the NIH Grants Policy Statement. NIH NOFOs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 2 CFR Part 200.301.

The Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over the threshold. See the NIH Grants Policy Statement for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 2 CFR Part 200.113 and Appendix XII to 2 CFR Part 200, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported 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 FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 2 CFR Part 200 – Award Term and Condition for Recipient Integrity and Performance Matters.

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: 1U01DK142283-01

INSTITUTION: The Rector and Visitors of the University of Virginia

Budget	Year 1	Year 2	Year 3
Salaries and Wages	$275,191	$275,191	$275,191
Fringe Benefits	$83,868	$83,868	$83,868
Personnel Costs (Subtotal)	$359,059	$359,059	$359,059
Materials & Supplies	$175,000	$175,000	$175,000
Travel	$10,000	$10,000	$10,000
Other	$10,941	$10,941	$10,941
Subawards/Consortium/Contractual Costs	$43,200	$43,200	$43,200
Publication Costs	$5,000	$5,000	$5,000
TOTAL FEDERAL DC	$603,200	$603,200	$603,200
TOTAL FEDERAL F&A	$359,775	$344,400	$344,400
TOTAL COST	$962,975	$947,600	$947,600

Facilities and Administrative Costs	Year 1	Year 2	Year 3
F&A Cost Rate 1	61.5%	61.5%	61.5%
F&A Cost Base 1	$585,000	$560,000	$560,000
F&A Costs 1	$359,775	$344,400	$344,400