THE UNIVERSITY OF SOUTH FLORIDA

SPONSORED RESEARCH PURCHASE EXEMPTION FROM GENERAL ACCOUNTING AND PURCHASING PROCEDURES

Under the provision of Section 1004.22, Florida Statutes, the exemption of the following purchase is recommended.

DESCRIPTION: AutoGen, Inc.
Subagreement #6163-1103-02-BZ

PURPOSE: To perform the services as described in the project funded by the National Institutes of Health

JUSTIFICATION: The services to be provided AutoGen, Inc. were approved by the National Institutes of Health. Due to time constraints, because it is more expeditious and efficient to the accomplishment of the project, and because funding to USF was contingent upon all parties participating and the expertise they house, this exception is granted.

DocuSigned by:
Stephanie Rios
8/6/2024 | 13:49 E
Stephanie Rios
Director
Sponsored Research

FDP Cost Reimbursement Subaward

Federal Awarding Agency: National Institutes of Health (NIH)

Pass-Through Entity (PTE):	**Subrecipient:**
The University of South Florida Board of Trustees	AutoGen, Inc.
PTE PI: Jeffrey Krischer	Sub PI: Michael Messier
PTE Federal Award No: 5U01DK128847-03	Subaward No: 6163-1103-02-BZ
Project Title: Limited Competition: Continued Follow-Up of Subjects and Initiation of a Second Case-control Cohort in The Environmental Determinants of Diabetes in The Young Study (TEDDY)	
Subaward Budget Period: Start: 07/01/2024 End: 12/31/2024	Amount Funded This Action (USD): $ 660,006.00
Estimated Period of Performance: Start: End:	Incrementally Estimated Total (USD): $

Terms and Conditions

1. PTE hereby awards a cost reimbursable subaward, (as determined by 2 CFR 200.331), to Subrecipient. The Statement of Work and budget for this Subaward are as shown in Attachment 5. In its performance of Subaward work, Subrecipient shall be an independent entity and not an employee or agent of PTE.

2. Subrecipient shall submit invoices not more often than monthly and not less frequently than quarterly for allowable costs incurred. Upon the receipt of proper invoices, the PTE agrees to process payments in accordance with this Subaward and 2 CFR 200.305. All invoices shall be submitted using Subrecipient's standard invoice, but at a minimum shall include current and cumulative costs (including cost sharing), breakdown by major cost category, Subaward number, and certification, as required in 2 CFR 200.415(a). Invoices that do not reference PTE Subaward number shall be returned to Subrecipient. Invoices and questions concerning invoice receipt or payments shall be directed to the party's Authorized Official Contact, shown in Attachment 3A.

3. A final statement of cumulative costs incurred, including cost sharing, marked "FINAL" must be submitted to PTE's Principal Investigator Contact, as shown in Attachment 3A, not later than 45 days after the final Budget Period end date. The final statement of costs shall constitute Subrecipient's final financial report.

4. All payments shall be considered provisional and are subject to adjustment within the total estimated cost in the event such adjustment is necessary as a result of an adverse audit finding against the Subrecipient.

5. Matters concerning the technical performance of this Subaward shall be directed to the appropriate party's Principal Investigator as shown in Attachments 3A and 3B. Technical reports are required as shown in Attachment 4.

6. Matters concerning the request or negotiation of any changes in the terms, conditions, or amounts cited in this Subaward, and any changes requiring prior approval, shall be directed to the PTE's Authorized Official Contact and the Subrecipient's Authorized Official Contact shown in Attachments 3A and 3B. Any such change made to this Subaward requires the written approval of each party's Authorized Official as shown in Attachments 3A and 3B.

7. The PTE may issue non-substantive changes to the Budget Period(s) and Budget Bilaterally. Unilateral modification shall be considered valid 14 days after receipt unless otherwise indicated by Subrecipient when sent to Subrecipient's Authorized Official Contact, as shown in Attachment 3B.

8. Each party shall be responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers, or directors, to the extent allowed by law.

9. Either party may terminate this Subaward with 30 days written notice. Notwithstanding, if the Awarding Agency terminates the Federal Award, PTE will terminate in accordance with Awarding Agency requirements. PTE notice shall be directed to the Authorized Official Contact, and Subrecipient notice shall be directed to the Authorized Official Contact as shown in Attachments 3A and 3B. PTE shall pay Subrecipient for termination costs as allowable under Uniform Guidance, 2 CFR 200, or 45 CFR Part 75 Appendix IX, as applicable

10. By signing this Subaward, including the attachments hereto which are hereby incorporated by reference, Subrecipient certifies that it will perform the Statement of Work in accordance with the terms and conditions of this Subaward and the applicable terms of the Federal Award, including the appropriate Research Terms and Conditions ("RTCs") of the Federal Awarding Agency, as referenced in Attachment 2. The parties further agree that they intend this subaward to comply with all applicable laws, regulations, and requirements.

By an Authorized Official of the PTE:	By an Authorized Official of the Subrecipient:
DocuSigned by: Stephanie Rios 98288351EB3548C... 8/6/2024 | 13:49 EDT	7/30/24
Name: Stephanie Rios Date	Name: Michael Messier Date
Title: Director, Sponsored Research	Title: CEO

Jeffrey P. Krischer, Ph.D.
Principal Investigator

DS

Attachment 1
Certifications and Assurances

Subaward Number:
6163-1103-02-BZ

Certification Regarding Lobbying (2 CFR 200.450)
By signing this Subaward, the Subrecipient Authorized Official certifies, to the best of his/her knowledge and belief, that no Federal appropriated funds have been paid or will be paid, by or on behalf of the Subrecipient, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement in accordance with 2 CFR 200.450.

If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or intending to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the Subrecipient shall complete and submit Standard Form -LLL, "Disclosure Form to Report Lobbying," to the PTE.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by 31 U.S.C. 1352. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Debarment, Suspension, and Other Responsibility Matters (2 CFR 200.214 and 2 CFR 180)
By signing this Subaward, the Subrecipient Authorized Official certifies, to the best of his/her knowledge and belief that neither the Subrecipient nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from participation in this transaction by any federal department or agency, in accordance with 2 CFR 200.214 and 2 CFR 180.

Audit and Access to Records
Subrecipient certifies that it will provide PTE with notice of any adverse findings which impact this Subaward. Subrecipient certifies compliance with applicable provisions of 2 CFR 200.501-200.521. If Subrecipient is not required to have a Single Audit as defined by 200.501, Awarding Agency requirements, or the Single Audit Act, then Subrecipient will provide notice of the completion of any required audits and will provide access to such audits upon request. Subrecipient will provide access to records as required by parts 2 CFR 200.332 (a)(5), 200.337, and 200.338 as applicable.

Program for Enhancement of Contractor Employee Protections (41 U.S.C 4712)
Subrecipient is hereby notified that they are required to: inform their employees working on any federal award that they are subject to the whistleblower rights and remedies of the program; inform their employees in writing of employee whistleblower protections under 41 U.S.C §4712 in the predominant native language of the workforce; and include such requirements in any agreement made with a subcontractor or subgrantee.

The Subrecipient shall require that the language of the certifications above in this Attachment 1 be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

Use of Name
Neither party shall use the other party's name, trademarks, or other logos in any publicity, advertising, or news release without the prior written approval of an authorized representative of that party. The parties agree that each party may use factual information regarding the existence and purpose of the relationship that is the subject of this Subaward for legitimate business purposes, to satisfy any reporting and funding obligations, or as required by applicable law or regulation without written permission from the other party. In any such statement, the relationship of the parties shall be accurately and appropriately described.

Prohibition on Certain Telecommunication and Video Surveillance Services or Equipment
Pursuant to 2 CFR 200.216, Subrecipient will not obligate or expend funds received under this Subaward to: (1) procure or obtain; (2) extend or renew a contract to procure or obtain; or (3) enter into a contract (or extend or renew a contract) to procure or obtain equipment, services, or systems that uses covered telecommunications equipment or services (as described in Public Law 115-232, section 889) as a substantial or essential component of any system, or as a critical technology as part of any system.

Attachment 2
Federal Award Terms and Conditions

Subaward Number: 6163-1103-02-BZ

Required Data Elements

The data elements required by Uniform Guidance are incorporated in the attached Federal Award.

Awarding Agency Institute (If Applicable): National Institute of Diabetes and Digestive and Kidney Diseases

Federal Award Issue Date	FAIN	Assistance Listing No.
02/13/24	U01DK128847	93.847

Assistance Listing Program Title (ALPT): Diabetes, Digestive, and Kidney Diseases Extramural Research

Key Personnel Per NOA:

This Subaward Is:

[■] Research & Development [■] Subject to FFATA

General Terms and Conditions

By signing this Subaward, Subrecipient agrees to the following:

1. To abide by the conditions on activities and restrictions on expenditure of federal funds in appropriations acts that are applicable to this Subaward to the extent those restrictions are pertinent. This includes any recent legislation noted on the Federal Awarding Agency's website:
   http://grants.nih.gov/policy/notices.htm
2. 2 CFR 200 and 45 CFR Part 75.
3. The Federal Awarding Agency's grants policy guidance, including addenda in effect as of the beginning date of the period of performance or as amended found at:
   http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf
4. Applicable Research Terms and Conditions, including any Federal Awarding Agency's Specific Requirements found at:
   https://www.nsf.gov/awards/managing/rtc.jsp except for the following :
   a. No-cost extensions require the written approval of the PTE. Any requests for a no-cost extension shall be directed to the Administrative Contact shown in Attachment 3A, not less than 30 days prior to the desired effective date of the requested change.
   b. Any payment mechanisms and financial reporting requirements described in the applicable Federal Awarding Agency Terms and Conditions and Agency-Specific Requirements are replaced with Terms and Conditions (1) through (4) of this Subaward; and
   c. Any prior approvals are to be sought from the PTE and not the Federal Awarding Agency.
   d. Title to equipment as defined in 2 CFR 200.1 that is purchased or fabricated with research funds or Subrecipient cost sharing funds, as direct costs of the project or program, shall vest in the Subrecipient subject to the conditions specified in 2 CFR 200.313.
   e. Prior approval must be sought for a change in Subrecipient PI or change in Key Personnel (defined as listed on the NOA).
5. Treatment of program income: Additive

Special Terms and Conditions:

Data Sharing and Access:
Subrecipient agrees to comply with the Federal Awarding Agency's data sharing and/or access requirements as reflected in the NOA or the Federal Awarding Agency's standard terms and conditions as referenced in General Terms and Conditions 1-4 above.

No additional requirements

Data Rights:
Subrecipient grants to PTE the right to use data created in the performance of this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its PTE Federal Award.

Copyrights:

Subrecipient Shall Grant to PTE an irrevocable, royalty-free, non-transferable, non-exclusive right and license to use, reproduce, make derivative works, display, and perform publicly any copyrights or copyrighted material (including any computer software and its documentation and/or databases) first developed and delivered under this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its PTE Federal Award.

Subrecipient grants to PTE the right to use any written progress reports and deliverables created under this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its Federal Award.

Promoting Objectivity in Research (COI):
Subrecipient must designate herein which entity's Financial Conflicts of Interest policy (COI) will apply: PTE

If applying its own COI policy, by execution of this Subaward, Subrecipient certifies that its policy complies with the requirements of the relevant Federal Awarding Agency as identified herein: NIH - 42 CFR Part 50 Subpart F

Subrecipient shall report any financial conflict of interest to PTE's Administrative Representative or COI contact, as designated on Attachment 3A. Any financial conflicts of interest identified shall, when applicable, subsequently be reported to Federal Awarding Agency. Such report shall be made before expenditure of funds authorized in this Subaward and within 45 days of any subsequently identified COI.

Work Involving Human or Vertebrate Animals (Select Applicable Options)

■ No Human or Vertebrate Animals

This section left intentionally blank.

Human Subjects Data (Select One) Human subjects data will not be addressed in this agreement

This section left intentionally blank

NIH Terms and Conditions

The Clinical Trial Indicator in Section IV of the PTE's NOA is stated as: No ?

Multiple PIs (MPI)

This subaward is not subject to an MPI Leadership Plan. ?

Certificate of Confidentiality:

The Parties agree that this research funded in whole or in part by the National Institutes of Health ("NIH"), is subject to NIH Policy NOT-OD-17-109 (the "Policy") and therefore is deemed under the Policy to be issued a Certificate of Confidentiality ("Certificate") should the conditions outlined within the Policy apply. Accordingly, the subrecipients who collect or receive identifiable, sensitive information are is required to adhere to the Policy and protect the privacy of individuals who are subjects of such research in accordance with the Policy and subsection 301(d) of the Public Health Service Act (the "PHS Act").

Additional Terms

Pass-through entity and Subrecipient agree to adhere to the Appendix II Part 200 of 2 CFR, Uniform Administrative Requirement, Cost Principles and Audit Requirements for Federal Awards, if applicable and Subrecipient meets the definition of "Contractor" as defined by 2 CFR § 200.1. The relevant provisions are attached after this subagreement and prior to the Notice of Award.

Bills for fees and other compensation for services or expenses shall be submitted in detail and include adequate support sufficient for a proper pre-audit and post-audit thereof.

ATTACHMENT 2A

State of Florida Requirements

The Subrecipient is notified that PTE is a public university of the State of Florida and is subject to the laws and regulations set forth below. As such, PTE notifies Subrecipient of the following:

1. PAYMENT. PTE will make payment in accordance with PTE's Regulation 2202 entitled "Prompt Payment." Upon receipt of goods or services, PTE has five (5) business days to inspect and approve the goods or services, unless Subaward specifies a greater period of time. If PTE does not issue payment within 40 days of receipt of a proper invoice, PTE will pay to Subrecipient, an interest penalty at the rate established pursuant to §55.03(1) Fla. Stat. if the interest exceeds one dollar ($1.00). Subrecipients experiencing payment problems may contact the Office of Sponsored Research at rsch-awards@usf.edu.

2. CONTRACT CANCELLATION. PTE may cancel this Subaward for Subrecipient's refusal to allow public access to all documents, papers, letters, or other material to which PTE is subject pursuant to the provisions of Chapter 119 and Fla. Stat. Section 1004.22(2) and made or received by the Subrecipient in conjunction with this Subaward. **IF SUBRECIPIENT HAS QUESTIONS REGARDING THE APPLICATION OF CHAPTER 119, FLORIDA STATUTES, TO ITS DUTY TO PROVIDE PUBLIC RECORDS RELATING TO THIS AGREEMENT, CONTACT THE OFFICE OF THE GENERAL COUNSEL (813) 974-2131, BY EMAIL AT usfpr@usf.edu, OR BY MAIL at 4202 E. Fowler Avenue, CGS 301, Tampa, FL 33620-4301.**

3. TRAVEL. If the Subrecipient is a State of Florida entity that is subject to Florida Statutes 112.061, Subrecipient shall incur travel expenses in accordance with that statute. If the Subrecipient is not a State of Florida entity that is subject to Florida Statutes 112.061, then Subrecipient shall incur travel expenses in accordance with the provisions of the applicable prime award or grant and the travel allowances established by the Subrecipient.

4. If this Subaward is for the purchase of commodities and/or services for a period in excess of one fiscal year, the following statement applies: "The PTE's performance and obligation to pay under this subaward is contingent upon an annual appropriation by the Legislature." As a State of Florida public university that receives annual appropriation for its operation from the Florida legislature, PTE is required to include this statement notwithstanding that the funding for the project which is the subject of this Agreement may be provided from a source other than the Florida legislature.

5. A person or affiliate who has been placed on the convicted vendor list following a conviction for a public entity crime may not submit a bid on a contract to provide any goods or services to a public entity for the construction or repair of a public building or public work, may not submit bids on leases of real property to public entity, may not be awarded or perform work as contractor, supplier, sub-contractor, or consultant under a contract with any public entity, and may not transact business with any public entity in excess of the threshold amount provided in Section 287.017, for CATEGORY TWO for a period of 36 months from the date of being placed on the convicted Subrecipient list.

6. E-Verify. Subrecipient certifies that it is registered with and uses the U.S. Department of Homeland Security's E-Verify system to verify the employment eligibility of all new employees hired by Subrecipient during the term of this Agreement. If Subrecipient enters into a contract with a subcontractor to perform work or provide services pursuant to this Agreement, Subrecipient shall likewise require the subcontractor to comply with the requirements of this section, and the subcontractor shall provide to Subrecipient an affidavit stating that the subcontractor does not employ, contract with or subcontract with an unauthorized alien. Subrecipient shall maintain a copy of such affidavit for the duration of this Agreement. This Section serves as notice to Subrecipient regarding the requirements set forth herein and of PTE's obligation to terminate the Agreement if it has a good faith belief that Subrecipient has knowingly violated the requirements set forth herein. PTE reserves the right to order the immediate termination of any contract between Subrecipient and a subcontractor performing work on its behalf should PTE develop a good faith belief that the subcontractor has knowingly violated the requirements herein.

Attachment 3A
Pass-Through Entity (PTE) Contacts

Subaward Number: 6163-1103-02-BZ

PTE Information

Entity Name: The University of South Florida Board of Trustees

Legal Address: 4202 East Fowler Ave.
Tampa, Florida 33620

Website: www.usf.edu

PTE Contacts

Central Email: rsch-awards@usf.edu

Principal Investigator Name: Jeffrey Krischer

Email: jeffrey.krischer@epi.usf.edu Telephone Number: (813) 396-9512

Administrative Contact Name: Silvia Alvarez

Email: silviaa@usf.edu Telephone Number: (813) 974-1089

COI Contact email (if different to above): coi-research@usf.edu

Financial Contact Name: Stephanie Rios

Email: rsch-awards@usf.edu Telephone Number: (813) 974-6001

Email invoices? (●) Yes ( ) No Invoice email (if different): susan.smith@epi.usf.edu

Authorized Official Name: Stephanie Rios

Email: rsch-awards@usf.edu Telephone Number: (813) 974-6001

PI Address:

3650 Spectrum Blvd.
Tampa, FL 33612

Administrative Address:

3702 Spectrum Blvd.
Suite 165
Tampa, FL 33612-9445

Invoice Address:

3650 Spectrum Blvd.
Tampa, FL 33612

Attachment 3B

Subrecipient Contacts

Subaward Number: 6163-1103-02-BZ

Subrecipient Information for FFATA reporting

Entity's UEI Name: AutoGen, Inc.

EIN No.:

Institution Type: Small Business

UEI: LM26J1F6JJD5

Currently registered in SAM.gov: (•) Yes ( ) No

Exempt from reporting executive compensation: (•) Yes ( ) No *(if no, complete 3Bpg2)*

Parent UEI:

This section for U.S. Entities: Zip Code Look-up

Congressional District: MA-02 Zip Code+4: 01746-1371

Place of Performance Address

84 October Hill Road
Holliston, MA 01746-1371

Subrecipient Contacts

Central Email:

Website: http://www.autogen.com

Principal Investigator Name: Michael Messier

Email: mmessier@autogen.com Telephone Number: (774) 233-3002

Administrative Contact Name: Rob Osborn

Email: rosborn@autogen.com Telephone Number: (508) 395-8161

Financial Contact Name: Michael Messier

Email: mmessier@autogen.com Telephone Number: (774) 233-3002

Invoice Email:

Authorized Official Name: Michael Messier

Email: mmessier@autogen.com Telephone Number: (774) 233-3002

Legal Address:

84 October Hill Road
Holliston, MA 01746-1371

Administrative Address:

84 October Hill Road
Holliston, MA 01746-1371

Payment Address:

84 October Hill Road
Holliston, MA 01746-1371

Attachment 3B-2

Highest Compensated Officers

Subaward Number: 6163-1103-02-BZ

Subrecipient:

Institution Name: AutoGen, Inc.

PI Name: Michael Messier

Highest Compensated Officers

The names and total compensation of the five most highly compensated officers of the entity(ies) must be listed if the entity in the preceding fiscal year received 80 percent or more of its annual gross revenues in Federal awards; and $25,000,000 or more in annual gross revenues from Federal awards; and the public does not have access to this information about the compensation of the senior executives of the entity through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. §§ 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. See FFATA § 2(b)(1) Internal Revenue Code of 1986.

Officer 1 Name:

Officer 1 Compensation:

Officer 2 Name:

Officer 2 Compensation:

Officer 3 Name:

Officer 3 Compensation:

Officer 4 Name:

Officer 4 Compensation:

Officer 5 Name:

Officer 5 Compensation:

Attachment 4
Reporting and Prior Approval Terms

Subaward Number: 6163-1103-02-BZ

Subrecipient agrees to submit the following reports (PTE contacts are identified in Attachment 3A):

Technical Reports:

☐ Monthly technical/progress reports will be submitted to the PTE's Administrative Contact within 15 days of of the end of the month.

☐ Quarterly technical/progress reports will be submitted within 30 days after the end of each project quarter to the PTE's Administrative Contact.

☐ Annual technical / progress reports will be submitted within 60 days prior to the end of each budget period to the PTE's Administrative Contact. Such report shall also include a detailed budget for the next Budget Period, updated other support for key personnel, certification of appropriate education in the conduct of human subject research of any new key personnel, and annual IRB or IACUC approval, if applicable.

☐ A Final technical/progress report will be submitted to the PTE's Administrative Contact within 60 days of the end of the Project Period or after termination of this award, whichever comes first.

■ Technical/progress reports on the project as may be required by PTE's Principal Investigator in order for the PTE to satisfy its reporting obligations to the Federal Awarding Agency.

Prior Approvals:

Carryover:

Carryover is restricted for this subaward by the: Pass-Through Entity

Carryover instructions and requirements are as stated by the Federal Awarding Agency guidance or as shown below.

Submit carryover requests to the Principal Investigator.

Other Reports:

☐ In accordance with 37 CFR 401.14, Subrecipient agrees to notify both the Federal Awarding Agency via iEdison and PTE's Administrative Contact within 60 days after Subrecipient's inventor discloses invention(s) in writing to Subrecipient's personnel responsible for patent matters. The Subrecipient will submit a final invention report using Federal Awarding Agency specific forms to the PTE's Administrative Contact within 60 days of the end of the Project Period to be included as part of the PTE's final invention report to the Federal Awarding Agency.

A negative report is required: ☐

☐ Property Inventory Report (only when required by Federal Awarding Agency), specific requirements below.

Additional Technical and Reporting Requirements:

Attachment 5
Statement of Work, Cost Sharing, Indirects & Budget

Subaward Number: 6163-1103-02-BZ

Statement of Work

○ Below ◉ Attached, 7 pages

If award is FFATA eligible and SOW exceeds 4000 characters, include a *Subrecipient Federal Award Project Description*

Budget Information

Indirect Information Indirect Cost Rate (IDC) Applied	0 %	**Cost Sharing**	No
Rate Type:	Modified Total Direct Costs	If Yes, include Amount: $	

Budget Details

○ Below ◉ Attached, 1 pages

Budget Totals

Direct Costs	$ 660,006.00
Indirect Costs	$ 0.00
Total Costs	$ 660,006.00

All amounts are in United States Dollars

autogen

Statement of Work

DNA from Stool

From: AutoGen, Inc, Holliston, MA

For: Health Informatics Institute,

University of South Florida, Tampa, FL

July 19, 2024

Overview:

The University of South Florida and NIDDK intends to ship 21,000 Stool samples collected in 8ml barcoded storage tubes that are stored at -80c from Fisher BioServices in Maryland. The samples will be shipped per the Teddy Twist proposed shipping schedule document, on dry ice, approximately every three-four weeks. In advance of each shipment, the TEDDY study project team will provide an electronic manifest of the samples being sent and their specific order.

AutoGen will receive each batch of samples, accession into the lab by checking the manifest against what is received and then storing at -80c. AutoGen would report any discrepancies between what is received and the electronic manifest.

AutoGen will extract the DNA out of these stool tubes, elute those in 100ul of hydration buffer into a 500ul SBS storage rack, quantify, and aliquot into a skirted or semi-skirted PCR plate (per VANTAGE requirement) at a volume of 20ul. In coordination with the TEDDY project team, AutoGen will follow the "extraction lab SOW, appendix A". Upon completion is isolation and plating, AutoGen will ship the 20ul aliquot in the PCR plate of extracted DNA to Vanderbilt University's VANTAGE sequencing core for downstream testing. The remainder of the DNA eluate that was not transferred into PCR plates will be stored at -80c in 500ul tricoded tubes (1d, 2d, human-readable barcodes) in SBS racks. The un-extracted stool samples will be refrozen at -80 and shipments will be prepared to Fisher BioServices, together with appropriate reporting. Shipping material fees apply.

Details:

Start date – The TEDDY coordinating team will ship the first batch of approximately 3040 samples in August. Shipping schedule will follow the "TEDDY_24378_TWIST_Shipment_Schedule _Proposed Appendix B" document.

Shipping Method – Samples will be shipped with next day delivery using TEDDY's FedEx account. Shipping material for shipments to VANTAGE and back to Fisher Bio (coolers, Dry Ice, etc) charges will apply.

Extraction - AutoGen will extract DNA from a portion of the Stool sample. Our workflow can

AutoGen, Inc
84 October Hill Road
Holliston, MA 01746
774-233-3000

autogen

handle up to 200mgs of sample, the exact starting amount will be confirmed at a later date. The remainder of the stool sample will be stored at -80 and then shipped back to Fisher Bioservices.

Quantification - After the DNA is extracted it will be measured on a Nanodrop and recorded in our reporting.

Replication - After the samples have been isolated and quantified, AutoGen will transfer 20-25ul's into full or semi-skirted PCR plates, as per VANTAGE requirements. All original tubes will be stored together, and any remaining DNA eluates will be stored at -80 in order to be shipped back to Fisher Bioservices.

Storage Tubes – AutoGen will return all samples back to Fisher Biosciences in 500ul externally threaded tri- coded tubes (2d, 1d and human readable). Each SBS rack will also be bar coded. All barcoding information will be included in our reporting.

Return/Shipment of Samples – AutoGen will work with the TEDDY team to arrange for the timely return of samples and eluates to Fisher Bioservices, in addition to shipping out approximately 1,000 samples with a soon to be determined frequency to VANTAGE using the TEDDY fedex shipping account. An electronic manifest reflecting the samples within each shipment will be provided by AutoGen to the TEDDY research team and VANTAGE and a physical copy of the shipment manifest will accompany the sample shipment to Fisher Bioservices AND to VANTAGE. Separate shipping Materials, dry ice, etc, charges are applicable per sample/shipment.

Sharing of concentration and yield Data.

AutoGen will upload all pertinent data using the electronic data sharing portal provided by the TEDDY team.

AutoGen, Inc
84 October Hill Road
Holliston, MA 01746
774-233-3000

autogen

Invoicing and Prices:

Invoicing – AutoGen will invoice for each batch of extracted, quantified, and plated samples received from Fisher Bio per the shipping schedule, AutoGen will issue an invoice. Payment terms on all invoicing is Net 30 days.

Pricing - Pricing for the project is as follows, replicating the "Appendix C" budget provided by the TEDDY Team.

Isolate DNA from stool, as outlined, 21,000 samples at $29.91 each = $628,110.00

- Returning of the eluate to Fisher Biosciences Included in this Price.

20ng/ul transfer into PCR plates, 21,000 samples at $0.84 per sample = $17,640.00

Skirted PCR plate for all samples, sent to VANTAGE, 95 samples per plate = $2,916.00

Shipping materials for PCR plates to VANTAGE at $0.13 per sample = $2,730.00

Shipping materials for returning Stool sample to Fisher Bio - $0.41 per sample = $8,610.00

- *Note returning un-extracted stool is assuming we are able to re-use some of the shipping materials from when the samples are delivered to AutoGen. IE coolers, etc. If we are unable to do so, the cost per sample is $0.55. AutoGen will do everything possible to reduce shipping material costs.

- **Total agreed upon budget = $660,006.00***

We are very excited to partner with the University of South Florida and the TEDDY research team on this project. You can be assured that we will execute with professionalism and dedication and correspond thoroughly through the entire process.

Best regards,

_____

Michael R. Messier, CEO
Rob Osborn, EVP
AutoGen, Inc.

AutoGen, Inc
84 October Hill Road
Holliston, MA 01746
774-233-3000

TEDDY Stool DNA Extraction Lab (AutoGen) SOW – Appendix A

The lab will:

1. Develop a protocol for receipt, short-term storage and preservation of samples sent from the Fisher BioServices Repository.
2. Receive specimens (with etched vial barcode numbers) from the Fisher BioServices repository. The laboratory must have a system for handling specimens with bar-coded IDs.
3. Review/inspect samples upon receipt; report receipt and integrity of samples (e.g., missing, thawed, broken) and report any problems in handling and shipping directly to the Fisher BioServices repository, and to the Data Coordinating Center using TEDDY data systems. The laboratory must work with the Fisher BioServices repository to resolve any shipping issues and discrepancies.
4. Provide the necessary freezer space for short-term storage of TEDDY samples.
5. It is expected that all sample information be transmitted using TEDDY data systems to the TEDDY Data Coordinating Center. All information must be transmitted electronically to the DCC following set guidelines that will be outlined by the DCC. Lab must have e-mail communication capabilities and Internet access. Retention of a copy of the data on the Subcontractor's computers is allowed but analysis and/or release of such data is subject to review and approval from TEDDY.

NOTES

1. The Data Coordinating Center or TEDDY Laboratory Implementation Committee will conduct a site visit of the Laboratory at its discretion.
2. Costs associated with transport of samples to the Laboratory will be paid by the Data Coordinating Center.
3. Costs associated with transmitting the data to the Data Coordinating Center are assumed by the Laboratory.

Deliverables/Reporting Requirements

The following will be deliverable to the TEDDY Data Coordinating Center, University of South Florida:

1. All data on study specimens must be transmitted electronically to the Data Coordinating Center on an agreed upon basis.
2. Laboratory data books and/or computer files containing study data must be made available to the Data Coordinating Center or Laboratory Implementation Committee upon request.
3. Internal quality control data (for the period of specimen analysis) must be made available to the Data Coordinating Center or Laboratory Monitoring Committee on a quarterly basis.

TEDDY Study Data Policy

All the instrument generated data files, quality control (QC) related files, QC reports, Laboratory Information Management System (LIMS) log files, intermediate data files, processed/normalized/summarized data files (after QCing the data) and any other files in various formats from all the samples (including internal/external Lab QC samples) requested by the TEDDY members are required to be transferred to the TEDDY Data Coordinating Center (DCC). Additionally, the

lab is required to describe the structured relationships between each of these digital objects, share the source code and the bioinformatics analytical pipelines (including the name and version number of the tools/software, parameters used and reference files (e.g. reference genome build)) used for the analysis with DCC. The lab is required to provide description (as ReadMe.txt file) and md5sum (to verify data integrity and detect unintentional data corruption) for each of the transferred data files to the DCC.

TEDDY TWIST Study Proposed Sample Shipment Schedule Appendix B July 10, 2024		
Shipment #	**Sample Shipment Details**	**Repository to AutoGen Shipment Date**
1	3040 Stool samples (Runs 1 - 32)	8/12/2024
2	1900 Stool samples (Runs 33 - 52)	9/16/2024
3	1900 Stool samples (Runs 53 - 72)	10/14/2024
4	1900 Stool samples (Runs 73 - 92)	11/11/2024
5	1900 Stool samples (Runs 93 - 112)	12/16/2024
6	1900 Stool samples (Runs 113 - 132)	1/13/2025
7	1900 Stool samples (Runs 133 - 152)	2/10/2025
8	1900 Stool samples (Runs 153 - 172)	3/10/2025
9	1900 Stool samples (Runs 173 - 192)	4/14/2025
10	2440 Stool samples (Runs 193 - 218)	5/12/2025

AutoGen - TEDDY Twist Stool Sample DNA Extraction

21,000 Stool Samples

Budget period: July 1, 2024 - December 31, 2024

	Cost/sample	Total Cost
Isolate DNA from stool	$ 29.91	$ 628,110
20ng/ul transfer into PCR plates	$ 0.84	$ 17,640
Skirted PCR plate for all samples, sent to VANTAGE, 95 samples per plate	N/A	$ 2,916
Shipping to Repository/VANTAGE	N/A	$ 11,340
Total Costs		**$ 660,006**

AutoGen - TEDDY Twist Stool Sample DNA Extraction

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Skirted PCR plate for all samples, sent to VANTAGE, 95 samples per plate	N/A	$ 2,916
Shipping to Repository/VANTAGE	N/A	$ 11,340
Total Costs		**$ 660,006**

Subaward Number:
6163-1103-02-BZ

Attachment 6

Notice of Award (NOA) and any additional documents

◉ The following pages include the NOA and if applicable any additional documentation referenced throughout this Subaward.

○ Not incorporating the NOA or any additional documentation to this Subaward.

Appendix II to Part 200 - Contract Provisions for Non-Federal Entity Contracts Under Federal Awards

In addition to other provisions required by the Federal agency or non-Federal entity, all contracts made by the non-Federal entity under the Federal award must contain provisions covering the following, as applicable.

(A) Contracts for more than the simplified acquisition threshold, which is the inflation adjusted amount determined by the Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (Councils) as authorized by 41 U.S.C. 1908, must address administrative, contractual, or legal remedies in instances where contractors violate or breach contract terms, and provide for such sanctions and penalties as appropriate.

(B) All contracts in excess of $10,000 must address termination for cause and for convenience by the non-Federal entity including the manner by which it will be effected and the basis for settlement.

(C) Equal Employment Opportunity. Except as otherwise provided under 41 CFR Part 60, all contracts that meet the definition of "federally assisted construction contract" in 41 CFR Part 60-1.3 must include the equal opportunity clause provided under 41 CFR 60-1.4(b), in accordance with Executive Order 11246, "Equal Employment Opportunity" (30 FR 12319, 12935, 3 CFR Part, 1964-1965 Comp., p. 339), as amended by Executive Order 11375, "Amending Executive Order 11246 Relating to Equal Employment Opportunity," and implementing regulations at 41 CFR part 60, "Office of Federal Contract Compliance Programs, Equal Employment Opportunity, Department of Labor."

(D) Davis-Bacon Act, as amended (40 U.S.C. 3141-3148). When required by Federal program legislation, all prime construction contracts in excess of $2,000 awarded by non-Federal entities must include a provision for compliance with the Davis-Bacon Act (40 U.S.C. 3141-3144, and 3146-3148) as supplemented by Department of Labor regulations (29 CFR Part 5, "Labor Standards Provisions Applicable to Contracts Covering Federally Financed and Assisted Construction"). In accordance with the statute, contractors must be required to pay wages to laborers and mechanics at a rate not less than the prevailing wages specified in a wage determination made by the Secretary of Labor. In addition, contractors must be required to pay wages not less than once a week. The non-Federal entity must place a copy of the current prevailing wage determination issued by the Department of Labor in each solicitation. The decision to award a contract or subcontract must be conditioned upon the acceptance of the wage determination. The non-Federal entity must report all suspected or reported violations to the Federal awarding agency. The contracts must also include a provision for compliance with the Copeland "Anti-Kickback" Act (40 U.S.C. 3145), as supplemented by Department of Labor regulations (29 CFR Part 3, "Contractors and Subcontractors on Public Building or Public Work Financed in Whole or in Part by Loans or Grants from the United States"). The Act provides that each contractor or subrecipient must be prohibited from inducing, by any means, any person employed in the construction, completion, or repair of public work, to give up any part of the compensation to which he or she is otherwise entitled. The non-Federal entity must report all suspected or reported violations to the Federal awarding agency.

(E) Contract Work Hours and Safety Standards Act (40 U.S.C. 3701-3708). Where applicable, all contracts awarded by the non-Federal entity in excess of $100,000 that involve the employment of mechanics or laborers must include a provision for compliance with 40 U.S.C. 3702 and 3704, as supplemented by Department of Labor regulations (29 CFR Part 5). Under 40 U.S.C. 3702 of the Act, each contractor must be required to compute the wages of every mechanic and laborer on the basis of a standard work week of 40 hours. Work in excess of the standard work week is permissible provided that the worker is compensated at a rate of not less than one and a half times the basic rate of pay for all hours worked in excess of 40 hours in the work week. The requirements of 40 U.S.C. 3704 are applicable to construction work and provide that no laborer or mechanic must be required to work in surroundings or under working conditions which are unsanitary, hazardous or dangerous. These requirements do not apply to the purchases of supplies or materials or articles ordinarily available on the open market, or contracts for transportation or transmission of intelligence.

(F) Rights to Inventions Made Under a Contract or Agreement. If the Federal award meets the definition of "funding agreement" under 37 CFR § 401.2 (a) and the recipient or subrecipient wishes to enter into a contract with a small business firm or nonprofit organization regarding the substitution of parties, assignment or performance of experimental, developmental, or research work under that "funding agreement," the recipient or subrecipient must comply with the requirements of 37 CFR Part 401, "Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts and Cooperative Agreements," and any implementing regulations issued by the awarding agency.

(G) Clean Air Act (42 U.S.C. 7401-7671q.) and the Federal Water Pollution Control Act (33 U.S.C. 1251-1387), as amended - Contracts and subgrants of amounts in excess of $150,000 must contain a provision that requires the non-Federal award to agree to comply with all applicable standards, orders or regulations issued pursuant to the Clean Air Act (42 U.S.C. 7401-7671q) and the Federal Water Pollution Control Act as amended (33 U.S.C. 1251-1387). Violations must be reported to the Federal awarding agency and the Regional Office of the Environmental Protection Agency (EPA).

(H) Debarment and Suspension (Executive Orders 12549 and 12689) - A contract award (see 2 CFR 180.220) must not be made to parties listed on the governmentwide exclusions in the System for Award Management (SAM), in accordance with the OMB guidelines at 2 CFR 180 that implement Executive Orders 12549 (3 CFR part 1986 Comp., p. 189) and 12689 (3 CFR part 1989 Comp., p. 235), "Debarment and Suspension." SAM Exclusions contains the names of parties debarred, suspended, or otherwise excluded by agencies, as well as parties declared ineligible under statutory or regulatory authority other than Executive Order 12549.

(I) Byrd Anti-Lobbying Amendment (31 U.S.C. 1352) - Contractors that apply or bid for an award exceeding $100,000 must file the required certification. Each tier certifies to the tier above that it will not and has not used Federal appropriated funds to pay any person or organization for influencing or attempting to influence an officer or employee of any agency, a member of Congress, officer or employee of Congress, or an employee of a member of Congress in connection with obtaining any Federal contract, grant or any other award covered by 31 U.S.C. 1352. Each tier must also disclose any lobbying with non-Federal funds that takes place in

connection with obtaining any Federal award. Such disclosures are forwarded from tier to tier up to the non-Federal award.

(J) See § 200.323.

(K) See § 200.216.

(L) See § 200.322.

[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75888, Dec. 19, 2014; 85 FR 49577, Aug. 13, 2020]

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Notice of Award
FAIN# U01DK128847
Federal Award Date
02/13/2024

Recipient Information

1. Recipient Name
UNIVERSITY OF SOUTH FLORIDA
4202 E FOWLER AVE
TAMPA, FL 33620

2. Congressional District of Recipient
15

3. Payment System Identifier (ID)
1593102112A1

4. Employer Identification Number (EIN)
593102112

5. Data Universal Numbering System (DUNS)
069687242

6. Recipient's Unique Entity Identifier
NKAZLXLL7Z91

7. Project Director or Principal Investigator
JEFFREY P KRISCHER, PHD
Director
JPKRISCHER@epi.USF.EDU
813-396-9512

8. Authorized Official
ANA LUIZA OLIVEIRA
analuiza19@usf.edu
813-974-0249

Federal Agency Information

9. Awarding Agency Contact Information
NATASHA LOVELESS
Grants Management Specialist
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES
lovelessnd@mail.nih.gov
301-594-8853

10. Program Official Contact Information
Arthur Castle
Program Director
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES
castlea@niddk.nih.gov
301.594.7719

Federal Award Information

11. Award Number
5U01DK128847-03

12. Unique Federal Award Identification Number (FAIN)
U01DK128847

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

14. Federal Award Project Title
Limited Competition: Continued Follow-up of Subjects and Initiation of a Second Case-control Cohort in The Environmental Determinants of Diabetes in The Young Study (TEDDY)

15. Assistance Listing Number
93.847

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

17. Award Action Type
Non-Competing Continuation

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 01/01/2024 – **End Date** 12/31/2024
20. Total Amount of Federal Funds Obligated by this Action [redacted]
20 a. Direct Cost Amount
20 b. Indirect Cost Amount
21. Authorized Carryover
22. Offset
23. Total Amount of Federal Funds Obligated this budget period [redacted]
24. Total Approved Cost Sharing or Matching, where applicable
25. Total Federal and Non-Federal Approved this Budget Period

26. Project Period Start Date 04/28/2021 – **End Date** 12/31/2025
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period [redacted]

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.

Notice of Award

RESEARCH PROJECT COOPERATIVE AGREEMENT
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

SECTION I – AWARD DATA – 5U01DK128847-03

Principal Investigator(s):
JEFFREY P KRISCHER, PHD

Award e-mailed to: rsch-awards@usf.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of [redacted] (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF SOUTH FLORIDA 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 U01DK128847. 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	[redacted]
Fringe Benefits	
Personnel Costs (Subtotal)	
Consultant Services	
Equipment	
Materials & Supplies	
Travel	
Other	
Subawards/Consortium/Contractual Costs	
Federal Direct Costs	[redacted]
Federal F&A Costs	
Approved Budget	
Total Amount of Federal Funds Authorized (Federal Share)	
TOTAL FEDERAL AWARD AMOUNT	
AMOUNT OF THIS ACTION (FEDERAL SHARE)	

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	THIS AWARD	CUMULATIVE TOTALS
3	[redacted]	[redacted]
4		

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

Fiscal Information:

Payment System Identifier:	1593102112A1
Document Number:	UDK128847A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2024

IC	CAN	2024	2025
DK	8033711	[redacted]	[redacted]
DK	8059525		$0

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

NIH Administrative Data:
PCC: DAC TEDY / **OC:** 41029 / **Released:** ROSENBERG, MARY 02/13/2024
Award Processed: 02/14/2024 12:09:00 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5U01DK128847-03

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 – 5U01DK128847-03

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) U01DK128847. 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 is funded by the following list of institutes. Any papers published under the auspices of this award must cite the funding support of all institutes.

National Institute Of Diabetes And Digestive And Kidney Diseases (NIDDK)

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 – 5U01DK128847-03

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.

Delayed Award

The issuance of this award has been delayed due to *administrative considerations*. According to NIH policy, if pre-award costs are necessary, they may be approved by the Authorized Organization Representative.

INTERIM PROGRESS REPORT

This award is issued with the requirement of an 6 months progress report due August 1st 2024 to assess progress, the funding of the previous sub awards from year 01 and unobligated balance spend down of this award. The progress report can be sent to the Program Director and the Grants Management Specialist named on the notice of grant award. In addition to the interim progress report the annual progress report will be due. Failure to comply with the above requirements can result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action.

Human Subjects Enrollment Reporting
The NIH is mandated by law (Public Health Service Act sec. 492B, 42 U.S.C. sec. 289a-2) to ensure the inclusion of women and minority groups in clinical research. The goal is to ensure that individuals are included in clinical research in a manner that is appropriate to the scientific question under study.

Investigators must report sex/gender, race, and ethnicity information using the Human Subjects System (HSS) module in the eRA Commons.

For more information see the NIH Guide Notice NOT-OD-18-179.

Milestones
Future year support is contingent on satisfactory achievement of approved performance milestones. If approved milestones are not achieved fully, NIDDK may request development of a remedial plan and more frequent monitoring of progress or take other remedial actions.

Data and Safety Monitoring Plan
The recipient is required to follow the data and safety monitoring plan included in the application and may not implement any changes in the plan without the written prior approval of the NIDDK. For all trials (including low risk trials where routine program review is based on the annual RPPR), unexpected serious adverse events should be reported to the Program Director at the same time that they are sent to the IRB (i.e., within 7 calendar days of the initial receipt of information for fatal or life-threatening suspected unexpected, serious adverse reactions, and within 15 calendar days of receipt of information for non-fatal, non-life-threatening unexpected, suspected serious adverse reactions). **The annual progress report should provide dates of meetings and action items from all DSMB or other safety monitoring meetings during the previous reporting period (if applicable), any data and safety monitoring issues that have occurred since the previous reporting period (including any IRB or FDA actions), and a description of any changes in the protocol, consent, or DSMP.**

RESOURCE SHARING
Dissemination of study data will be in accord with the grantee's accepted genomic data sharing plan as stated in the application. Failure to adhere to the sharing plan as mutually agreed upon by the Grantee and the NIH/IC may result in Enforcement Actions as described in the NIH Grants Policy Statement.

Key Personnel
In addition to the PI, the following individuals are named as key personnel: **Drs. Erlund, Kim-Schulze, Fiehn, Gabriel, Seo, Petrosino,** 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 Activity
This award includes funds awarded for consortium activity with the following organizations.

National Institute Health & Welfare-$[redacted]
The Broad Institute-[redacted]
Univ of Michigan-$[redacted]
Virome Lab-$[redacted]
University of Bristol-$[redacted]
University of Colorado-$ [redacted]
Tampere University-[redacted]
University of Missouri-[redacted]
Benaroya Research Institute at Virginia Mason-$[redacted]
University of Florida-$[redacted]
Fisher BioServices-$[redacted]
Infinity Bio-$[redacted]
Benaroya Research Institute at Virginia Mason-$[redacted]
Tampere University-$[redacted]
Atlas Genomics-$[redacted]
University of Colorado HCS Barbara Davis Center-[redacted]
Pacific Northwest Research Institute-[redacted]
Augusta University Research Institute-$ [redacted]
Diabetes Research Institute-$[redacted]
Wellbeing Services County of Southwest Finland-Varsinais-Suo-$[redacted]
University of Oulu-$[redacted]
Wellbeing Services County of Pirkanmaa-$[redacted]
Skane County Council, University Hospital MAS-[redacted]
Lund University-[redacted]
Tampere University-[redacted]

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 45 CFR Part 75, 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 awardees 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 awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and the NIH as defined below.

The PD(s)/PI(s) will have the primary responsibility for:
1. Developing the research design and study protocol, including definition of objectives and approaches, sample size and power calculations, and establishing procedures for participant recruitment and follow-up, data collection, quality control, interim data and safety monitoring, final data analysis and interpretation, and publication of results.
2. Establishing a Steering Committee to implement, coordinate and manage the project(s). Awardee(s) will name investigators to serve as members on a Steering Committee and other subcommittees, as appropriate, meeting periodically. Awardees will be required to accept and implement the common protocol(s) and procedures approved by the Steering Committee.
3. Designating Protocol Chairs. The Program Directors/Principal Investigators (for studies involving multiple protocols) shall designate a single Protocol Chairperson (if the Program Director/Principal Investigator does not assume this role) for each protocol to be carried out by the study group. The Protocol Chairperson shall function as the scientific coordinator for the

protocol and shall assume responsibility for obtaining approval to implement the protocol from the Steering Committee and for developing and monitoring the protocol. Significant modifications to approved protocols must be approved by the Steering Committee.
4. Implementing collection of data specified by the study protocol. For a multi-center study, each awardee/site is required to ensure that data will be submitted expeditiously to the Data Coordinating Center. Additionally, individual investigators/sites must demonstrate the ability to implement the strategy specifically designed for their individual study population.
5. Establishing procedures for data quality and completeness. Awardees are responsible for ensuring accurate and timely assessment of the progress of each study, including development of procedures to ensure that data collection and management are: (1) adequate for quality control and analysis; (2) for clinical trials, as simple as appropriate in order to facilitate cooperation/referral of study participants by physicians to avoid unnecessary expense; and (3) sufficiently staffed across the participating institutions. For research involving multiple sites, a plan for analysis of pooled data will be developed by the Steering Committee.
6. Submitting interim progress reports, when requested or agreed upon by both parties, to the NIDDK Program Official including as a minimum, summary data on protocol performance. For coordinated multiple awards or a multi-site single award, the NIDDK Program Official may require additional information from individual awardees/sites. Such reports are in addition to the required annual noncompeting continuation progress report.
7. Reporting of the study findings. Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and NIH policies. The awardee must also be adherent to Study Publication and Presentation Policy. The NIDDK will have access to and may periodically review all data generated under an award. NIDDK staff may co-author publications of findings with awardees consistent with NIH and study policies.
8. Any third-party (including industry, academia, and foundations) collaboration 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, and with written approval from NIDDK Program staff. Any relevant proposed third-party agreements related to the network 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 policies. Further, at the request of the NIDDK Program staff, any other network-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."
9. Any involvement of a third-party (including industry, academia, and foundations) in the study and network activities that includes access to any network study data and biosamples, or study results that are not publicly available, or using the name of the network 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.
10. Study investigators are required to publish and to release publicly and disseminate results and other products of the study, in accordance with study protocols and steering committee policies on publications.
11. Maintaining confidentiality of information: The awardee(s) will maintain the confidentiality of the information developed by the investigators (i.e., protocols, data analysis, conclusions, etc.) as well as proprietary information of an individual company or other entity collaborating with the study. Any exception requires written approval from NIDDK Program staff.
12. The NIDDK has established Central Biosample, Genetic, and Data Repositories for the archiving and storage of data and biosamples collected in large, multi-site studies funded by NIDDK. Prior to enrolling participants, the PI or his/her designee will coordinate with the NIDDK Central Repository to develop a Data Sharing Plan and prepare the collected data for eventual archiving and distribution. In addition, if applicable, the PI or his/her designee will work with the NIDDK Biosample Repository to coordinate procedures for coding, shipping, processing, receipt, storage, and sharing of study samples that are to be maintained in the Repository. All samples

and data transferred to the Repositories will be under the custodianship of the NIDDK, although the study's leadership will have proprietary control of and exclusive access to the samples and data for an agreed-upon period of time. Subsequently samples and data will be available to the wider scientific community in accordance with the NIH policy on Data Sharing (http://grants.nih.gov/grants/policy/data_sharing/ and, https://grants.nih.gov/policy/sharing.htm, and http://grants.nih.gov/grants/policy/data_sharing/data_sharing_faqs.htm), as well as the NIDDK policy for data sharing in multi-center and large single-center clinical studies http://www.niddk.nih.gov/research-funding/process/human-subjects-research/Documents/PublicversionNIDDKdatasharingpolicy2013July2013.pdf.

13. Study investigators are required to comply with NIH Policy on the Dissemination of NIH Funded Clinical Trial Information as stated at https://grants.nih.gov/policy/clinical-trials/reporting/understanding/nih-policy.htm. Per policy, the awardee is responsible for meeting the expectations of this policy. Refer to additional information at https://grants.nih.gov/policy/clinical-trials/reporting/index.htm.

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

An NIDDK Project Scientist with substantial involvement will:

1. Serve as the contact point for all facets of the scientific interaction with the awardee (s). As required for the coordination of activities and to expedite progress, NIDDK may designate additional NIDDK staff to provide advice to the awardee on specific scientific and/or analytic issues. Such staff may include another Project Scientist or Project Coordinator, who will provide direct technical assistance to the awardees to optimize the conduct and/or analysis of the study; or who may assist in the coordination of activities across multiple sites.
2. For multi-center studies, participate in the Steering Committee that oversees study conduct. The NIDDK Project Scientist or Project Coordinator 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 activities that may be relevant to the study to facilitate compatibility with the NIDDK missions and avoid unnecessary duplication of effort.
4. Have substantial involvement assisting in the design and coordination of research activities for awardees as elaborated below:

a. Assisting by providing advice in the management and technical performance of the investigations, coordinating required regulatory clearances for investigational agents used in the study, which are held by NIDDK. The NIDDK may reserve the right to cross file or independently file an Investigational New Drug Application or an Investigational Device Exemption form with the FDA.

b. The NIDDK Project Scientist or Project Coordinator may coordinate activities among awardees 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.

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

d. The NIDDK Project Scientist or Project Coordinator may be co-authors on study publications. In general, to warrant co-authorship, NIDDK 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 insure 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) patient 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.

Areas of Joint Responsibility include:
In addition to the interactions defined above, NIDDK Project Scientist and Awardees shall share responsibility for the following activities:
Steering Committee
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 awardees, 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-investigators as deemed necessary, and the NIDDK Project Scientist. The final structure of the Steering Committee and voting procedures will be established at the first meeting. The NIDDK 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.
A Chairperson of the Steering Committee, other than the NIDDK Project Scientist, will be selected by the NIDDK, in consultation with the Steering Committee. The Chairperson provides leadership to the Committee by conducting the Steering Committee meetings, representing the study group to the External Oversight Committee established by the NIDDK and by interacting closely with the awardees during protocol development and implementation.

Dispute Resolution
Any disagreement that may arise on scientific/programmatic matters (within the scope of the award), between award recipients and the NIDDK may be brought to dispute resolution. A dispute resolution panel will be composed of three members --one selected by the awardee (or the Steering Committee, with the NIDDK member not voting), a second member selected by NIDDK, and the third member elected by the two prior selected members. These special dispute resolution procedures in no way affect the awardee's right to appeal an adverse action that is otherwise appealable in accordance with PHS regulations at 42 CFR Part 50, Subpart D, and HHS regulations at 45 CFR Part 16.

Budget	Year 3	Year 4
Salaries and Wages	[redacted]	[redacted]
Fringe Benefits		
Personnel Costs (Subtotal)		
Consultant Services		
Equipment		
Materials & Supplies		
Travel		
Other		
Subawards/Consortium/Contractual Costs		
TOTAL FEDERAL DC		
TOTAL FEDERAL F&A		
TOTAL COST		

Facilities and Administrative Costs	Year 3	Year 4
F&A Cost Rate 1	[redacted]	[redacted]
F&A Cost Base 1		
F&A Costs 1		