FDP Subaward Amendment

Amendment No: 1 | Subaward No: R000003157

Pass-Through Entity (PTE)		Subrecipient
Florida State University	Entity Name	San Francisco Department of Health
subcontracts@fsu.edu	Contact Email	greg.wagner@sfdph.org
Lisa Hightow-Weidman	Principal Investigator	Susan Buchbinder

Project Title: Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) Scientific Leadership Center

PTE/Prime Award No.: 5UM2HD111102-02 | Awarding Agency: National Institutes of Health (NIH)

Cumulative Budget Period(s) (Agreement Start Date) – (End Date of Latest Budget Period)	Amount Funded This Action	Total Amount of Funds Obligated to Date
Start Date: 01/25/2023 End Date: 11/30/2024	$ 138,434.00	$ 173,063.00

Subrecipient Cost Share ☐ | Subject to FFATA ■ | Subrecipient UEI (Unique Entity Identifier - May leave blank if unchanged from prior Agreement): DCTNHRGU1K75

Amendment(s) to Original Terms and Conditions

This Amendment revises the above-referenced Subaward Agreement as follows:

■ **Additional Budget Period**

Additional budget period 12/01/2023 - 11/30/2024 is hereby added to this Subaward.

☐ **No Cost Extension**

■ **Additional Funding**

Additional funding in the amount of $ 138,434.00 is hereby obligated to this Subaward.

☐ **Deobligation**

Carryover is Not Automatic Carryover across budget periods requires prior approval.

☐ **Carryover Authorized**

If carryover is not automatic, the "Total Amount of Funds Obligated to Date" stated above may not reflect the actual balance available. The Subrecipient is responsible for tracking unobligated balances and subsequent carryover approvals from prior budget periods. In the event that funding was not fully expended by the Subrecipient during the prior period, the Subrecipient is not authorized to use funds from any prior periods, unless approval is granted by the PTE.

■ **Detailed Budget/Scope of Work/Notice of Award Attached** (Specify if the Budget and Scope of Work are "New", "Revised", or "Supplemental" in dropdown or "Other")

A Notice of Award and Budget is incorporated by attachment to this Amendment.

■ **Other (See Below)**

1. The FSU project number for this increment is 102619. Invoices that do not reference both the subaward number and the project number may be subject to delay.
2. Attachment 2: Data Sharing Agreement is hereby replaced with the attached Data Sharing and Management Plan below.
3. In Attachment 4: Annual Technical / Progress reports due date is changed from "60 days prior" to "75 days prior".
4. Attached Year 2 Budget and Budget Justification are hereby added to Attachment 5.
5. Notice of Award 5UM2HD111102-02 is hereby added to Attachment 6.
6. Attachment 7, "Human Subjects Data Transfer and Use Terms" is hereby added to this subaward agreement.

For clarity: all amounts stated in this amendment are in United States Dollars.

All other terms and conditions of this Subaward Agreement remain in full force and effect.

By an Authorized Official of PTE:	By an Authorized Official of Subrecipient:
Date:	Date:
Name: Stacey Patterson	Name:
Title: Vice President for Research	Title:

ATN Policy and Procedure

NUMBER: PP 3

TITLE: ATN Data Sharing and Management Plan

EFFECTIVE DATE:

Change History Log:

Effective Date	Version	Revisions
	01	New

I. PURPOSE

The purpose of this policy and procedure is to provide a data sharing and management plan (DSMP) for within the ATN and outside the network for future use.

II. RESPONSIBILITY

- ATN Scientific Leadership Center (SLC) and Operations and Collaboration Center (OCC) Principal Investigators are responsible for ensuring that the policy and procedures are followed.

III. ACRONYMS

- American Public Health Association (APHA)
- Adolescent Trials Network for HIV Interventions (ATN)
- Communication and Dissemination Hub (C-D Hub)
- Case report forms (CRFs)
- Conference on Retroviruses and Opportunistic Infections (CROI)
- Data sharing and management plan (DSMP)
- Electronic data capture (EDC)
- Food and Drug Administration (FDA)
- Florida State University (FSU)
- Health Insurance Portability and Accountability Act (HIPAA)
- International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH)
- NICHD Data and Specimen Hub (N-DASH)
- *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)
- National Institute on Drug Abuse (NIDA)
- National Institutes of Health (NIH)
- Nation Institute of Mental Health (NIMH)
- Operations and Collaborations Center (OCC)
- Protected Health Information (PHI)
- Personally Identifiable Information (PII)
- Society for Behavioral Medicine (SBM)
- Statistical and Data Management Center (SDMC)
- Single IRB (sIRB)
- Scientific Leadership Center (SLC)
- University of North Carolina (UNC)

IV. BACKGROUND

The Adolescent Trials Network for HIV Interventions (ATN) is a multi-component collaborative research enterprise in which all components contribute essential functions necessary to support a large-scale, complex clinical research program. Such a complex structure requires thoughtful, ethical, and legal policies for data management and sharing a) within the ATN for data management, monitoring and analyses, and b) outside of the network for future use.

V. PROCEDURE

A. Data sharing within the ATN

All individuals within any component of the ATN are required to adhere to this networkwide DSMP. The ATN is comprised of the following components through which participant data will flow in multi-directional ways:

- Scientific Leadership Center (SLC) – led by Florida State University (FSU);
- Operations and Collaborations Center (OCC) – led by Westat;
- Statistical and Data Management Center (SDMC) – led by FSU, and inclusive of University of North Carolina (UNC), Emmes and other SDMC components;
- Site Consortiums – 12 clinical sites in the U.S. under subaward from Westat;
- Protocol Teams – researchers at various U.S. institutions including ancillary groups collaborating on study data collection and analysis, under subaward from FSU;
- Central Laboratory – led by Johns Hopkins Laboratory under subcontract from FSU; and
- Authorized representatives of the sponsor (NICHD, NIMH, NIDA), representatives of the single IRB (sIRB) of Record (Sterling), and regulatory agencies.

Methods for Protecting Participant Data and Privacy

Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule
Participant confidentiality and privacy is strictly held in trust by all components of the ATN. This confidentiality is extended to cover testing of biological specimens and genetic tests in addition to the clinical information relating to participants. No information concerning the study, or the data will be released to any unauthorized third party outside of the ATN without prior written approval and formal data sharing agreements. The ATN will ensure that the use and disclosure of PHI obtained during any research study complies with the HIPAA Privacy Rule. The rule provides U.S. federal protection for the privacy of PHI by implementing standards to protect and guard against the misuse of individually identifiable health information of participants participating in clinical trials.

National Institutes of Health (NIH) Policy NOT-OD-17-109 – Certificate of Confidentiality
Per Section 2012 of the 21st Century Cures Act as implemented in the 2017 NIH Certificates of Confidentiality Policy, all ongoing or new research funded wholly or in part by NIH as of December 13, 2016 that is collecting or using identifiable, sensitive information is automatically deemed to be issued a CoC.. These Certificates protect the privacy of subjects by limiting the disclosure of identifiable, sensitive information (PII) outside of the network. This Certificate applies to all biomedical, behavioral, clinical, or other research funded wholly or in part by the NIH, whether supported through grants, cooperative agreements, contracts, other transaction awards, or conducted by the NIH Intramural Research Program, which collects or uses identifiable, sensitive information. For the purposes of this Policy, consistent with subsection 301(d) of the Public Health Service Act (42 U.S.C 241), the term “identifiable, sensitive information” means information about an individual that is gathered or used during the course of biomedical, behavioral, clinical, or other research, where the following may occur:

- Through which an individual is identified; or

- For which there is at least a very small risk, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.

Informed Consent

All study participants from ATN clinical trial Site Consortiums will be provided with informed consent forms that outline data sharing within the network and include study-specific disclosures. The Privacy Rule permits covered entities to use or disclose PHI for research purposes when a research participant authorizes the use or disclosure of information about themself provided the authorization satisfies the requirements of 45 CFR 164.508. Authorization is required from each research participant (i.e., specific permission granted by an individual for the use or disclosure of an individual's PHI) or parent/legal guardian when applicable. A valid authorization must meet the implementation specifications under the HIPAA Privacy Rule. Authorization may be combined in the informed consent document (if approved by the sIRB). sIRB approval will be obtained for each ATN clinical trial, corresponding consent forms and HIPAA authorizations. Informed consent documents will include disclosure information for both PHI and PII.

Data Systems

Data will be entered into a password protected, 21 CFR Part 11-compliant web-based EDC system provided by Emmes. Each participating Site Consortium will maintain appropriate medical and research records for ATN studies in compliance with International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) E6 (R2), Section 4.9 and 21 CFR 312.62, and regulatory and institutional requirements for the protection of confidentiality of participants. Each Site Consortium will permit authorized representatives of the sponsor, its designees, and appropriate regulatory agencies to examine (and, when required by applicable law, to copy) clinical records for the purposes of quality assurance reviews, audits, and evaluation of the study safety and progress.

Qualitative interviews and focus groups will be digitally recorded and transcribed. All digital audio files will be transmitted to and stored on a secured server maintained by FSU. FSU authorized individuals or a third-party HIPAA-compliant transcription service company will transcribe digital audio files under the supervision of FSU. Transcripts will only be labeled with Participant ID. IRB-approved FSU team members will also review the transcripts to ensure that any personally identifying information is removed before providing the electronic transcripts to coders and analysts. The electronic transcript files will be stored on a secured server at FSU until it is transmitted to the SDMC to be stored with the rest of the study data. The digital audio files will be destroyed within the protocol-specified timeframe. A HIPAA-compliant qualitative data analysis software (e.g., Atlas.ti, Dedoose) will be used to perform all qualitative analyses. These programs employ HIPAA-compliant data encryption and allow for password-protected, project specific access. Only approved study staff will have access to these data.

Study participant research data will be transmitted to and stored at the SDMC. All participant-related study information will be identified through the Participant ID on all case report forms (CRFs), laboratory reports, clinical assessments, surveys, and questionnaires (paper and electronic). Participant ID may be linked with name, email, phone number, and address for specific studies and laboratory reports. The study data entry and study management systems used by Site Consortiums and the ATN collaborators are secured, and password protected.

As part of the Pre-Screening Survey and the Advantage eClinical Cloud (AEC) ePRO, the SDMC will collect participant name, address, email, phone number and IP address. Participants may be asked to upload photos of rapid test results within AEC ePRO. There is no guarantee that a photo with the participant's face or other identifying information will not be uploaded. This information is needed for sites to contact potential participants for screening, to send reminders for data entry, facilitate shipment of lab specimen collection kits, and allow Site Consortium staff to evaluate rapid test results for remote participants. Participant contact information will be collected but access limited to applicable Site Consortium staff within AEC. This data will be encrypted within the affiliated datasets.

All PII will be kept confidential and secure with access limited to only needed project staff and site staff as applicable. PII in AEC will be controlled by user access rights, PII on the servers will either be encrypted or stored in a location with access limited to applicable programmers and statisticians. PII on the website will be controlled by user access rights and files with name, address, email and phone number will be password protected.

Any PII collected may be shared with network members listed in the HIPAA data authorization components of the signed informed consent forms. Any PII will only be shared through secure, password-protected mechanisms, typically either the SDMC website or AEC.

Data Records at the ATN Site Consortiums including Other Participating Sites

Study documents will be kept locked in a limited access area. At each Site Consortium, a list of Participant IDs that links the numbers to the participant names will be kept under double locks separate from all study documents or secure electronic system, accessible only to Site Consortium study staff and representatives from (NICHD, site monitors on behalf of NICHD, and regulatory authorities (e.g., local IRB, Sterling IRB, U.S. Food and Drug Administration (FDA)). Screening Logs will also be stored in the same manner and accessible only to those personnel noted above. Original source documents for individual participants will be maintained at the respective Site Consortium and will be accessible only to ATN study staff. The participant's contact information will be securely stored at each Site Consortium for use during the ATN project period. At the end of the project period, all records will continue to be kept in a secure location for as long a period as dictated by the sIRB, the local IRB, Institutional policies, and/or Sponsor requirements. Both the Site Consortium Project Lead and the Institution at which the studies are conducted will hold the responsibility to maintain custody of all study records until the Sponsor permits their destruction.

Personal Data Protection by ATN components

Per this ATN DSMP, all grantees within any of the ATN components are responsible for ensuring their compliance with any applicable data protection laws related to its services. To the extent that any grantee staff member shares any personal data, as defined by applicable data protection laws, on behalf of the ATN, grantees shall:

1. Act only on instructions from the ATN when sharing personal data and keep records of all activities;

2. Take all appropriate technical and organizational measures to protect against unauthorized or unlawful sharing of, or accidental loss, destruction, or damage to, personal data;

3. Share personal data in accordance with applicable data protection laws;

4. Not do or permit anything to be done which might cause the ATN or any of its affiliates to be in violation of applicable data protection laws;

5. Immediately inform the ATN SLC and OCC Principal Investigators if they believe performance of the services or compliance with any ATN instruction violates or might reasonably be considered to violate any applicable data protection laws;

6. Notify the ATN SLC and OCC Principal Investigators promptly and without undue delay upon becoming aware of any unauthorized loss, corruption, damage, destruction, alteration, disclosure, or access to, or unauthorized or unlawful processing of, any personal data ("Personal Data Breach"), or any circumstances that are likely to give rise to a Personal Data Breach, providing the ATN with sufficient information for it to meet its obligation, if any, to report a Personal Data Breach under applicable data protection laws; and

7. Cooperate with the ATN and take reasonable steps as may be directed by the ATN to assist in the investigation, mitigation, and remediation of any Personal Data Breach.

B. Future Sharing of De-Identified Data

Public dissemination of ATN scientific results can facilitate the creation of collaborative efforts with domestic and international collaborators resulting in novel ideas that could benefit the research and medical community, medical education providers and accreditors, and the public at large. Therefore, research data will be shared openly, proactively, and timely in accordance with the most recent NIH guidelines while being mindful that the confidentiality and privacy of participants in research must always be protected.

NICHD requires that data, biospecimens, and results of NICHD-funded research will be shared with the wider scientific community to the extent feasible and in a timely manner. The NIH Data Sharing Policy expects the timely release and sharing of data to be no later than the acceptance for publication of the main findings from the final dataset. The ATN will comply with the NIH Data Sharing Policy and Policy on the Dissemination of NIH-Funded Clinical Trial Information and the Clinical Trials Registration and Results Information Submission rule (NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information | grants.nih.gov). As such, applicable studies will be registered at ClinicalTrials.gov, and results will be submitted to ClinicalTrials.gov.

After the ATN study's analyses are completed, information including study data will be submitted to the NICHD Data and Specimen Hub or DASH (https://dash.nichd.nih.gov). With NICHD approval, the data submitted to DASH may be used by other researchers for additional, unrelated research. NICHD will review any request prior to release of the data to ensure that all appropriate approvals have been obtained. The study data submitted to DASH will be de-identified, meaning it will not include any direct or indirect identifiers linking the data to the participant's identity so there is no potential for deductive disclosure. With SLC approval, the Protocol Teams may also share the de-identified study data with other researchers. When the participant's de-identified study data are provided to other researchers for the purposes of future

research, it will be done without obtaining additional permission from the participant. Permission to transmit data to DASH will be included in the informed consent.

Dissemination of ATN Data

Findings resulting from ATN research will be disseminated in a variety of ways highlighted below.

1. Formal academic dissemination in the form of journal articles and abstracts: ATN research results will be rapidly disseminated to the scientific community, including through open access channels whenever possible. Publications will be made available to the NIH for online distribution via the NIH manuscript submission system (http://www.nihms.nih.gov). It will be ensured that no study participants are individually identified (i.e., participant level data) in any published or shared data. All publications, presentations, and press releases using ATN data will acknowledge the study investigators, NIH sponsorship with the relevant grant number.

2. Data sharing with community members: SCs via the OCC, as well the ATN Communication and Dissemination Hub (C-D Hub) will be active partners collaborating with the study team on the development of culturally appropriate dissemination of research results (i.e., publications and other means of dissemination). Multi-directional information exchange between the Protocol Teams, Site Consortium staff, and members of advisory boards will be critical to the design and execution of project outreach, communication, and culturally appropriate dissemination activities.

3. Data sharing with scientific and health service community: The SDMC will compile structured de-identified datasets and make them available for additional/secondary data analyses. For data sharing, the Protocol Team will follow the “standards for privacy of individually identifiable health information.” Participants' records and results will not be identified. No contact information will be included in any archived datasets. To preclude indirect identification, certain data elements such as date of birth will be transformed; date of birth will be used to provide a categorical age variable at a specific time point on the study such as enrollment. All other dates will be transformed in a similar manner. Formal data sharing agreements will be developed to guide and encourage further data mining of the proposed datasets for various purposes.

4. Data sharing with NIH. NIH, the Scientific Program Officer, ATN SLC, and Protocol Teams will work closely to disseminate and incorporate required/requested measures to provide data and results as requested. Feedback will be regularly and expeditiously requested on study results from each aim, as well as successes and challenges related to implementation with NIH and other grantees.

5. Presentations at national and international scientific meetings: ATN SLC members and Protocol Teams will regularly attend national and international annual conferences, such as for the Society for Behavioral Medicine (SBM), American Public Health Association (APHA), Conference on Retroviruses and Opportunistic Infections (CROI), and International AIDS Society Meetings (including HIV R4P and International AIDS Conferences) to disseminate our research findings and to keep abreast of new and innovative projects in this area of research. Presentation of data at scientific meetings is a

critical way to ensure wider awareness of research findings. An acknowledgement and disclaimer will be included in all presentations produced under this NIH support.

6. Local and regional presentations: Presentations will be provided on ATN study results to the Site Consortiums located throughout the United States. Throughout the project period, dissemination will occur through discussions and presentations at adult and pediatric medical clinics, community-based organizations, and annual conference presentations to both behavioral and medical audiences.

7. ATN website and social media: The OCC with input from the C-D Hub, will develop and manage the ATN website that includes information about all ATN studies designed for potential participants and the public at large. Social media platforms will be utilized (e.g., Facebook, Instagram, Twitter) to communicate information about the project and its findings.

VI. REVIEW AND REVISION

This policy and procedure will be reviewed every two years for consistency with current regulations and practice.

RESEARCH & RELATED BUDGET - Budget Period 2

OMB Number: 4040-0001
Expiration Date: 12/31/2022

UEI: DCTNHRGU1K75 **Enter name of Organization:** City and County of San Francisco - DPH

Budget Type: ☐ Project ☒ Subaward/Consortium **Budget Period: 2** **Start Date:** 12/01/2023 **End Date:** 11/30/2024

A. Senior/Key Person

Prefix	First	Middle	Last	Suffix	Base Salary ($)	Months Cal.	Months Acad.	Months Sum.	Requested Salary ($)	Fringe Benefits ($)	Funds Requested ($)
	Susan		Buchbinder		203,700.00	2.40			40,740.00	14,633.00	55,373.00
Project Role:	PD/PI										
	Albert		Liu		203,700.00	1.20			20,370.00	7,317.00	27,687.00
Project Role:	Co-PI										
	Hyman		Scott		203,700.00	1.20			20,370.00	7,317.00	27,687.00
Project Role:	Co-Inv										

Additional Senior Key Persons: Add Attachment | Delete Attachment | View Attachment

Total Funds requested for all Senior Key Persons in the attached file:

Total Senior/Key Person: 110,747.00

B. Other Personnel

Number of Personnel	Project Role	Months Cal.	Months Acad.	Months Sum.	Requested Salary ($)	Fringe Benefits ($)	Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						

Total Number Other Personnel

Total Other Personnel

Total Salary, Wages and Fringe Benefits (A+B): 110,747.00

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment item	Funds Requested ($)

Additional Equipment: Add Attachment | Delete Attachment | View Attachment

Total funds requested for all equipment listed in the attached file

Total Equipment

D. Travel

	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs

	Funds Requested ($)
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other	
Number of Participants/Trainees — **Total Participant/Trainee Support Costs**	

F. Other Direct Costs

Attachment 5

		Funds Requested ($)
1.	Materials and Supplies	
2.	Publication Costs	
3.	Consultant Services	
4.	ADP/Computer Services	
5.	Subawards/Consortium/Contractual Costs	
6.	Equipment or Facility Rental/User Fees	
7.	Alterations and Renovations	
8.		
9.		
10.		
11.		
12.		
13.		
14.		
15.		
16.		
17.		
	Total Other Direct Costs	

G. Direct Costs

	Funds Requested ($)
Total Direct Costs (A thru F)	110,747.00

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)
Total Personnel Cost	25.00	110,747.00	27,687.00

Total Indirect Costs 27,687.00

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): Dept of Transportaton, Office of Inspector General, 783-284-2600

I. Total Direct and Indirect Costs

	Funds Requested ($)
Total Direct and Indirect Institutional Costs (G + H)	138,434.00

J. Fee

	Funds Requested ($)

K. Total Costs and Fee

	Funds Requested ($)
Total Costs and Fee (I + J)	138,434.00

L. Budget Justification

(Only attach one file.) CCSF Budget Justification_2.pdf [Add Attachment] [Delete Attachment] [View Attachment]

BUDGET JUSTIFICATION
City and County of San Francisco (CCSF)
San Francisco Department of Public Health (SFDPH)

PERSONNEL

Total Personnel: $110,747 Year 2

Personnel costs calculated using the current NIH salary cap of $203,700 and includes fringe benefit rate applied at *36%*

Susan Buchbinder, MD (Principal Investigator): Dr. Buchbinder is Director of Bridge HIV at the San Francisco Department of Public Health and Professor of Medicine, Epidemiology and Biostatistics at the University of California, San Francisco. She provides scientific leadership in the NIH sponsored HIV Vaccine Trials Network and HIV Prevention Trials Network and leads several multi-site HIV prevention efficacy trials, with a focus on advancing integrated prevention strategies in diverse populations of men who have sex with men (MSM) and transgender/gender non-binary persons (TG/GNB) in the US and globally. Most recently, she has focused on the use of mHealth technology for young MSM and TG/GNB to increase access to prevention and treatment services for populations at risk for or living with HIV infection, and implementation of prevention strategies. As Principal Investigator (PI) of the PrEP CHOICE proposal, she will be responsible for the overall scientific vision and implementation of the specific aims of this study. Dr. Buchbinder will have responsibility for maintaining the proposed study schedule, ensuring quality control over all aspects of the study, including data analysis, presentations, publications, and dissemination of results. She will lead weekly team meetings. Dr. Buchbinder will serve as primary liaison with the ATN and will oversee all budgetary issues for the project. In addition, throughout the 7-year cycle of the ATN grant, Dr. Buchbinder will serve on the Biomedical Therapeutics team, and contribute to the successful completion of the ATN SLC grant application, generate and review the scientific priorities within the ATN; assist ATN PIs to pursue new scientific partnerships and funding opportunities; oversee the research project teams and protocol development within the Team agenda areas; identify gaps in the scientific agenda of the Team; review manuscripts and discretionary proposals within the Team's area of expertise; participate on at least 80% of scheduled Team calls; participate in bi-annual face-to-face ATN meetings; and participate in other ad hoc leadership meetings, as needed.
Dr. Buchbinder will devote 2.40 Cal Mos ($55,373) year 2.

Albert Liu, MD, MPH (Co-Principal Investigator): Dr. Liu is Clinical Research Director at Bridge HIV at the San Francisco Department of Public Health and Associate Clinical Professor of Medicine at the University of California, San Francisco (UCSF). Dr. Liu is a well-established, successful, clinical investigator who has been conducting clinical studies developed by NIH HIV/AIDS Clinical Trials Networks for 15 years. He is currently an active investigator in the ATN iTech U19, serving as PI of two studies testing mobile apps to increase HIV testing and PrEP uptake among young MSM. He has also served as protocol chair and/or site investigator for several protocols within the HIV Prevention Trials Network (HPTN) and Microbicide Trials Network (MTN) and served on the MTN's Executive Committee. Dr. Liu has served as the Protocol Chair of the PrEP Demonstration Project in MSM and the NIMH- sponsored EPIC study to develop the PrEPmate SMS intervention for young MSM and transgender and non-binary individuals. Dr. Liu will be responsible for overseeing technology development and optimization of the PrEP CHOICE package, assisting with scientific design of research protocols and procedures, overseeing study coordinator activities, and monitoring study implementation. He will maintain frequent contact with Dr. Buchbinder and the other Co-Investigators through meetings, conference calls, e-mail, and drafting and presenting emerging findings of the research. He will also work closely with the research team in data analysis, manuscript preparation, and dissemination of results. In addition, throughout the 7-year cycle of the ATN grant, Dr. Liu will serve on the Biomedical Therapeutics team, and contribute to the successful completion of the ATN SLC grant application, generate and review the scientific priorities within the ATN; assist ATN PIs to pursue new scientific partnerships and funding opportunities; oversee the research project teams and protocol development within the Team agenda areas; identify gaps in the scientific agenda of the Team; review manuscripts and discretionary proposals within the Team's area of expertise; participate on at least 80% of scheduled Team calls; participate in bi-annual face-to-

face ATN meetings; and participate in other ad hoc leadership meetings, as needed. **Dr. Liu will devote 1.20 Cal Mos to the project each year 2 Total Salary: $27,687 year 2.**

Hyman Scott, MD, MPH (Co-investigator): Dr. Scott is the Medical Director of Clinical Research at Bridge HIV at the San Francisco Department of Public Health, an Assistant Professor of Medicine at the University of California, San Francisco (UCSF), and a physician at the Positive Health Program (Ward 86) at San Francisco General Hospital. His primary research area is HIV-related racial/ethnic disparities with a focus on biomedical HIV and STI prevention and has worked closely with Drs. Liu and Buchbinder on the development of a risk assessment tool for MSM (Sex Pro). He is currently the Director of the PrEP clinic at Ward 86 and has developed a PrEP Clinical Protocol for use across the public health clinics in San Francisco. Dr. Scott oversees Bridge HIV research associates conducting qualitative focus groups and interviews, will assist with technology development and scientific design of research protocols, and provide clinical guidance, training and safety monitoring regarding administration of various PrEP agents to youth in this study. He will maintain frequent contact with Dr. Buchbinder and the other Co-Investigators through meetings, conference calls and e-mail. He will also work closely with the research team in data analysis, manuscript preparation, and dissemination of results. **Dr. Scott will devote 1.20 Cal Mos to the project each year 2. Total Salary: $27,687 year 2.**

Total Direct Costs: $110,747 year 2.

Indirect Costs: Total and $27,687 year 2.
CCSF indirect costs are calculated at 25% of the modified total direct cost. This rate is for the other sponsored activities approved by Department of Health and Human Services (DHHS).

Total Costs: $138,434: Combined direct and indirect costs year 2.

Department of Health and Human Services
National Institutes of Health
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Notice of Award
FAIN# UM2HD111102
Federal Award Date
12/01/2023

Recipient Information

1. Recipient Name
FLORIDA STATE UNIVERSITY
874 TRADITIONS WAY
TALLAHASSEE, FL 32306

2. Congressional District of Recipient
02

3. Payment System Identifier (ID)
1596001138A1

4. Employer Identification Number (EIN)
596001138

5. Data Universal Numbering System (DUNS)
790877419

6. Recipient's Unique Entity Identifier
JF2BLNN4PJC3

7. Project Director or Principal Investigator
Lisa B Hightow-Weidman, MD (Contact)
Professor
lhightowweidman@fsu.edu
850-644-3296

8. Authorized Official
Stacey Patterson

Federal Agency Information

9. Awarding Agency Contact Information
Mahasin Ingram

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
ingrammk@mail.nih.gov
(201) 780-0309

10. Program Official Contact Information
Denise Russo
Program Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
drusso1@mail.nih.gov
301-435-6871

Federal Award Information

11. Award Number
5UM2HD111102-02

12. Unique Federal Award Identification Number (FAIN)
UM2HD111102

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

14. Federal Award Project Title
Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) Scientific Leadership Center

15. Assistance Listing Number
93.865

16. Assistance Listing Program Title
Child Health and Human Development 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 12/01/2023 **– End Date** 11/30/2024	
20. Total Amount of Federal Funds Obligated by this Action	$9,417,285
20 a. Direct Cost Amount	$7,776,821
20 b. Indirect Cost Amount	$1,640,464
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$9,417,285
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$9,417,285
26. Project Period Start Date 01/25/2023 **– End Date** 11/30/2029	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$22,534,260

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Teri A. Pailen

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

Cooperative Agreement
Department of Health and Human Services
National Institutes of Health

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 5UM2HD111102-02

Principal Investigator(s):
Lisa B Hightow-Weidman (contact), MD
Sybil Hosek, PHD

Award e-mailed to: SRA-Pre@fsu.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $9,417,285 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to FLORIDA STATE UNIVERSITY in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 31 USC 6305 42 CFR Part 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 Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number UM2HD111102. 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,

Teri A. Pailen
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Additional information follows

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

Salaries and Wages	$693,486
Fringe Benefits	$216,076
Personnel Costs (Subtotal)	$909,562
Consultant Services	$62,325
Materials & Supplies	$45,419
Travel	$47,700
Other	$1,746,600
Subawards/Consortium/Contractual Costs	$4,886,015
ADP/Computer Services	$79,200
Federal Direct Costs	$7,776,821
Federal F&A Costs	$1,640,464
Approved Budget	$9,417,285
Total Amount of Federal Funds Authorized (Federal Share)	$9,417,285
TOTAL FEDERAL AWARD AMOUNT	$9,417,285
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$9,417,285

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
2	$9,417,285	$9,417,285
3	$10,333,316	$10,333,316
4	$10,283,125	$10,283,125
5	$10,173,415	$10,173,415
6	$10,161,519	$10,161,519
7	$10,113,635	$10,113,635

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

Fiscal Information:

Payment System Identifier: 1596001138A1
Document Number: UHD111102A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024	2025	2026	2027	2028	2029
HD	8014710	$6,417,285	$7,333,316	$7,283,125	$7,173,415	$7,161,519	$7,113,635
MH	8472592	$1,000,000	$1,000,000	$1,000,000	$1,000,000	$1,000,000	$1,000,000
DA	8472628	$2,000,000	$2,000,000	$2,000,000	$2,000,000	$2,000,000	$2,000,000

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

NIH Administrative Data:
PCC: MPIDB-DR / **OC**: 41029 / **Released**: Pailen, Teri 11/30/2023
Award Processed: 12/01/2023 12:05:07 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5UM2HD111102-02

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 – 5UM2HD111102-02

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

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) UM2HD111102. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

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

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration System Information Website. NIH encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/
This award provides support for one or more NIH defined Phase III Clinical Trials. The NIH Policy for research supported as an NIH Phase III Clinical Trial has been amended in Section II.B. of the NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research – Amended October 2001 (see http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm).

A description of plans to conduct analyses, as appropriate, by sex/gender and racial/ethnic groups must be included in clinical trial protocols. Cumulative subject accrual and progress in conducting subset analyses must be reported to NIH in the annual Progress Reports. Final analyses of sex/gender and racial/ethnic differences must be reported in the required Final Progress Report or Competitive Renewal Applications (or Contract Renewals/Extensions) as stated in Section II.B. of the Guidelines.
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.

Eunice Kennedy Shriver National Institute Of Child Health & Human Development (NICHD) National Institute Of Mental Health (NIMH) National Institute On Drug Abuse (NIDA)

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 – HD SPECIFIC AWARD CONDITIONS – 5UM2HD111102-02

Clinical Trial Indicator: Yes

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

CONTINUING RESOLUTION: NIH is currently funding through a Continuing Resolution at the FY2023 level as stated in NIH Guide Notice NOT-OD-24-007. Therefore, this non-competing award has been made at a level below that committed for FY2024 in the previous Notice of Award. If the final appropriation permits, adjustments may be made up to the FY2024 funding plan level.

RESTRICTION: This award is being made without a currently valid certification of Institutional Review Board (IRB) approval and is issued with the following restriction: Only activities that are clearly severable and independent from activities that involve human subjects may be conducted pending NICHD acceptance of the certification of IRB review and approval. No funds may be drawn down from the Payment Management System and no obligations may be made against Federal funds for any research involving human subjects prior to issuance of a revised Notice of Award rescinding this restriction.

IRB approval verification must be submitted within 60 days of the date of this Notice of Award to the Grants Management Specialist (GMS). Please contact the GMS if the IRB approval will be delayed beyond 60 days. 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.

MULTI-PI: The recipient must follow the Multiple Principal Investigator Leadership Plan included in the application dated 11/05/2022 and may not implement any changes in the plan without written NICHD prior approval.

Although the signatures of all PI/PD(s) are not required on prior approval requests, the recipient institution must secure and retain the signatures of all of PI/PD(s) within their own internal processes. See NIH Guide Notice NOT-OD-06-054.

SUBPROJECT: Subproject funding information is available via the NIH RePORTER System.

HUMANS: For all competing applications or new protocols, the NICHD expects investigators for ALL NICHD Clinical Trials to abide by the requirements stated in NIH Guide Notice NOT-HD-20-036 "NICHD Data Safety Monitoring Guidelines for Extramural Clinical Trials and Clinical Research". All NICHD applications which include Clinical Trials must include a Data Safety Monitoring Plan. All NIH-sponsored multi-site clinical trials, NIH-defined Phase III clinical trials and some single site clinical trials that pose potential risk to participants require Data and Safety Monitoring Board (DSMB) oversight. Applicants are expected to establish an independent, external DSMB when required by this policy.

For all competing applications or new protocols, the NICHD expects investigators for ALL human subject research to abide by the requirements stated in NIH Guide Notice NOT-HD-20-035 "NICHD Serious Adverse Event, Unanticipated Problem, and Serious Adverse Event Reporting Guidance".

DISSEMINATION: The clinical trial(s) supported by this award are subject to the Dissemination Plan specified in the application dated 11/05/2022 and the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. The policy states that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant and that primary summary results will be reported in ClinicalTrials.gov not later than one year after the trial completion date. The reporting of summary results is required even if the primary trial completion date occurs after the period of performance.

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

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

RISK ASSESSMENT:

Clinical Trial Study/Studies:

416802

This Clinical Trial Study or Studies listed above have been determined by NICHD to be considered **LOW** risk. Oversight by NICHD will occur in the standard manner through the annual RPPR. An annual update (no additional reports) on the status of the milestones included in Section 6 of the eRA HSS and any additional agreed-upon milestones are due in the RPPR. Information and procedures concerning these requirements are available on the NICHD Policies on Clinical Research site.

Clinical Trial Study/Studies:

416804

This Clinical Trial Study or Studies listed above have been determined by NICHD to be considered **LOW** risk. Oversight by NICHD will occur in the standard manner through the annual RPPR. An annual update (no additional reports) on the status of the milestones included in Section 6 of the eRA HSS and any additional agreed-upon milestones are due in the RPPR. Information and procedures concerning these requirements are available on the NICHD Policies on Clinical Research site.

Clinical Trial Study/Studies:

416806

This Clinical Trial Study or Studies listed above have been determined by NICHD to be considered **LOW** risk. Oversight by NICHD will occur in the standard manner through the annual RPPR. An annual update (no additional reports) on the status of the milestones included in Section 6 of the eRA HSS and any additional agreed-upon milestones are due in the RPPR. Information and procedures concerning these requirements are available on the NICHD Policies on Clinical Research site.

Clinical Trial Study/Studies:

416813

The Clinical Trial Study or Studies listed above have been determined by NICHD to be considered **HIGH** risk requiring increased oversight by NICHD. A **quarterly update** on the status of the milestones included in Section 6 of the eRA Human Subjects System (HSS) and any additional agreed-upon milestones are due **three times a year** as well as being included in the annual RPPR. The update cycle due date is based on the budget period start date referenced in this Notice of Award. Information and procedures concerning these requirements are available on the NICHD Policies on Clinical Research site. Updates must be provided through the eRA HSS accessible through the eRA Commons.

Clinical Trial Study/Studies:

416814

The Clinical Trial Study or Studies listed above have been determined by NICHD to be considered **MEDIUM** risk requiring increased oversight by NICHD. An update on the status of the milestones included in Section 6 of the eRA Human Subjects System (HSS) and any additional agreed-upon milestones will be due **once a year (generally halfway through the budget period)** as well as being included in the annual RPPR. The update cycle due date is based on the budget period start date referenced in this Notice of Award. Information and procedures concerning these requirements are available on the NICHD Policies on Clinical Research site. Updates must be provided through the eRA HSS accessible through the eRA Commons.

Clinical Trial Study/Studies:

416815

This Clinical Trial Study or Studies listed above have been determined by NICHD to be considered **LOW** risk. Oversight by NICHD will occur in the standard manner through the annual RPPR. An annual update (no additional reports) on the status of the milestones included in Section 6 of the eRA HSS and any additional agreed-upon milestones are due in the RPPR. Information and procedures concerning these requirements are available on the NICHD Policies on Clinical Research site.

SPREADSHEET SUMMARY
AWARD NUMBER: 5UM2HD111102-02

INSTITUTION: FLORIDA STATE UNIVERSITY

Budget	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Salaries and Wages	$693,486	$751,040	$767,707	$754,951	$1,013,454	$974,867
Fringe Benefits	$216,076	$234,159	$239,223	$236,572	$314,932	$301,943
Personnel Costs (Subtotal)	$909,562	$985,199	$1,006,930	$991,523	$1,328,386	$1,276,810
Consultant Services	$62,325	$69,250	$69,250	$69,250	$69,250	$69,250
Materials & Supplies	$45,419	$44,168	$53,132	$39,191	$126,235	$161,476
Travel	$47,700	$56,400	$56,400	$56,400	$101,400	$113,500
Other	$1,746,600	$1,962,702	$1,968,576	$2,003,078	$2,292,163	$2,954,614
Subawards/Consortium/Contractual Costs	$4,886,015	$5,472,329	$5,379,321	$5,261,674	$4,059,371	$3,067,134
ADP/Computer Services	$79,200	$30,000	$30,000	$30,000	$45,000	
TOTAL FEDERAL DC	$7,776,821	$8,620,048	$8,563,609	$8,451,116	$8,021,805	$7,642,784
TOTAL FEDERAL F&A	$1,640,464	$1,713,268	$1,719,516	$1,722,299	$2,139,714	$2,470,851
TOTAL COST	$9,417,285	$10,333,31	$10,283,12	$10,173,41	$10,161,51	$10,113,63

		6	5	5	9	5

Facilities and Administrative Costs	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
F&A Cost Rate 1	54%	54%	54%	54%	54%	54%
F&A Cost Base 1	$3,037,896	$3,172,719	$3,184,288	$3,189,442	$3,962,434	$4,575,650
F&A Costs 1	$1,640,464	$1,713,268	$1,719,516	$1,722,299	$2,139,714	$2,470,851

Attachment 7

Human Subjects Data Transfer and Use Terms

Human Subjects Data ("Data") will be exchanged under this Subaward (check all that apply):

☒ From Subrecipient to PTE
☒ From PTE to Subrecipient

1. The Party providing the Data will be referred to as the "Provider," and the Party receiving the Data will be referred to as the "Recipient" as reflected above in this section.
2. The Data to be shared will be Personally Identifiable Information (PII)
3. Provider authorizes Recipient to share the Data as may be required under the data sharing plan for this project, and may be required by the Data Sharing & Access section of this Subaward.
4. Upon completion of the Project Period End Date Recipient shall retain or destroy the Data as instructed by the Provider; provided, however, that Recipient may retain one (1) archival copy of the Data.
5. Description of Data (Required)

Description of Data:

Human participant data will be collected across all IRB-approved ATN protocols. Data may include clinical information, surveys and questionnaires, laboratory results, hospital records, pharmacy dispensing records, participant diaries, and transcriptions from audio recordings. Each IRB-approved protocol will include its own description of the study-specific data to be collected.

PII (that isn't PHI) Additional Terms and Conditions:

Data transferred under this Subaward contains identifiable data elements derived from human subjects and constitutes Personally Identifiable Information ("PII Data"), as that is defined in OMB Memorandum M-17-16 and the Common Rule implementing regulation 45 CFR 46, and is not covered under HIPAA, FERPA, or similar laws or regulations governing personal information that require the addition of special terms beyond those included herein.

Provider certifies that it will only provide PII Data to Recipient after the transfer has been authorized by Provider's IRB.

Notwithstanding any statment herein to the contrary, Provider represents that it has full authority to share the Data with the Recipient and has confirmed that the Statement of Work is consistent with such consents as Provider may have obtained form individuals how are the subjects of the Data.

Recipient may only access, use and disclose data as permitted by this Subaward, the Informed Consent ("ICF"), the IRB-approved protocol ("Protocol"), the Common Rule or as permitted by law.

Recipient must use appropriate technical, administrative, and physical safeguards to prevent use or disclosure of PII Data other than as allowed by this Subaward.

Recipient shall only use the Data for the purposes of this Subaward and shall protect the Data from any other unauthorized use and disclosure.

If Recipient becomes aware of any use or disclosure of PII Data not allowed by this Subaward, including if disclosure of PII Data is required by law or court order, Recipient will notify Provider as soon as possible, and in no event later than five (5) business days after its discovery. Recipient will reasonably cooperate with Provider in taking all appropriate or required steps to minimize the impact of any disclosure of PII Data. Provider may have an obligation to make further notifications under applicable state law and Recipient shall cooperate with the Provider to the extent necessary to enable Provider to meet all such obligations.

Recipient will not use PII Data to contact any individuals who are or may be the sources of PII Data without specific written approval from Provider and appropriate IRB approval.

Recipient will remove and securely destroy or return, as directed by the Provider, the part or parts of the PII Data that identifies the individual who is the subject of the PII Data at the earliest time at which removal and destruction or return can be accomplished, consistent with the purpose of the Project.

Recipient will remain in compliance with all applicable U.S. federal, state, and local laws and regulations regarding handling or storing PII Data and record retention requirements.