FDP Cost Reimbursement Subaward

Federal Awarding Agency: National Institutes of Health (NIH)

Pass-Through Entity (PTE):	**Subrecipient:**
Florida State University	San Francisco Department of Health
PTE PI: Lisa Hightow-Weidman	Sub PI: Susan Buchbinder
PTE Federal Award No: 1UM2HD111102-01	Subaward No: R000003157
Project Title: Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) Scientific Leadership Center	
Subaward Budget Period: Start: 01/25/2023 End: 11/30/2023	Amount Funded This Action (USD): $ 34,629.00
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 Financial Contact, shown in Attachment 3A.

3. A final statement of cumulative costs incurred, including cost sharing, marked "FINAL" must be submitted to PTE's Financial Contact, as shown in Attachment 3A, not later than 60 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 Administrative Contact and the Subrecipient's Administrative 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 Unilaterally. 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:
Digitally signed by Russell D. Lentz for Stacey Patterson, VP for Research, Florida State University Date: 2023.04.28 07:43:08 -04'00'	DocuSigned by: Greg Wagner 285275247529491F...
Name: Stacey Patterson Date:	Name: Grant Colfax, MD Date: 4/27/2023 | 11:21
Title: Vice President for Research	Title: Director of Health

Approved as to form, David Chiu, City Attorney
By: DocuSigned by: Henry Lifton
Henry Lifton, Deputy City Attorney

Attachment 1
Certifications and Assurances

Subaward Number: R000003157

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 200.213 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 200.337 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: R000003157

Required Data Elements

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

Awarding Agency Institute (If Applicable): EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Federal Award Issue Date	FAIN	Assistance Listing No.
01/24/23	UM2HD111102	93.865

Assistance Listing Program Title (ALPT): Child Health and Human Development 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. 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.

Attached is a Data Management and/or Sharing Plan that incorporates additional requirements as submitted to the Federal Awarding Agency.

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 Grants 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: Subrecipient

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.

RESOURCE AND DATA SHARING

We recognize that the public dissemination of ATN scientific results can facilitate the creation of collaborative efforts with domestic and international collaborators. Furthermore, we recognize that the proposed ATN Research Projects may result 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 be always protected.**

Sharing of data generated by ATN work will be carried out in several different ways, including with other researchers, as well as the community at large, in accordance with directives by NIH. Following the NIH data sharing policy, the timely release and sharing of data will be no later than the acceptance for publication of the main findings from the final dataset of each Research Project and will include public-use analysis datasets along with the final version of the study protocol, data dictionaries, and brief instructions. Specifically, we intend to use the Data and Specimen Hub (DASH), a centralized resource for researchers to store and access de-identified human subjects data from studies funded by NICHD. Should biospecimens be stored for any study, then the information about the location and availability of biospecimens will be registered with DASH as well.

In collaboration with the Statistical and Data Management Core (SDMC), data files can be made available securely in any universally acceptable format accessible for transmission to study stakeholders. The SDMC has several types of data transfer packages that are made available depending on data ownership and its intended use, including transfers to DASH; transfers to collaborators containing a portion or subset of data; and transfers to external entities to support further analyses, review or publication.

Findings resulting from each of the ATN Research Projects will be disseminated in a variety of ways, as outlined in our Dissemination Plan and highlighted below.

1. **Formal academic dissemination in the form of journal articles and abstracts:** We will work diligently to process and analyze data obtained from ATN projects to aid in disseminating the results rapidly to the scientific community, including through open access channels whenever possible. We will make publications available to the NIH for online distribution via the NIH manuscript submission system (http://www.nihms.nih.gov). We will ensure that no study participants are individually identified 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**: Site Consortiums via the Operations and Collaborations Center (OCC), as well the ATN Communication and Dissemination Hub and Diversity Equity and Inclusion Research Consultants (DEI RC), 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). Bi-directional information exchange between the research team, site 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 can make them available for additional/secondary data analyses. For data sharing, the research 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. 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**. We will work closely with the NIH and our Scientific Program Officer to disseminate and incorporate required/requested measures and to provide data and results as requested. We will regularly and expeditiously share and request feedback 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:** The ATN Scientific Leadership Center (SLC) PIs, Scientific Leadership Group (SLG) team members, and Research Project 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. We will an acknowledgement and disclaimer on all presentations produced under this NIH support.

6. **Local and regional presentations:** We will continue to provide presentations on research study results to the Site Consortiums that are located throughout the United States. Throughout the project, dissemination will occur though through discussions and presentations at adult and pediatric medical clinics, community-based organizations, and annual conference presentations to both behavioral and medical audiences.

7. **Project website:** The SLC's Communication and Dissemination Hub, in collaboration with the OCC, will design a website that includes information about all ATN studies designed for potential participants and the public at large. We will also utilize social media platforms (e.g., Facebook, Instagram, Twitter) to communicate information about the project and its findings.

Work Involving Human or Vertebrate Animals (Select Applicable Options)

☐ No Human or Vertebrate Animals

☒ Human Subjects

IRB Not required for the following reason:

There is an sIRB designated

☐ Vertebrate Animals

The PTE requires verification of IRB and/or IACUC approval be sent to the *Administrative Contact* *as required above:*

Subrecipient agrees that any non-exempt human and/or vertebrate animal research protocol conducted under this Subaward shall be reviewed and approved by the appropriate Institutional Review Board (IRB) and/or its Institutional Animal Care and Use Committee (IACUC), as applicable and that it will maintain current and duly approved research protocols for all periods of the Subaward involving human and/or vertebrate animal research. Subrecipient certifies that the appropriate IRB and/or IACUC are in full compliance with applicable state and federal laws and regulations. The Subrecipient certifies that any submitted IRB / IACUC approval represents a valid, approved protocol that is entirely consistent with the Project associated with this Subaward. In no event shall Subrecipient invoice or be reimbursed for any human or vertebrate animals related expenses incurred in a period where any applicable IRB / IACUC approval is not properly in place.

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: Yes ?

The work being conducted by this subrecipient per this agreement is a clinical trial.

Multiple PIs (MPI)

This subaward is subject to an MPI Leadership Plan. Both parties will follow the finalized MPI Leadership Plan. ?

The MPI plan is attached as part of Attachment 6.

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

Attachment 3A

Research Subaward Agreement

Pass-Through Entity (PTE) Contacts

Subaward Number: R000003157

PTE Information

Entity Name: Florida State University

Legal Address:
Sponsored Research Administration
874 Traditions Way, 3rd Floor
Tallahassee, FL 32306-4166

Website: https://www.research.fsu.edu/research-offices/sra/

PTE Contacts

Central Email: subcontracts@fsu.edu

Principal Investigator Name: Lisa Hightow-Weidman

Email: lbh22c@fsu.edu Telephone Number: 850-644-5260

Administrative Contact Name: Aras Aziz

Email: asaziz@fsu.edu Telephone Number: 850-644-8654

COI Contact email (if different to above): Diana Key, Director of Research Compliance, dkey@fsu.edu

Financial Contact Name: Angelle Gomez, Sponsored Research Accounting Manager II

Email: agomez@fsu.edu Telephone Number: 850-644-8653

Email invoices? (●) Yes ( ) No Invoice email (if different): SRASsubcontracts@fsu.edu

Authorized Official Name: Stacey Patterson, Vice President for Research

Email: subcontracts@fsu.edu Telephone Number: 850-644-5260

PI Address:

Center for Translational Behavorial Science
2010 Levy Ave Building B
Suite B0266
Tallahassee, FL 32310

Administrative Address:

Sponsored Research Administration
874 Traditions Way, 3rd Floor
Tallahassee, FL 32306-4166

Invoice Address:

Sponsored Research Administration
874 Traditions Way, 3rd Floor
Tallahassee, FL 32306-4166

Attachment 3B

Research Subaward Agreement

Subrecipient Contacts

Subaward Number: R000003157

Subrecipient Information for FFATA reporting

Entity's UEI/DUNS Name: San Francisco Department of Health

EIN No.: 94-6000417 Institution Type: County Government

UEI / DUNS: DCTNHRGU1K75 Currently registered in SAM.gov: (•) Yes ( ) No

Parent UEI / DUNS: Exempt from reporting executive compensation: Yes (•) No ( )
(if no, complete 3B pg2)

Place of Performance Information for FFATA reporting
Physical Address, City, State (if U.S.) and Country:

25 Van Ness, Suite 500
San Francisco, CA 94102

U.S. Entities only (insert information for Place of Performance):
Congressional District: CA-12 Zip Code+4: 94102-4505

Zip Code Look-up

Subrecipient Contacts

Central Email:

Website:

Principal Investigator Name: Susan Buchbinder

Email: susan.buchbinder@sfdph.org Telephone Number: 415-437-7479

Administrative Contact Name: Eduardo Sida

Email: eduardo.sida@sfdph.org Telephone Number: 628-217-6322

Financial Contact Name: Sajid Shaikh

Email: sajid.shaikh@sfdph.org Telephone Number: 415-255-3512

Invoice Email: sajid.shaikh@sfdph.org

Authorized Official Name: Greg Wagner

Email: greg.wagner@sfdph.org Telephone Number: 415-554-2900

Legal Address:

101 Grove Street
San Francisco, CA 94103

Administrative Address:

1380 Howard Street, 4th Floor
San Francisco, CA 94103

Payment Address:

1380 Howard Street, 4th Floor
San Francisco, CA 94103

Attachment 3B-2

Highest Compensated Officers

Subaward Number: R000003157

Subrecipient:

Institution Name: San Francisco Department of Health

PI Name: Susan Buchbinder

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: R000003157

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 Principal Investigator 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 Principal Investigator.

☒ Annual technical / progress reports will be submitted within 60 days prior to the end of each budget period to the PTE's Principal Investigator. 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 Principal Investigator 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: Federal Awarding Agency

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 Principal Investigator 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 Principal Investigator 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: Yes

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

Additional Technical and Reporting Requirements:

Subaward Number: R000003157

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

Statement of Work

○ Below ◉ Attached, 1 pages

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

See Attachment 5A (1 page)

Budget Information

Indirect Information Indirect Cost Rate (IDC) Applied 25 %

Rate Type: Modified Total Direct Costs

Cost Sharing No

If Yes, include Amount: $

Budget Details

◉ Below ○ Attached, pages

Susan Buchbinder, MD - 0.6 calendar months
$10,185.50 Salary, $3,666 Fringe

Albert Liu, MD - 0.6 calendar months
$10,185.50 Salary, $3,666 Fringe

Indirect: $6,926

Total: $34,629 per year

See Budget Justification below, Attachment 5B (2 pages)

Budget Totals

Direct Costs	$ 27,703.00
Indirect Costs	$ 6,926.00
Total Costs	$ 34,629.00

All amounts are in United States Dollars

ATN Scientific Leadership Group
Scope of Work – Team Member

Project Description Summary

The ATN Scientific Leadership Group (SLG) will provide the necessary multidisciplinary expertise to set, prioritize and manage the ATN scientific agenda. The ATN SLG will develop and refine the research agenda of the ATN, convene working groups as needed, prioritize emerging research projects, efficiently manage the development of clinical protocols, implement and complete clinical trials and ensure timely publication and communication of results. The ATN SLG will work in collaboration with the ATN Scientific Leadership Center (SLC) PIs, the Statistical and Data Management Center, the Operations and Collaboration Center, and NIH and industry partners.

Funding for subsequent periods of performance is contingent upon satisfactory performance and additional funding from NICHD.

Role of the ASLG Teams

The ATN SLG Teams form the scientific nucleus of ATN. Each scientific Team is responsible for:

- Developing a content-specific research strategy to contribute to the overall ATN research agenda;
- Continually reassessing research priorities in light of new ideas and research opportunities;
- Overseeing the formulation and review of concept plans based on the priorities in the research plan; and
- Monitoring the status of protocol development and implementation and reporting to the SLC leadership.

Key Deliverables

As a Team Member, Dr. Buchbinder, in close consultation with the Team Leads, will:

- 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;
- participate in other ad hoc leadership meetings, as needed

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

PERSONNEL

Total Personnel: $514,991 years 1 through 7

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 to the project each year 2 through 5 and and 0.6 Cal Mos in years 1, 6, and .36 FTE in Yr 7. Total Salary: $257,496 requested at $13,852 year 1, $13,843 in year 6 and $8,306 Year 7 and $55,373 year 2 through 5.

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 through 5 and 0.6 Ca. Mos in years 1, 6, and .36 FTE in year 7. Total Salary: $146,748 requested at $13,852 year 1, $13,843 in year 6 and $8,306 in year 7 and $27,687 year 2 through 5.**

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 through 5. Total Salary: $110,747 requested at $27,687 each year 2 through 5.**

Total Direct Costs: $514,990: $27,703 year 1, $27,687 in year 6, and $16,612 in year 7 and $110,747 year 2 through 5.

Indirect Costs: Total $128,748: $6,926 year 1, $6,922 year 6 and $4,153 year 7 and $27,687 year 2 through 5.

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: $643,739: Combined direct and indirect costs **$34,629 year 1, $34,609 year 6 and $20,765 year 7 and $138,434 year 2 through 5.**

Subaward Number:
R000003157

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.

LEADERSHIP PLAN FOR MULTIPLE PRINCIPAL INVESTIGATORS

This application's PIs, Drs. Sybil Hosek and Lisa Hightow-Weidman will provide oversight of the entire project, along with development and implementation of all policies, procedures and processes. Dr. Hosek is a licensed clinical psychologist and Director of Research in the Department of Psychiatry at Stroger Hospital of Cook County and an Associate Professor in the Division of Infectious Diseases at Rush University Chicago; Lisa Hightow-Weidman is Distinguished and Endowed McKenzie Professor at the College of Nursing at Florida State University and current PI of the iTech U19 within the Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN). These PIs have worked together for many years in various capacities: as part of the leadership of the ATN, as Co-Investigators on multiple grants, administratively on research and clinical policy pertaining to HIV prevention among adolescents and young adults through NIH-sponsored workshops, HANC working groups, and the HIV Prevention Trials Network (HPTN). Both PIs are in a position to provide ongoing support as contact PI in the event that is needed.

As contact PI, Dr. Hightow-Weidman, supported by her departmental infrastructure within the College of Nursing, will assume fiscal and administrative management, including official communications with NIH in terms of administrative details such as assuring annual progress reports and associated fiscal invoicing/reports are submitted on time as well as ensuring regulatory compliance. Dr. Hightow-Weidman, along with Dr. Hosek, will ensure systems are in place to guarantee institutional compliance with US laws, DHHS and NIH policies including biosafety, human research, data, and facilities.

Research implementation: Both PIs will be responsible for the timely implementation of the research plans, coordination of interactions with academic and Public Health partners; supervision of the clinical research team; data management and analysis; ethics, and youth community engagement. Both PIs will also work collaboratively with the Operations and Collaborations Center (OCC), NIH and other network entitities. While both PIs will participate in the oversight of the Network and implementation of the ATN scientific agenda, each PI has complementary scientific strengths (e.g., Dr. Hosek –biomedical HIV prevention studies for youth, behavioral science interventions for adolescent sexual and reproductive health; Dr. Hightow-Weidman – clinical oversight combination prevention interventions, the use of digital technologies (mHealth) for implementation, intervention and evaluation of HIV studies among youth), which will guide which aims/procedures are primarily overseen by which PI. However, both PIs will provide oversight as well as jointly decide upon strategic directions with new findings or budgetary decisions and are ultimately and equally responsible for scientific integrity.

'Contact PI' role and plans: The feasibility of cross-coverage potential of 'contact PI' role is essential and assured by (1) the close communication and working relationships of the two PIs, (2) their long history of collaborations, (3) their shared dedication to the ATN and passion to end the HIV epidemic among youth.

Communication responsibilities: Both PIs will be responsible for maintaining communication amongst themselves, the SLG, and all other components of the ATN. This will include standing weekly meetings for Drs. Hosek and Hightow-Weidman. Drs. Hosek and Hightow-Weidman are generally in constant communication by email, and text messages, making communication nearly instantaneous and seamless. Teleconferencing (e.g. Zoom) and other web-based secure interfacing (e.g. OneDrive) of data, forms, protocols, and progress notes/minutes will be used to maximize communication between all groups.

Process for Making Decisions on Scientific Direction: The PIs will discuss all programmatic, scientific, financial and logistical aspects of the proposed work, and make final decisions in agreement with NICHD program representation. Due to our long-term productive collaborations, we anticipate that decision by consensus can be achieved for essentially all issues.

Process for Resolving Conflicts: Both PIs participated in the preparation of the proposal, and the proposed scientific and management plans contain no conflicts, nor are conflicts expected in the future. Conflicts will be openly discussed, and the PIs are optimistic that this will allow for resolution of the issue. Differences that arise between the the PIs will be presented to the appropriate NICHD Program representatives for assistance with resolution.

Publications: Authorship will be based on the relative scientific contributions of the PIs and key personnel. Both PIs will follow a publication policy which clearly fulfills the NIH requirements for manuscript development to (1) ensure accurate reporting of scientific data arising from studies conducted under this application, (2) facilitate timely review and publication of data, and (3) protect participant confidentiality.

Manuscript review process: All grant-related publications (conference abstracts and papers) will be reviewed first by the PIs and then circulated to all other authors, including those within the SDMC. It is anticipated that abstracts would be reviewed within 72 hours and manuscripts within 2 weeks of receipt.

NIH Public Access Policy: The PIs will ensure that, in accordance with the requirements of Division G, Title II of Section 218 of PL 110-161, known as the Consolidated Appropriations Act of 2008, all peer-reviewed articles that arise from work funded in part or in whole by the direct cost portion of grants or contracts awarded by the National Institutes of Health (NIH) must be made publicly available no later than 12 months after the official date of publication.

Both PIs will be responsible for ensuring compliance with the Policy even if they are not an author or co-author of a publication arising from the NIH-funded work. The 'contact PI' (Dr. Hightow-Weidman) will take primary responsibility to ensure compliance with this policy; Drs. Hightow-Weidman and Hosek will review these topics and planned publications during their weekly meetings. They will undertake the three key elements of this policy:

- Address copyright when submitting a manuscript to a journal for review
- Submit the accepted manuscript to the NIH
- Cite the manuscript using the PubMed Central reference number

Acknowledgements: NIH funding will be acknowledged in all publications with a statement such as: "This publication was made possible by Grant Number XXXXX" or as otherwise guided.

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
01/24/2023

Recipient Information

1. Recipient Name
FLORIDA STATE UNIVERSITY
874 TRADITIONS WAY

TALLAHASSEE, 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
919-966-6714

8. Authorized Official
Lizzy McCawley

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
Deputy Branch Chief, Pama Branch
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
drusso1@mail.nih.gov
301-435-6871

Federal Award Information

11. Award Number
1UM2HD111102-01

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
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 01/25/2023 **– End Date** 11/30/2023	
20. Total Amount of Federal Funds Obligated by this Action	$11,162,061
20 a. Direct Cost Amount	$8,786,078
20 b. Indirect Cost Amount	$2,375,983
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$11,162,061
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$11,162,061
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	$11,162,061

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

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 – 1UM2HD111102-01

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 $11,162,061 (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	$737,725
Fringe Benefits	$228,890
Personnel Costs (Subtotal)	$966,615
Consultant Services	$69,250
Materials & Supplies	$54,107
Travel	$91,425
Other	$2,207,006
Subawards/Consortium/Contractual Costs	$5,397,675
Federal Direct Costs	$8,786,078
Federal F&A Costs	$2,375,983
Approved Budget	$11,162,061
Total Amount of Federal Funds Authorized (Federal Share)	$11,162,061
TOTAL FEDERAL AWARD AMOUNT	$11,162,061
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$11,162,061

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$11,162,061	$11,162,061
2	$10,463,649	$10,463,649
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: 2023

IC	CAN	2023	2024	2025	2026	2027	2028	2029
HD	8014710	$11,162,061	$10,463,649	$10,333,316	$10,283,125	$10,173,415	$10,161,519	$10,113,635

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**: 41026 / **Released**: Pailen, Teri 01/18/2023
Award Processed: 01/24/2023 12:08:43 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1UM2HD111102-01

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1UM2HD111102-01

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

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

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

This 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.

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 – 1UM2HD111102-01

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

RESTRICTION: This award is 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.

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This award includes funds for twelve months of support but is awarded for less than twelve months. Noncompeting Continuation awards will cycle on **December 01, 2023**. NICHD is taking this action to redistribute start dates more evenly throughout the fiscal year.

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Due to the impact of the Coronavirus disease 2019 (COVID-19) outbreak, NICHD will consider providing greater flexibilities to recipients in meeting administrative, financial management and audit requirements. Please contact the Grants Management Specialist and Program Official indicated on this Notice of Award for more information.

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In accordance with the NICHD FY2023 fiscal policy, escalation on recurring costs has been removed. See NICHD Funding Strategies for Fiscal Year 2023.

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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.

****

Beginning January 2021, 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.

Beginning January 2021, 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".

****

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".

SPREADSHEET SUMMARY
AWARD NUMBER: 1UM2HD111102-01

INSTITUTION: FLORIDA STATE UNIVERSITY

Budget	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Salaries and Wages	$737,725	$770,540	$751,040	$767,707	$754,951	$1,013,454	$974,867
Fringe Benefits	$228,890	$240,084	$234,159	$239,223	$236,572	$314,932	$301,943
Personnel Costs (Subtotal)	$966,615	$1,010,624	$985,199	$1,006,930	$991,523	$1,328,386	$1,276,810
Consultant Services	$69,250	$69,250	$69,250	$69,250	$69,250	$69,250	$69,250
Materials & Supplies	$54,107	$50,465	$44,168	$53,132	$39,191	$126,235	$161,476
Travel	$91,425	$53,000	$56,400	$56,400	$56,400	$101,400	$113,500
Other	$2,207,006	$1,940,667	$1,962,702	$1,968,576	$2,003,078	$2,292,163	$2,954,614
Subawards/Consortium/Contractual Costs	$5,397,675	$5,428,905	$5,472,329	$5,379,321	$5,261,674	$4,059,371	$3,067,134
ADP/Computer Services		$88,000	$30,000	$30,000	$30,000	$45,000	
TOTAL FEDERAL DC	$8,786,078	$8,640,911	$8,620,048	$8,563,609	$8,451,116	$8,021,805	$7,642,784

TOTAL FEDERAL F&A	$2,375,983	$1,822,738	$1,713,268	$1,719,516	$1,722,299	$2,139,714	$2,470,851
TOTAL COST	$11,162,061	$10,463,649	$10,333,316	$10,283,125	$10,173,415	$10,161,519	$10,113,635

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
F&A Cost Rate 1	54%	54%	54%	54%	54%	54%	54%
F&A Cost Base 1	$4,399,969	$3,375,440	$3,172,719	$3,184,288	$3,189,442	$3,962,434	$4,575,650
F&A Costs 1	$2,375,983	$1,822,738	$1,713,268	$1,719,516	$1,722,299	$2,139,714	$2,470,851