

FDP Subaward Amendment

Awarding Agency

Amendment No

PTE/Prime Award No.

Subaward No

Pass-Through Entity (PTE)

Subrecipient

Entity Name

Contact Email

Principal Investigator

Project Title

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:

End Date:

Subrecipient Cost Share

Subject to FFATA

Subrecipient UEI

(Unique Entity Identifier - May leave blank if unchanged from prior Agreement)

Amendment(s) to Original Terms and Conditions

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

Carryover is

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:

Date

By an Authorized Official of Subrecipient:

Date

Name

Title

Name

Title

RESEARCH & RELATED BUDGET - Budget Period 1

OMB Number: 4040-0001
Expiration Date: 11/30/2025

UEI:

Enter name of Organization:

Budget Type: Project Subaward/Consortium

Budget Period: 1 Start Date: End Date:

A. Senior/Key Person

Prefix	First	Middle	Last	Suffix	Base Salary (\$)	Months			Requested Salary (\$)	Fringe Benefits (\$)	Funds Requested (\$)
						Cal.	Acad.	Sum.			
	Susan		Buchbinder		225,700.00	2.40			45,140.00	16,251.00	61,391.00
Project Role: <input type="text" value="PD/PI"/>											
	Albert		Liu		225,700.00	1.80			33,855.00	12,188.00	46,043.00
Project Role: <input type="text" value="Co-PI"/>											
	Hyman		Scott		225,700.00	1.20			22,570.00	8,126.00	30,696.00
Project Role: <input type="text" value="Co-PI"/>											

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

Total Senior/Key Person

B. Other Personnel

Number of Personnel	Project Role	Months			Requested Salary (\$)	Fringe Benefits (\$)	Funds Requested (\$)
		Cal.	Acad.	Sum.			
<input type="text"/>	Post Doctoral Associates	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	Graduate Students	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	Undergraduate Students	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	Secretarial/Clerical	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	Total Number Other Personnel						<input type="text"/>
							Total Other Personnel <input type="text"/>
							Total Salary, Wages and Fringe Benefits (A+B) <input type="text" value="138,130.00"/>

C. Equipment Description

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

Equipment item	Funds Requested (\$)
<input type="text"/>	<input type="text"/>

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**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. <input type="text"/>	
9. <input type="text"/>	
10. <input type="text"/>	
11. <input type="text"/>	
12. <input type="text"/>	
13. <input type="text"/>	
14. <input type="text"/>	
15. <input type="text"/>	
16. <input type="text"/>	
17. <input type="text"/>	
Total Other Direct Costs	

G. Direct Costs**Funds Requested (\$)****Total Direct Costs (A thru F)** **H. Indirect Costs**

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)
<input type="text" value="25% of Total Personnel Cost"/>	<input type="text" value="25.00"/>	<input type="text" value="138,130.00"/>	<input type="text" value="34,533.00"/>

Total Indirect Costs **Cognizant Federal Agency**

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs**Funds Requested (\$)****Total Direct and Indirect Institutional Costs (G + H)** **J. Fee****Funds Requested (\$)****K. Total Costs and Fee****Funds Requested (\$)****Total Costs and Fee (I + J)** **L. Budget Justification**

(Only attach one file.)

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

PERSONNEL

Personnel costs calculated using the current NIH salary cap of \$225,700 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 Prevention Trials Network and leads several multi-site HIV prevention efficacy trials, with a focus on advancing integrated prevention strategies in the US and globally. Most recently, she has focused on the use of mHealth technology to increase access to prevention and treatment services for those at risk for or living with HIV infection, and implementation of prevention strategies. As Principal Investigator (PI) of the ATN 166 protocol, 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, Dr. Buchbinder will serve on the Biomedical Therapeutics, Comorbidities, and Coinfections team, 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 semi-annual ATN meetings; and participate in other ad hoc leadership meetings, as needed. **Dr. Buchbinder will devote 2.40 Cal Mos to the project.**

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 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 was an investigator in the ATN iTech U19, serving as PI of two studies testing mobile apps to increase HIV testing and PrEP uptake among young men. 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 and the NIMH- sponsored EPIC study to develop the PrEPmate SMS intervention for youth. Dr. Liu will be responsible for overseeing technology development and optimization of the PrEP CHOICE package for the ATN 166 CHOOSE protocol, 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, Dr. Liu will co-lead the Biomedical Therapeutics, Comorbidities and Coinfections team, 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 semi-annual ATN meetings; and participate in other ad hoc leadership meetings, as needed. **Dr. Liu will devote 1.8 Cal Mos to the project.**

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 biomedical HIV and STI prevention and has worked closely with Drs. Liu and Buchbinder on the development of a risk assessment tool for men (Sex Pro) and the PrEP

decision support tool (MyPrEP). 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.**



<p>Recipient Information</p> <p>1. Recipient Name FLORIDA STATE UNIVERSITY 874 TRADITIONS WAY TALLAHASSEE, FL 32306</p> <p>2. Congressional District of Recipient 02</p> <p>3. Payment System Identifier (ID) 1596001138A1</p> <p>4. Employer Identification Number (EIN) 596001138</p> <p>5. Data Universal Numbering System (DUNS) 790877419</p> <p>6. Recipient's Unique Entity Identifier JF2BLNN4PJC3</p> <p>7. Project Director or Principal Investigator Lisa B Hightow-Weidman, MD (Contact) Professor lhightowweidman@fsu.edu 850-644-3296</p> <p>8. Authorized Official Stacey Patterson</p>	<p>Federal Award Information</p> <p>11. Award Number 5UM2HD111102-03</p> <p>12. Unique Federal Award Identification Number (FAIN) UM2HD111102</p> <p>13. Statutory Authority 42 USC 241 31 USC 6305 42 CFR Part 52</p> <p>14. Federal Award Project Title Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) Scientific Leadership Center</p> <p>15. Assistance Listing Number 93.865</p> <p>16. Assistance Listing Program Title Child Health and Human Development Extramural Research</p> <p>17. Award Action Type Non-Competing Continuation (REVISED)</p> <p>18. Is the Award R&D? Yes</p>
<p>Federal Agency Information</p> <p>9. Awarding Agency Contact Information Mahasin Ingram</p> <p>EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT ingrammk@mail.nih.gov (201) 780-0309</p> <p>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</p>	<p>19. Budget Period Start Date 12/01/2024 – End Date 01/14/2026</p> <p>20. Total Amount of Federal Funds Obligated by this Action \$0</p> <p>20 a. Direct Cost Amount \$0</p> <p>20 b. Indirect Cost Amount \$0</p> <p>21. Authorized Carryover</p> <p>22. Offset</p> <p>23. Total Amount of Federal Funds Obligated this budget period \$11,647,748</p> <p>24. Total Approved Cost Sharing or Matching, where applicable \$0</p> <p>25. Total Federal and Non-Federal Approved this Budget Period \$11,647,748</p> <hr/> <p>26. Project Period Start Date 01/25/2023 – End Date 01/14/2030</p> <p>27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period \$36,023,354</p> <p>28. Authorized Treatment of Program Income Additional Costs</p> <p>29. Grants Management Officer - Signature Melissa R Copeland</p>
<p>30. Remarks</p> <p>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.</p>	



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

Notice of Award



EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 5UM2HD111102-03 REVISED

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 revises this award (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,

Melissa R Copeland
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	\$829,730
Fringe Benefits	\$266,026
Personnel Costs (Subtotal)	\$1,095,756
Consultant Services	\$387,198
Materials & Supplies	\$44,168
Travel	\$56,400
Other	\$2,104,186
Subawards/Consortium/Contractual Costs	\$5,908,978
ADP/Computer Services	\$30,000
Federal Direct Costs	\$9,626,686
Federal F&A Costs	\$2,021,062
Approved Budget	\$11,647,748
Total Amount of Federal Funds Authorized (Federal Share)	\$11,647,748
TOTAL FEDERAL AWARD AMOUNT	\$11,647,748
AMOUNT OF THIS ACTION (FEDERAL SHARE)	\$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	THIS AWARD	CUMULATIVE TOTALS
3	\$11,647,748	\$11,647,748
4	\$11,427,023	\$11,427,023
5	\$11,335,727	\$11,335,727
6	\$11,044,477	\$11,044,477
7	\$11,003,588	\$11,003,588

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: 2025

IC	CAN	2025	2026	2027	2028	2029
HD	8014710	\$8,647,748	\$8,427,023	\$8,335,727	\$8,044,477	\$8,003,588
MH	8472592	\$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

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: 12/04/2025
 Award Processed: 12/05/2025 04:20:51 PM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5UM2HD111102-03 REVISED

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 – 5UM2HD111102-03 REVISED

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. 2 CFR Part 200.
- 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 2 CFR Part 200. 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.

Through acceptance of this award, recipient, and through implementation of this provision by recipient to each recipient investigator conducting work under this award, hereby grants to NIH a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use for federal purposes and to authorize others to do so, all Author Accepted Manuscripts that result from this award, which includes making Author Accepted Manuscripts publicly available in PubMed Central upon the Official Date of Publication, in accordance with the 2024 NIH Public Access Policy.

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.

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

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 2 CFR Part 200, 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 that is found in [SAM.gov](https://www.sam.gov). Full reporting requirements and procedures are found in 2 CFR Part 200. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV – HD SPECIFIC AWARD CONDITIONS – 5UM2HD111102-03 REVISED

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.

REVISION: This revised award extends the budget and project period end dates without additional funds. Noncompeting continuation awards will cycle on **January 15**.

The previous terms and conditions of award remain in effect as stated below.

REVISION: The sole purpose of this revision is an NICHD administrative action internal purposes. No action is required on the part of the recipient.

The previous terms and conditions of award remain in effect as stated below.

REVISION: The sole purpose of this revised Notice of Award is to adjust the awarded amount to align with the original budget.

The previous terms and conditions of award remain in effect as stated below.

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 modification via the revised aims submitted on April 15, 2025 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

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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:

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: 5UM2HD111102-03 REVISED

INSTITUTION: FLORIDA STATE UNIVERSITY

Budget	Year 3	Year 4	Year 5	Year 6	Year 7
Salaries and Wages	\$829,730	\$846,397	\$1,000,000	\$1,092,144	\$1,053,557
Fringe Benefits	\$266,026	\$271,090	\$31,867	\$346,799	\$333,810
Personnel Costs (Subtotal)	\$1,095,756	\$1,117,487	\$1,031,867	\$1,438,943	\$1,387,367
Consultant Services	\$387,198	\$265,211	\$232,918	\$199,569	\$184,475
Materials & Supplies	\$44,168	\$53,132	\$39,191	\$126,235	\$161,476
Travel	\$56,400	\$56,400	\$56,400	\$101,400	\$113,500
Other	\$2,104,186	\$2,106,560	\$2,595,986	\$2,355,147	\$3,017,598
Subawards/Consortium/Contractual Costs	\$5,908,978	\$5,838,686	\$5,459,365	\$4,474,384	\$3,512,387
ADP/Computer Services	\$30,000	\$30,000	\$30,000	\$45,000	
TOTAL FEDERAL DC	\$9,626,686	\$9,467,476	\$9,445,727	\$8,740,678	\$8,376,803
TOTAL FEDERAL F&A	\$2,021,062	\$1,959,547	\$1,890,000	\$2,303,799	\$2,626,785
TOTAL COST	\$11,647,748	\$11,427,023	\$11,335,727	\$11,044,477	\$11,003,588

Facilities and Administrative Costs	Year 3	Year 4	Year 5	Year 6	Year 7
F&A Cost Rate 1	54%	54%	54%	54%	54%
F&A Cost Base 1	\$3,742,708	\$3,628,790	\$3,500,000	\$4,266,294	\$4,864,416
F&A Costs 1	\$2,021,062	\$1,959,547	\$1,890,000	\$2,303,799	\$2,626,785



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 Award Information 11. Award Number 5UM2HD111102-04 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																										
	<table border="1"> <thead> <tr> <th colspan="2" style="text-align: center;">Summary Federal Award Financial Information</th> </tr> </thead> <tbody> <tr> <td colspan="2">19. Budget Period Start Date 01/15/2026 – End Date 01/14/2027</td> </tr> <tr> <td>20. Total Amount of Federal Funds Obligated by this Action</td> <td style="text-align: right;">\$11,427,023</td> </tr> <tr> <td> 20 a. Direct Cost Amount</td> <td style="text-align: right;">\$9,467,476</td> </tr> <tr> <td> 20 b. Indirect Cost Amount</td> <td style="text-align: right;">\$1,959,547</td> </tr> <tr> <td>21. Authorized Carryover</td> <td></td> </tr> <tr> <td>22. Offset</td> <td></td> </tr> <tr> <td>23. Total Amount of Federal Funds Obligated this budget period</td> <td style="text-align: right;">\$11,427,023</td> </tr> <tr> <td>24. Total Approved Cost Sharing or Matching, where applicable</td> <td style="text-align: right;">\$0</td> </tr> <tr> <td>25. Total Federal and Non-Federal Approved this Budget Period</td> <td style="text-align: right;">\$11,427,023</td> </tr> <tr> <td colspan="2"><hr/></td> </tr> <tr> <td colspan="2">26. Project Period Start Date 01/25/2023 – End Date 01/14/2030</td> </tr> <tr> <td>27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period</td> <td style="text-align: right;">\$47,450,377</td> </tr> </tbody> </table>	Summary Federal Award Financial Information		19. Budget Period Start Date 01/15/2026 – End Date 01/14/2027		20. Total Amount of Federal Funds Obligated by this Action	\$11,427,023	20 a. Direct Cost Amount	\$9,467,476	20 b. Indirect Cost Amount	\$1,959,547	21. Authorized Carryover		22. Offset		23. Total Amount of Federal Funds Obligated this budget period	\$11,427,023	24. Total Approved Cost Sharing or Matching, where applicable	\$0	25. Total Federal and Non-Federal Approved this Budget Period	\$11,427,023	<hr/>		26. Project Period Start Date 01/25/2023 – End Date 01/14/2030		27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	\$47,450,377
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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	28. Authorized Treatment of Program Income Additional Costs 29. Grants Management Officer - Signature Mahasin Ingram																										
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.																											



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

Notice of Award



EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 5UM2HD111102-04

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 \$11,427,023 (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,

Mahasin Ingram
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	\$846,397
Fringe Benefits	\$271,090
Personnel Costs (Subtotal)	\$1,117,487
Consultant Services	\$265,211
Materials & Supplies	\$53,132
Travel	\$56,400
Other	\$2,106,560
Subawards/Consortium/Contractual Costs	\$5,838,686
ADP/Computer Services	\$30,000
Federal Direct Costs	\$9,467,476
Federal F&A Costs	\$1,959,547
Approved Budget	\$11,427,023
Total Amount of Federal Funds Authorized (Federal Share)	\$11,427,023
TOTAL FEDERAL AWARD AMOUNT	\$11,427,023
AMOUNT OF THIS ACTION (FEDERAL SHARE)	\$11,427,023

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	THIS AWARD	CUMULATIVE TOTALS
4	\$11,427,023	\$11,427,023
5	\$11,335,727	\$11,335,727
6	\$11,044,477	\$11,044,477
7	\$11,003,588	\$11,003,588

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: 2026

IC	CAN	2026	2027	2028	2029
HD	8014710	\$8,427,023	\$8,335,727	\$8,044,477	\$8,003,588
MH	8472592	\$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

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: 01/12/2026
 Award Processed: 01/16/2026 03:03:50 PM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5UM2HD111102-04

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 – 5UM2HD111102-04

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. 2 CFR Part 200.
- 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 2 CFR Part 200. 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.

Through acceptance of this award, recipient, and through implementation of this provision by recipient to each recipient investigator conducting work under this award, hereby grants to NIH a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use for federal purposes and to authorize others to do so, all Author Accepted Manuscripts that result from this award, which includes making Author Accepted Manuscripts publicly available in PubMed Central upon the Official Date of Publication, in accordance with the 2024 NIH Public Access Policy.

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.

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

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 2 CFR Part 200, 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 that is found in [SAM.gov](https://www.sam.gov). Full reporting requirements and procedures are found in 2 CFR Part 200. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

Termination. This award is subject to the termination provisions at 2 CFR 200.340. Pursuant to 2 CFR 200.340, the recipient agrees by accepting this award that continued funding for the award is contingent upon the availability of appropriated funds, recipient satisfactory performance, compliance with the Terms and Conditions of the award, and may also otherwise be terminated, to the extent authorized by law, if the agency determines that the award no longer effectuates program goals or agency priorities in line with 2 CFR 200.340(a)(4).

SECTION IV – HD SPECIFIC AWARD CONDITIONS – 5UM2HD111102-04

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.

REBUDGETING OF FOREIGN SUBAWARD ACTIVITIES TO THE PARENT: NIH and Florida State University have renegotiated the subaward research activities performance site from University of Cape Town and WITS Health Consortium (PTY), LTD to Florida State University. Funds previously allocated to University of Cape Town and WITS Health Consortium (PTY), LTD may be rebudgeted to support these activities at Florida State University. NIH funds may not be used to support foreign subaward activities. Any funds used to support foreign subawards will result in a disallowance of costs, and funds will be recovered.

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.

NON-SNAP: NICHD has determined that the submitted Research Performance Progress Report is within the approved scope of work.

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 modification via the revised aims submitted on April 15, 2025 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](https://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](https://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.

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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:

Clinical Trial Study/Studies:

416815

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AWARD NUMBER: 5UM2HD111102-04

INSTITUTION: FLORIDA STATE UNIVERSITY

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Facilities and Administrative Costs	Year 4	Year 5	Year 6	Year 7
F&A Cost Rate 1	54%	54%	54%	54%
F&A Cost Base 1	\$3,628,790	\$3,500,000	\$4,266,294	\$4,864,416
F&A Costs 1	\$1,959,547	\$1,890,000	\$2,303,799	\$2,626,785