FDP Subaward Amendment

Awarding Agency: National Institutes of Health (NIH)
Amendment No: 3
PTE/Prime Award No.: 5UM2HD111102-03
Subaward No: R000003157

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

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

Cumulative Budget Period(s) (Agreement Start Date) Start Date: 01/25/2023 (End Date of Latest Budget Period) End Date: 11/30/2025	Amount Funded This Action	Total Amount of Funds Obligated to Date
	-$ 62,295.00	$ 235,358.00

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

Amendment(s) to Original Terms and Conditions

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

■ **Additional Budget Period**

Additional budget period 05/21/2025 - 11/30/2025 is hereby added to this Subaward.

☐ **No Cost Extension**

☐ **Additional Funding**

■ **Deobligation**

This Subaward funding is decreased in the amount of $ 62,295.00 from period 12/01/2024 - 03/21/2025

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

☐ **Carryover Authorized**

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

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

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

■ **Other (See Below)**

1. The FSU project number for this increment is 103382. Invoices that do not reference both the subaward number and the project number may be subject to delay.

2. Amendment 2 of this subaward provided additional funding in the amount of $124,590. This subaward is reduced overall by $62,295 due to prime sponsor re-budgeting and pauses in project effort. A budget for $62,295 or the budget period listed above is included below and hereby added to Attachment 5.

3. The parties acknowledge and agree that any provisions of this Agreement subject to the Preliminary Injunction issued in King County et al. v. Turner et al., No. 2:25-cv-00814-BJR (W.D. Wash.), dated August 12, 2025, shall not be enforceable or binding for the duration of such injunction. Upon the lifting, expiration, or dissolution of the Preliminary Injunction in whole or in part, either party may terminate this Agreement by providing fifteen (15) days' written notice to the other party, if such party reasonably determines that it is unable to comply with any reinstated terms and conditions of this Agreement. No invoices for work performed during any period in which the King County injunction is suspended or no longer binding shall be processed, unless expressly authorized in writing by both parties.

4. Notice of Award 5UM2HD111102-03 is hereby added to Attachment 6.

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

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

By an Authorized Official of PTE:		By an Authorized Official of Subrecipient:	
Rose Driber for Stacey Patterson, VPR (Digitally signed by Rose Driber for Stacey Patterson, VPR Date: 2025.09.30 13:35:49 -04'00')	Date	Signed by: Susan Philip	Date 09/26/2025 | 4:26 PM PDT
Name: Stacey Patterson		Name: Daniel Tsai	
Title: Vice President for Research		Title: Director of Health	

Approved as to form, David Chiu, City Attorney

By: Signed by: Bess Ibtisam Hanish D0523AF4F16D451...

RESEARCH & RELATED BUDGET - Budget Period 1

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

UEI: DCTNHRGU1K75 **Enter name of Organization:** City & County of San Francisco - SFDPH

Budget Type: ☐ Project ☒ Subaward/Consortium **Budget Period: 1** **Start Date:** 05/21/2025 **End Date:** 11/30/2025

A. Senior/Key Person

Prefix	First	Middle	Last	Suffix	Base Salary ($)	Months Cal.	Months Acad.	Months Sum.	Requested Salary ($)	Fringe Benefits ($)	Funds Requested ($)
	Susan		Buchbinder		225,700.00	2.30			21,630.00	5,767.00	27,397.00
Project Role:	CO-I										
	Albert		Liu		225,700.00	1.00			9,405.00	2,507.00	11,912.00
Project Role:	Co-PI										
	Hyman		Scott		225,700.00	1.00			9,405.00	2,507.00	11,912.00
Project Role:	Co-PI										

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

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

Total Senior/Key Person: 51,221.00

B. Other Personnel

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

Total Number Other Personnel

Total Other Personnel

Total Salary, Wages and Fringe Benefits (A+B): 51,221.00

C. Equipment Description

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

Equipment item	Funds Requested ($)

Additional Equipment: Add Attachment | Delete Attachment | View Attachment

Total funds requested for all equipment listed in the attached file

Total Equipment

D. Travel

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

E. Participant/Trainee Support Costs

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

F. Other Direct Costs

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

G. Direct Costs

	Funds Requested ($)
Total Direct Costs (A thru F)	51,221.00

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)
21.62% of total personnel cost	21.62	51,223.00	11,074.00

Total Indirect Costs	11,074.00

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)	62,295.00

J. Fee

	Funds Requested ($)

K. Total Costs and Fee

	Funds Requested ($)
Total Costs and Fee (I + J)	62,295.00

L. Budget Justification

(Only attach one file.) Add Attachment | Delete Attachment | View Attachment

Recipient Information

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

2. Congressional District of Recipient
02

3. Payment System Identifier (ID)
1596001138A1

4. Employer Identification Number (EIN)
596001138

5. Data Universal Numbering System (DUNS)
790877419

6. Recipient's Unique Entity Identifier
JF2BLNN4PJC3

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

8. Authorized Official
Stacey Patterson

Federal Agency Information

9. Awarding Agency Contact Information
Mahasin Ingram

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

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

Federal Award Information

11. Award Number
5UM2HD111102-03

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 (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 12/01/2024 **– End Date** 11/30/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	$0
22. Offset	$0
23. Total Amount of Federal Funds Obligated this budget period	$11,647,748
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$11,647,748
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	$36,023,354

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Margaret A. Young

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

SECTION I – AWARD DATA – 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,

Margaret A. Young
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	$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:	2025

IC	CAN	2025	2026	2027	2028	2029
HD	8014710	$8,647,748	$7,283,125	$7,173,415	$7,161,519	$7,113,635
MH	8472592	$1,000,000	$1,000,000	$1,000,000	$1,000,000	$1,000,000
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**: 05/08/2025
Award Processed: 05/15/2025 12:54:54 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. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.

e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

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

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

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

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

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

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

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

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

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

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

A description of plans to conduct analyses, as appropriate, by sex/gender and racial/ethnic groups must be included in clinical trial protocols. Cumulative subject accrual and progress in conducting subset analyses must be reported to NIH in the annual Progress Reports. Final analyses of sex/gender and racial/ethnic differences must be reported in the required Final Progress Report or Competitive Renewal Applications (or Contract Renewals/Extensions) as stated in Section II.B. of the Guidelines.
This award is funded by the following list of institutes. Any papers published under the auspices of this award must cite the funding support of all institutes.

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

Recipient is compliant with Title IX of the Education Amendments of 1972, as amended, 20 U.S.C. §§ 1681 et seq., including the requirements set forth in Presidential Executive Order 14168 titled Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government, and Title VI of the Civil Rights Act of 1964, 42 U.S.C. §§ 2000d et seq., and Recipient will remain compliant for the duration of the Agreement.

- The above requirements are conditions of payment that go the essence of the Agreement and are therefore material terms of the Agreement.
- Payments under the Agreement are predicated on compliance with the above requirements, and therefore Recipient is not eligible for funding under the Agreement or to retain any funding under the Agreement absent compliance with the above requirements.
- Recipient acknowledges that this certification reflects a change in the government's position regarding the materiality of the foregoing requirements and therefore any prior payment of similar claims does not reflect the materiality of the foregoing requirements to this Agreement.
- Recipient acknowledges that a knowing false statement relating to Recipient's compliance with the above requirements and/or eligibility for the Agreement may subject Recipient to liability under the False Claims Act, 31 U.S.C. § 3729, and/or criminal liability, including under 18 U.S.C. §§ 287 and 1001.

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.

REVISED AWARD:

Effective with the date of this revised Notice of Award, funding for Project Number 5 UM2 HD0111102-03 the termination letter dated March 31, 2025 is rescinded with conditions. Funds made available to Florida State University used to support "Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) Scientific Leadership Center" are no longer restricted and are available for use in accordance with the revised terms and conditions of the award below:

NIH and the recipient have renegotiated the scope of this award. Pursuant to the revised scope, NIH funds may only be used to support activities within the revised scope of the award. NIH funds may not be used to support activities that are outside the revised scope of the award, including diversity, equity and inclusion (DEI) research programs, research or related research training activities or programs. Any funds used to support activities outside the scope will result in a disallowance of costs, and funds will be recovered.

This term is consistent with NIH's ongoing internal review of NIH's priorities and the alignment of awards with those priorities as well as a review of program integrity of awards. Such review includes, but is not limited to, a review for fraud, waste and abuse, and a review of the NIH portfolio to determine whether awards are in the best interests of the government and consistent with policy priorities. If recipients are unclear on whether a specific activity constitutes diversity, equity and inclusion (DEI) research programs, or has questions regarding other activities that could be considered outside the scope of the award, refrain from drawing down funds and consult with the funding IC, particularly where the activity may impact the specific aims, goals, and objectives of the project.

The previous terms and conditions below have revised due to the renegotiated scope of work.

****

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

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

Clinical Trial Study/Studies:

416813

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

Clinical Trial Study/Studies:

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	$767,707	$754,951	$1,013,454	$974,867
Fringe Benefits	$266,026	$239,223	$236,572	$314,932	$301,943
Personnel Costs (Subtotal)	$1,095,756	$1,006,930	$991,523	$1,328,386	$1,276,810
Consultant Services	$387,198	$69,250	$69,250	$69,250	$69,250
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	$1,968,576	$2,003,078	$2,292,163	$2,954,614
Subawards/Consortium/Contractual Costs	$5,908,978	$5,379,321	$5,261,674	$4,059,371	$3,067,134
ADP/Computer Services	$30,000	$30,000	$30,000	$45,000	
TOTAL FEDERAL DC	$9,626,686	$8,563,609	$8,451,116	$8,021,805	$7,642,784
TOTAL FEDERAL F&A	$2,021,062	$1,719,516	$1,722,299	$2,139,714	$2,470,851
TOTAL COST	$11,647,748	$10,283,125	$10,173,415	$10,161,519	$10,113,635

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	$3,184,288	$3,189,442	$3,962,434	$4,575,650
F&A Costs 1	$2,021,062	$1,719,516	$1,722,299	$2,139,714	$2,470,851