File No. 251153 **Committee Item No.** 12
Board Item No. 20

COMMITTEE/BOARD OF SUPERVISORS

AGENDA PACKET CONTENTS LIST

Committee: Budget and Finance Committee **Date** December 10, 2025
Board of Supervisors Meeting **Date** December 16, 2025

Cmte Board

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OTHER **(Use back side if additional space is needed)**

☒	☒	Amendment No. 1 4/15/2024
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☐	☐	

Completed by: Brent Jalipa **Date** December 4, 2025
Completed by: Brent Jalipa **Date** December 11, 2025

FILE NO. 251153 RESOLUTION NO.

[Accept and Expend Grant - Retroactive - National Institutes of Health - Florida State University - Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) Scientific Leadership Center - $235,358]

Resolution retroactively authorizing the Department of Public Health to accept and expend a grant from the National Institutes of Health through Florida State University for participation in a program, entitled "Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) Scientific Leadership Center," for an increased amount of $62,295 for a total amount of $235,358 effective on May 21, 2025, for the total period of January 25, 2023, through November 30, 2025.

WHEREAS, The National Institutes of Health (NIH), through Florida State University (FSU) as a pass-through entity, has agreed to fund the Department of Public Health (DPH) in the amount of $235,358 for participation in a program, entitled "Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) Scientific Leadership Center," for the period of January 25, 2023, through November 30, 2025; and

WHEREAS, The Adolescent Medicine Trials Network for human immunodeficiency virus (HIV)/ acquired immunodeficiency syndrome (AIDS) Interventions (ATN) Scientific Leadership Group (SLG) will provide the necessary multidisciplinary expertise to set, prioritize and manage the ATN scientific agenda; and

WHEREAS, The ATN SLG will develop and refine the research agenda of the ATN, convene working groups as needed, prioritize emerging research projects, efficiently manage the development of clinical protocols, implement and complete clinical trials and ensure timely publication and communication of results; and

WHEREAS, DPH will lead the site consortium, support site infrastructure, and contribute to development and implementation of innovative recruitment and retention strategies and maintain internal metrics; and

WHEREAS, DPH will lead and contribute to drafting protocol-specific budgets, initiate and maintain community partnerships, and participate in the development of trials; and

WHEREAS, The grant does not require an Annual Salary Ordinance Amendment; and

WHEREAS, A request for retroactive approval is being sought because DPH received the original grant award on April 5, 2023, for a project start date of January 25, 2023, in the amount of $34,629, then received an increase in grant funds on June 6, 2024 in the amount of $138,434 for a total amount of $173,063 which was approved by the Board under File number 240788 for a project start date of December 1, 2023, and finally received another increase in grant funds on September 6, 2025 in the amount of $62,295 for a total amount of $235,358 for a project start date of May 21, 2025, through November 30, 2025; and

WHEREAS, The grant budget includes a provision for indirect costs in the amount of $11,074; now, therefore, be it

RESOLVED, That DPH is hereby authorized to retroactively accept and expend a grant increase in the amount of $62,295 from the NIH through FSU; and, be it

FURTHER RESOLVED, That DPH is hereby authorized to retroactively accept and expend the grant funds pursuant to Administrative Code, Section 10.170-1; and, be it

FURTHER RESOLVED, That the Director of Health is authorized to enter into the Agreement on behalf of the City; and, be it

FURTHER RESOLVED, That the Board of Supervisors hereby authorizes the Director of Health or the Director's designee to enter into any amendments or modifications to the Grant Agreement that the Department determines, in consultation with the City Attorney, are in the best interests of the City, do not otherwise materially increase the obligations or

liabilities of the City, are necessary to effectuate the purposes of the Grant, and are in compliance with all applicable laws; and, be it

FURTHER RESOLVED, That within thirty (30) days of the Grant Agreement being fully executed by all parties, the Director of Health shall provide a copy to the Clerk of the Board of Supervisors for inclusion in the official file.

Recommended:

_/s/Jenny Louie for_____

Daniel Tsai

Director of Health

Approved: _/s/ Sophia Kittler_____

Mayor Daniel Lurie

Approved: /s/ Jocelyn Quintos for___

Greg Wagner, Controller

Docusign Envelope ID: F419C235-8060-4657-AE60-89E0881C7C87

File Number: 251153
(Provided by Clerk of Board of Supervisors)

Grant Resolution Information Form
(Effective July 2011)

Purpose: Accompanies proposed Board of Supervisors resolutions authorizing a Department to accept and expend grant funds.

The following describes the grant referred to in the accompanying resolution:

1. Grant Title: **Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) Scientific Leadership Center**

2. Department: **Department of Public Health**
Population Health Division

3. Contact Person: **Susan Buchbinder** Telephone: **415-437-7479**

4. Grant Approval Status (check one):

[**X**] Approved by funding agency [ ] Not yet approved

5. Amount of Grant Funding Approved or Applied for: **$235,358**
(Year 1 January 25, 2023 – November 30, 2023: $34,629
Year 2 December 1, 2023 – November 30, 2024: $138,434
Year 3 May 21, 2025 – November 30, 2025: $62,295)

6a. Matching Funds Required: **$0**
b. Source(s) of matching funds (if applicable): **N.A.**

7a. Grant Source Agency: **National Institutes of Health**
b. Grant Pass-Through Agency (if applicable): **Florida State University**

8. Proposed Grant Project Summary: **The Adolescent Medicine Trials Network for human immunodeficiency virus (HIV)/ acquired immunodeficiency syndrome (AIDS) Interventions (ATN) Scientific Leadership Group (SLG) will provide the necessary multidisciplinary expertise to set, prioritize and manage the ATN scientific agenda. The ATN SLG will develop and refine the research agenda of the ATN, convene working groups as needed, prioritize emerging research projects, efficiently manage the development of clinical protocols, implement and complete clinical trials and ensure timely publication and communication of results. The ATN SLG will work in collaboration with the ATN Scientific Leadership Center (SLC) PIs, the Statistical and Data Management Center, the Operations and Collaboration Center, and NIH and industry partners. The Department of Public Health (DPH) will lead the site consortium, support site infrastructure, and contribute to development and implementation of innovative recruitment and retention strategies and maintain internal metrics. DPH will also contribute to, review and approve site consortium standard operating procedures and quality management plan. DPH will lead and contribute to drafting protocol-specific budgets, initiate and maintain community partnerships, and participate in the development of trials.**

9. Grant Project Schedule, as allowed in approval documents, or as proposed:

Approved Year one project:	Start-Date: **01/25/2023**	End-Date: **11/30/2023**
Approved Year two project:	Start-Date: **12/01/2023**	End-Date: **11/30/2024**
Approved Year three project:	Start-Date: **05/21/2025**	End-Date: **11/30/2025**

Docusign Envelope ID: F419C235-8060-4657-AE60-89E0881C7C87

10a. Amount budgeted for contractual services: **$0**

b. Will contractual services be put out to bid? **N.A.**

c. If so, will contract services help to further the goals of the Department's Local Business Enterprise (LBE) requirements? **N.A.**

d. Is this likely to be a one-time or ongoing request for contracting out? **N.A.**

11a. Does the budget include indirect costs? [**X**] Yes [ ] No

b1. If yes, how much? **$45,687 ($11,074 is for grant increase portion)**
b2. How was the amount calculated? **24% of Personnel Costs**

c1. If no, why are indirect costs not included? **N.A.**
[ ] Not allowed by granting agency [ ] To maximize use of grant funds on direct services
[ ] Other (please explain):

c2. If no indirect costs are included, what would have been the indirect costs? **N.A.**

12. Any other significant grant requirements or comments:

We respectfully request for approval to accept and expend these funds retroactive to May 21, 2025. The Department received the grant increase of $62,295 on September 6, 2025, for the period of May 1, 2025, to November 30, 2025. The AL # for this grant is 93.865.

The grant does not require an ASO amendment, does not create net new positions, and partially reimburses the department for the existing positions:

No.	Class	Job Title	FTE	Start Date	End Date
1	0943	Manager VIII	0.192	05/21/2025	11/30/2025
2	2232	Senior Physician Specialist	0.083	05/21/2025	11/30/2025
3	2232	Senior Physician Specialist	0.083	05/21/2025	11/30/2025

Project Description: Adolescent Medicine Trials Network for HIV/AIDS Interven
Project ID: 10042439
Proposal ID: CTR00004809
Dept ID: 162646
Authority ID: 10001
Activity ID: 0001
Version ID: V101

Docusign Envelope ID: F419C235-8060-4657-AE60-89E0881C7C87

****Disability Access Checklist***(Department must forward a copy of all completed Grant Information Forms to the Mayor's Office of Disability)**

13. This Grant is intended for activities at (check all that apply):

[X] Existing Site(s)	[ ] Existing Structure(s)	[ ] Existing Program(s) or Service(s)
[ ] Rehabilitated Site(s)	[ ] Rehabilitated Structure(s)	[ ] New Program(s) or Service(s)
[ ] New Site(s)	[ ] New Structure(s)	

14. The Departmental ADA Coordinator or the Mayor's Office on Disability have reviewed the proposal and concluded that the project as proposed will be in compliance with the Americans with Disabilities Act and all other Federal, State and local disability rights laws and regulations and will allow the full inclusion of persons with disabilities. These requirements include, but are not limited to:

1. Having staff trained in how to provide reasonable modifications in policies, practices and procedures;
2. Having auxiliary aids and services available in a timely manner in order to ensure communication access;
3. Ensuring that any service areas and related facilities open to the public are architecturally accessible and have been inspected and approved by the DPW Access Compliance Officer or the Mayor's Office on Disability Compliance Officers.

If such access would be technically infeasible, this is described in the comments section below:

Comments:

Departmental ADA Coordinator or Mayor's Office of Disability Reviewer:

Toni Rucker, PhD
(Name)

DPH ADA Coordinator
(Title)

Date Reviewed: 11/7/2025 | 12:34 PM PST

DocuSigned by:
Toni Rucker
A64292F7331F44D...
(Signature Required)

Department Head or Designee Approval of Grant Information Form:

Daniel Tsai
(Name)

Director of Health
(Title)

Date Reviewed: 11/7/2025 | 2:52 PM PST

Signed by:
jenny louie for daniel tsai
40CFE25DD8B4464...
(Signature Required)

File 251153: Grant Accept & Expend

National Institutes of Health - Florida State University - Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) Scientific Leadership Center

BOS Budget & Finance Committee
December 10, 2025

Susan Buchbinder, MD, Director, Bridge HIV
Population Health Division, San Francisco Department of Public Health

SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

Overview of Grant

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

- **Total Amount:** $235,358
  - **Grant Increase:** $62,295
- **Timeline:** January 25, 2023 – November 30, 2025
- **Funder:** National Institutes of Health, through Florida State University
- **Grant Summary:** ATN Scientific Leadership Group (SLG) will provide multidisciplinary expertise to set, prioritize, and manage the ATN scientific agenda.
  - DPH will lead site consortium, support site infrastructure, and contribute to the development and implementation of recruitment and retention strategies
  - DPH will also contribute to, review, and approve consortium SOPs and QM plan.
  - DPH will lead and contribute to budget drafting, community partnerships, and development of trials

Retroactivity

We are seeking **retroactive authorization** to approve this grant accept and expend.

- The project period for this grant increase is May 21, 2025 through November 30, 2025. The start date was predetermined by the grantor.
- SFDPH received notice of this grant increase on September 6, 2025, after the project start date.
- DPH brought this item to the BOS after going through the fiscal approvals process, including Controller's Office review and approval.

Conclusion

DPH respectfully requests retroactive approval of this item. Thank you!

Docusign Envelope ID: F419C235-8060-4657-AE60-89E0881C7C87

SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH
Population Health Division – Center for Public Research
Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) Scientific Leadership Center
January 25, 2023 - November 30, 2025

		Year 1 Project: 10040067 1/25/23-11/30/23	Year 2 Project: 10041595 12/01/23-11/30/24	Year 3 Project: 10042439 05/21/25-11/30/25	Total Amount
	Personnel -				-
	Manager VIII		40,740	21,630	62,370
	Senior Physician Specialist	10,186	20,370	9,405	39,961
	Senior Physician Specialist	10,186	20,370	9,405	39,961
					-
	Fringe benefits	7,332	29,267	10,781	47,380
					-
	Travel	-			-
					-
	Contractual				-
					-
					-
	Indirect Costs	6,926	27,687	11,074	45,687
Total		**34,629**	**138,434**	**62,295**	**235,358**

Recipient Information

1. Recipient Name
FLORIDA STATE UNIVERSITY
874 TRADITIONS WAY

TALLAHASSEE, 32306

2. Congressional District of Recipient
02

3. Payment System Identifier (ID)
1596001138A1

4. Employer Identification Number (EIN)
596001138

5. Data Universal Numbering System (DUNS)
790877419

6. Recipient's Unique Entity Identifier
JF2BLNN4PJC3

7. Project Director or Principal Investigator
Lisa B Hightow-Weidman, MD (Contact)
Professor
lhightowweidman@fsu.edu
919-966-6714

8. Authorized Official
Lizzy McCawley

Federal Agency Information

9. Awarding Agency Contact Information
Mahasin Ingram

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

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

Federal Award Information

11. Award Number
1UM2HD111102-01

12. Unique Federal Award Identification Number (FAIN)
UM2HD111102

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

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

15. Assistance Listing Number
93.865

16. Assistance Listing Program Title
Child Health and Human Development Extramural Research

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 01/25/2023 **– End Date** 11/30/2023	
20. Total Amount of Federal Funds Obligated by this Action	$11,162,061
20 a. Direct Cost Amount	$8,786,078
20 b. Indirect Cost Amount	$2,375,983
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$11,162,061
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$11,162,061
26. Project Period Start Date 01/25/2023 **– End Date** 11/30/2029	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$11,162,061

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Teri A. Pailen

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise

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requested from the grant payment system.

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

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 1UM2HD111102-01

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

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

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $11,162,061 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to FLORIDA STATE UNIVERSITY in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 31 USC 6305 42 CFR Part 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

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

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number UM2HD111102. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

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

Additional information follows

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

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

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$11,162,061	$11,162,061
2	$10,463,649	$10,463,649
3	$10,333,316	$10,333,316
4	$10,283,125	$10,283,125
5	$10,173,415	$10,173,415
6	$10,161,519	$10,161,519
7	$10,113,635	$10,113,635

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

Fiscal Information:

Payment System Identifier:	1596001138A1
Document Number:	UHD111102A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2023

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

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

NIH Administrative Data:
PCC: MPIDB-DR / **OC**: 41026 / **Released**: Pailen, Teri 01/18/2023
Award Processed: 01/24/2023 12:08:43 AM

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.
Treatment of Program Income:

Additional Costs

SECTION IV – HD SPECIFIC AWARD CONDITIONS – 1UM2HD111102-01

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

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

IRB approval verification must be submitted within 60 days of the date of this Notice of Award to the Grants Management Specialist (GMS). Please contact the GMS if the IRB approval will be delayed beyond 60 days. Failure to comply with the above requirements can result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action.

****

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

****

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

****

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

****

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

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

****

Beginning January 2021, for all competing applications or new protocols, the NICHD expects investigators for ALL NICHD Clinical Trials to abide by the requirements stated in NIH Guide Notice NOT-HD-20-036 "NICHD Data Safety Monitoring Guidelines for Extramural Clinical Trials and Clinical Research". All NICHD applications which include Clinical Trials must include a Data Safety Monitoring Plan. All NIH-sponsored multi-site clinical trials, NIH-defined Phase III clinical trials and some single site clinical trials that pose potential risk to participants require Data and Safety Monitoring Board (DSMB) oversight. Applicants are expected to establish an independent, external DSMB when required by this policy.

Beginning January 2021, for all competing applications or new protocols, the NICHD expects investigators for ALL human subject research to abide by the requirements stated in NIH Guide Notice NOT-HD-20-035 "NICHD Serious Adverse Event, Unanticipated Problem, and Serious Adverse Event Reporting Guidance".

****

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

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

SPREADSHEET SUMMARY
AWARD NUMBER: 1UM2HD111102-01

INSTITUTION: FLORIDA STATE UNIVERSITY

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

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

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

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FDP Cost Reimbursement Subaward

Federal Awarding Agency: National Institutes of Health (NIH)

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

Terms and Conditions

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

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

3. A final statement of cumulative costs incurred, including cost sharing, marked "FINAL" must be submitted to PTE's Financial Contact, as shown in Attachment 3A, not later than 60 days after the final Budget Period end date. The final statement of costs shall constitute Subrecipient's final financial report.

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

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

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

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

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

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

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

By an Authorized Official of the PTE:	By an Authorized Official of the Subrecipient:
_____ Date	DocuSigned by: Greg Wagner 285275247529491... 4/27/2023 | 11:21
Name: Stacey Patterson	Name: Grant Colfax, MD
Title: Vice President for Research	Title: Director of Health

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

DocuSign Envelope ID: CA2CC844-55D9-4BCD-ACF3-E02FD1545660

Attachment 1
Certifications and Assurances

Subaward Number: R000003157

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

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

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

Debarment, Suspension, and Other Responsibility Matters (2 CFR 200.214 and 2 CFR 180)
By signing this Subaward, the Subrecipient Authorized Official certifies, to the best of his/her knowledge and belief that neither the Subrecipient nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from participation in this transaction by any federal department or agency, in accordance with 2 CFR 200.213 and 2 CFR 180.

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

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

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

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

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

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Attachment 2
Federal Award Terms and Conditions

Subaward Number: R000003157

Required Data Elements

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

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

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

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

Key Personnel Per NOA:

This Subaward Is:

- [x] Research & Development
- [x] Subject to FFATA

General Terms and Conditions

By signing this Subaward, Subrecipient agrees to the following:

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

Special Terms and Conditions:

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

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

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

Copyrights:

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

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

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

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

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

RESOURCE AND DATA SHARING

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

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

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

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

1. **Formal academic dissemination in the form of journal articles and abstracts:** We will work diligently to process and analyze data obtained from ATN projects to aid in disseminating the results rapidly to the scientific community, including through open access channels whenever possible. We will make publications available to the NIH for online distribution via the NIH manuscript submission system (http://www.nihms.nih.gov). We will ensure that no study participants are individually identified in any published or shared data. All publications, presentations, and press releases using ATN data will acknowledge the study investigators, NIH sponsorship with the relevant grant number.

2. **Data sharing with community members**: Site Consortiums via the Operations and Collaborations Center (OCC), as well the ATN Communication and Dissemination Hub and Diversity Equity and Inclusion Research Consultants (DEI RC), will be active partners collaborating with the study team on the development of culturally appropriate dissemination of research results (i.e., publications and other means of dissemination). Bi-directional information exchange between the research team, site staff, and members of advisory boards will be critical to the design and execution of project outreach, communication, and culturally appropriate dissemination activities.

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

4. **Data sharing with NIH**. We will work closely with the NIH and our Scientific Program Officer to disseminate and incorporate required/requested measures and to provide data and results as requested. We will regularly and expeditiously share and request feedback on study results from each aim, as well as successes and challenges related to implementation with NIH and other grantees.

5. **Presentations at national and international scientific meetings:** The ATN Scientific Leadership Center (SLC) PIs, Scientific Leadership Group (SLG) team members, and Research Project teams will regularly attend national and international annual conferences, such as for the Society for Behavioral Medicine (SBM), American Public Health Association (APHA), Conference on Retroviruses and Opportunistic Infections (CROI), and International AIDS Society Meetings (including HIV R4P and International AIDS Conferences) to disseminate our research findings and to keep abreast of new and innovative projects in this area of research. Presentation of data at scientific meetings is a critical way to ensure wider awareness of research findings. We will an acknowledgement and disclaimer on all presentations produced under this NIH support.

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

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

Work Involving Human or Vertebrate Animals (Select Applicable Options)

☐ No Human or Vertebrate Animals

☒ Human Subjects

IRB Not required for the following reason:

There is an sIRB designated

☐ Vertebrate Animals

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

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

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

This section left intentionally blank

NIH Terms and Conditions

The Clinical Trial Indicator in Section IV of the PTE's NOA is stated as: Yes ?

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

Multiple PIs (MPI)

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

The MPI plan is attached as part of Attachment 6.

Certificate of Confidentiality:

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

Additional Terms

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Attachment 3A

Research Subaward Agreement

Pass-Through Entity (PTE) Contacts

Subaward Number: R000003157

PTE Information

Entity Name: Florida State University

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

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

PTE Contacts

Central Email: subcontracts@fsu.edu

Principal Investigator Name: Lisa Hightow-Weidman

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

Administrative Contact Name: Aras Aziz

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

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

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

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

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

Authorized Official Name: Stacey Patterson, Vice President for Research

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

PI Address:

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

Administrative Address:

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

Invoice Address:

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

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Attachment 3B

Research Subaward Agreement

Subrecipient Contacts

Subaward Number: R000003157

Subrecipient Information for FFATA reporting

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

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

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

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

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

25 Van Ness, Suite 500
San Francisco, CA 94102

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

Zip Code Look-up

Subrecipient Contacts

Central Email:

Website:

Principal Investigator Name: Susan Buchbinder

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

Administrative Contact Name: Eduardo Sida

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

Financial Contact Name: Sajid Shaikh

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

Invoice Email: sajid.shaikh@sfdph.org

Authorized Official Name: Greg Wagner

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

Legal Address:

101 Grove Street
San Francisco, CA 94103

Administrative Address:

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

Payment Address:

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

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Attachment 3B-2

Highest Compensated Officers

Subaward Number: R000003157

Subrecipient:

Institution Name: San Francisco Department of Health

PI Name: Susan Buchbinder

Highest Compensated Officers

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

Officer 1 Name:

Officer 1 Compensation:

Officer 2 Name:

Officer 2 Compensation:

Officer 3 Name:

Officer 3 Compensation:

Officer 4 Name:

Officer 4 Compensation:

Officer 5 Name:

Officer 5 Compensation:

DocuSign Envelope ID: CA2CC844-55D9-4BCD-ACF3-E02FD1545660

Attachment 4
Reporting and Prior Approval Terms

Subaward Number: R000003157

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

Technical Reports:

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

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

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

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

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

Prior Approvals:

Carryover:

Carryover is restricted for this subaward by the: Federal Awarding Agency

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

Submit carryover requests to the Principal Investigator.

Other Reports:

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

A negative report is required: Yes

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

Additional Technical and Reporting Requirements:

DocuSign Envelope ID: CA2CC844-55D9-4BCD-ACF3-E02FD1545660

Subaward Number: R000003157

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

Statement of Work

○ Below ◉ Attached, 1 pages

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

See Attachment 5A (1 page)

Budget Information

Indirect Information Indirect Cost Rate (IDC) Applied: 25 %

Rate Type: Modified Total Direct Costs

Cost Sharing: No

If Yes, include Amount: $

Budget Details

◉ Below ○ Attached, pages

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

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

Indirect: $6,926

Total: $34,629 per year

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

Budget Totals

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

All amounts are in United States Dollars

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ATN Scientific Leadership Group
Scope of Work – Team Member

Project Description Summary

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

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

Role of the ASLG Teams

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

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

Key Deliverables

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

- contribute to the successful completion of the ATN SLC grant application;
- generate and review the scientific priorities within the ATN;
- assist ATN PIs to pursue new scientific partnerships and funding opportunities;
- oversee the research project teams and protocol development within the Team agenda areas;
- identify gaps in the scientific agenda of the Team;
- review manuscripts and discretionary proposals within the Team's area of expertise;
- participate on at least 80% of scheduled Team calls;
- participate in bi-annual face-to-face ATN meetings;
- participate in other ad hoc leadership meetings, as needed

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

PERSONNEL

Total Personnel: $514,991 years 1 through 7

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

Susan Buchbinder, MD (Principal Investigator): Dr. Buchbinder is Director of Bridge HIV at the San Francisco Department of Public Health and Professor of Medicine, Epidemiology and Biostatistics at the University of California, San Francisco. She provides scientific leadership in the NIH sponsored HIV Vaccine Trials Network and HIV Prevention Trials Network and leads several multi-site HIV prevention efficacy trials, with a focus on advancing integrated prevention strategies in diverse populations of men who have sex with men (MSM) and transgender/gender non-binary persons (TG/GNB) in the US and globally. Most recently, she has focused on the use of mHealth technology for young MSM and TG/GNB to increase access to prevention and treatment services for populations at risk for or living with HIV infection, and implementation of prevention strategies. As Principal Investigator (PI) of the PrEP CHOICE proposal, she will be responsible for the overall scientific vision and implementation of the specific aims of this study. Dr. Buchbinder will have responsibility for maintaining the proposed study schedule, ensuring quality control over all aspects of the study, including data analysis, presentations, publications, and dissemination of results. She will lead weekly team meetings. Dr. Buchbinder will serve as primary liaison with the ATN and will oversee all budgetary issues for the project. In addition, throughout the 7-year cycle of the ATN grant, Dr. Buchbinder will serve on the Biomedical Therapeutics team, and contribute to the successful completion of the ATN SLC grant application, generate and review the scientific priorities within the ATN; assist ATN PIs to pursue new scientific partnerships and funding opportunities; oversee the research project teams and protocol development within the Team agenda areas; identify gaps in the scientific agenda of the Team; review manuscripts and discretionary proposals within the Team's area of expertise; participate on at least 80% of scheduled Team calls; participate in bi-annual face-to-face ATN meetings; and participate in other ad hoc leadership meetings, as needed.
Dr. Buchbinder will devote 2.40 Cal Mos to the project each year 2 through 5 and and 0.6 Cal Mos in years 1, 6, and .36 FTE in Yr 7. Total Salary: $257,496 requested at $13,852 year 1, $13,843 in year 6 and $8,306 Year 7 and $55,373 year 2 through 5.

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

face ATN meetings; and participate in other ad hoc leadership meetings, as needed. **Dr. Liu will devote 1.20 Cal Mos to the project each year 2 through 5 and 0.6 Ca. Mos in years 1, 6, and .36 FTE in year 7. Total Salary: $146,748 requested at $13,852 year 1, $13,843 in year 6 and $8,306 in year 7 and $27,687 year 2 through 5.**

Hyman Scott, MD, MPH (Co-investigator): Dr. Scott is the Medical Director of Clinical Research at Bridge HIV at the San Francisco Department of Public Health, an Assistant Professor of Medicine at the University of California, San Francisco (UCSF), and a physician at the Positive Health Program (Ward 86) at San Francisco General Hospital. His primary research area is HIV-related racial/ethnic disparities with a focus on biomedical HIV and STI prevention and has worked closely with Drs. Liu and Buchbinder on the development of a risk assessment tool for MSM (Sex Pro). He is currently the Director of the PrEP clinic at Ward 86 and has developed a PrEP Clinical Protocol for use across the public health clinics in San Francisco. Dr. Scott oversees Bridge HIV research associates conducting qualitative focus groups and interviews, will assist with technology development and scientific design of research protocols, and provide clinical guidance, training and safety monitoring regarding administration of various PrEP agents to youth in this study. He will maintain frequent contact with Dr. Buchbinder and the other Co-Investigators through meetings, conference calls and e-mail. He will also work closely with the research team in data analysis, manuscript preparation, and dissemination of results. **Dr. Scott will devote 1.20 Cal Mos to the project each year 2 through 5. Total Salary: $110,747 requested at $27,687 each year 2 through 5.**

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

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

CCSF indirect costs are calculated at 25% of the modified total direct cost. This rate is for the other sponsored activities approved by Department of Health and Human Services (DHHS).

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

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Subaward Number:
R000003157

Attachment 6

Notice of Award (NOA) and any additional documents

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

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

LEADERSHIP PLAN FOR MULTIPLE PRINCIPAL INVESTIGATORS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Notice of Award

FAIN# UM2HD111102
Federal Award Date
01/24/2023

Recipient Information

1. Recipient Name
FLORIDA STATE UNIVERSITY
874 TRADITIONS WAY

TALLAHASSEE, 32306

2. Congressional District of Recipient
02

3. Payment System Identifier (ID)
1596001138A1

4. Employer Identification Number (EIN)
596001138

5. Data Universal Numbering System (DUNS)
790877419

6. Recipient's Unique Entity Identifier
JF2BLNN4PJC3

7. Project Director or Principal Investigator
Lisa B Hightow-Weidman, MD (Contact)
Professor
lhightowweidman@fsu.edu
919-966-6714

8. Authorized Official
Lizzy McCawley

Federal Agency Information

9. Awarding Agency Contact Information
Mahasin Ingram

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

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

Federal Award Information

11. Award Number
1UM2HD111102-01

12. Unique Federal Award Identification Number (FAIN)
UM2HD111102

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

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

15. Assistance Listing Number
93.865

16. Assistance Listing Program Title
Child Health and Human Development Extramural Research

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 01/25/2023 **– End Date** 11/30/2023	
20. Total Amount of Federal Funds Obligated by this Action	$11,162,061
20 a. Direct Cost Amount	$8,786,078
20 b. Indirect Cost Amount	$2,375,983
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$11,162,061
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$11,162,061
26. Project Period Start Date 01/25/2023 **– End Date** 11/30/2029	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$11,162,061

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Teri A. Pailen

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise

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Notice of Award

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

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 1UM2HD111102-01

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

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

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $11,162,061 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to FLORIDA STATE UNIVERSITY in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 31 USC 6305 42 CFR Part 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

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

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number UM2HD111102. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

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

Additional information follows

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

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

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$11,162,061	$11,162,061
2	$10,463,649	$10,463,649
3	$10,333,316	$10,333,316
4	$10,283,125	$10,283,125
5	$10,173,415	$10,173,415
6	$10,161,519	$10,161,519
7	$10,113,635	$10,113,635

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

Fiscal Information:

Payment System Identifier:	1596001138A1
Document Number:	UHD111102A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2023

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

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

NIH Administrative Data:
PCC: MPIDB-DR / **OC**: 41026 / **Released**: Pailen, Teri 01/18/2023
Award Processed: 01/24/2023 12:08:43 AM

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.
Treatment of Program Income:

Additional Costs

SECTION IV – HD SPECIFIC AWARD CONDITIONS – 1UM2HD111102-01

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

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

IRB approval verification must be submitted within 60 days of the date of this Notice of Award to the Grants Management Specialist (GMS). Please contact the GMS if the IRB approval will be delayed beyond 60 days. Failure to comply with the above requirements can result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action.

****

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

****

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

****

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

****

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

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

****

Beginning January 2021, for all competing applications or new protocols, the NICHD expects investigators for ALL NICHD Clinical Trials to abide by the requirements stated in NIH Guide Notice NOT-HD-20-036 "NICHD Data Safety Monitoring Guidelines for Extramural Clinical Trials and Clinical Research". All NICHD applications which include Clinical Trials must include a Data Safety Monitoring Plan. All NIH-sponsored multi-site clinical trials, NIH-defined Phase III clinical trials and some single site clinical trials that pose potential risk to participants require Data and Safety Monitoring Board (DSMB) oversight. Applicants are expected to establish an independent, external DSMB when required by this policy.

Beginning January 2021, for all competing applications or new protocols, the NICHD expects investigators for ALL human subject research to abide by the requirements stated in NIH Guide Notice NOT-HD-20-035 "NICHD Serious Adverse Event, Unanticipated Problem, and Serious Adverse Event Reporting Guidance".

****

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

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

SPREADSHEET SUMMARY
AWARD NUMBER: 1UM2HD111102-01

INSTITUTION: FLORIDA STATE UNIVERSITY

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

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

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

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FDP Subaward Amendment

Amendment No: 1 | 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

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

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

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

Amendment(s) to Original Terms and Conditions

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

☒ **Additional Budget Period**

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

☐ **No Cost Extension**

☒ **Additional Funding**

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

☐ **Deobligation**

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

☐ **Carryover Authorized**

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

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

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

☒ **Other (See Below)**

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

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

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

By an Authorized Official of PTE:	By an Authorized Official of Subrecipient:
DocuSigned by: Pamela Ray 04491B81561242E...	DocuSigned by: Paulette Bolden 52BC36E46C...
Date: 4/15/2024 | 9:39 AM EDT	Date: 4/12/2024 | 1:34 P
Name: Stacey Patterson	Name: Grant Colfax, MD
Title: Vice President for Research	Title: Director of Health

Approved as to form, David Chiu, City Attorney

By: DocuSigned by: Henry Lifton 6D6CB58424584B1...

DocuSign Envelope ID: 245909DC-478C-4608-9C27-0377811F25B6

NUMBER: PP 3

TITLE: ATN Data Sharing and Management Plan

EFFECTIVE DATE:

Change History Log:

Effective Date	Version	Revisions
	01	New

DocuSign Envelope ID: 245909DC-478C-4608-9C27-0377811F25B6

I. PURPOSE

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

II. RESPONSIBILITY

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

III. ACRONYMS

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

IV. BACKGROUND

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

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V. PROCEDURE

A. Data sharing within the ATN

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

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

Methods for Protecting Participant Data and Privacy

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

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

- Through which an individual is identified; or

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

Informed Consent

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

Data Systems

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

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

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

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

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

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

Data Records at the ATN Site Consortiums including Other Participating Sites

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

Personal Data Protection by ATN components

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

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

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

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

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

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

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

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

B. Future Sharing of De-Identified Data

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

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

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

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

Dissemination of ATN Data

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

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

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

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

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

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

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

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

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

VI. REVIEW AND REVISION

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

Attachment 5

RESEARCH & RELATED BUDGET - Budget Period 2

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

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

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

A. Senior/Key Person

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

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

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

Total Senior/Key Person: 110,747.00

B. Other Personnel

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

Total Number Other Personnel

Total Other Personnel

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

Attachment 5

C. Equipment Description

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

Equipment item	Funds Requested ($)

Additional Equipment: Add Attachment | Delete Attachment | View Attachment

Total funds requested for all equipment listed in the attached file

Total Equipment

D. Travel

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

E. Participant/Trainee Support Costs

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

F. Other Direct Costs

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

G. Direct Costs

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

H. Indirect Costs

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

Total Indirect Costs	27,687.00

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

I. Total Direct and Indirect Costs

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

J. Fee

	Funds Requested ($)

K. Total Costs and Fee

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

L. Budget Justification

(Only attach one file.) CCSF Budget Justification 2.pdf [Add Attachment] [Delete Attachment] [View Attachment]

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

PERSONNEL

Total Personnel: $110,747 Year 2

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

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

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

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

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

Total Direct Costs: $110,747 year 2.

Indirect Costs: Total and $27,687 year 2.

CCSF indirect costs are calculated at 25% of the modified total direct cost. This rate is for the other sponsored activities approved by Department of Health and Human Services (DHHS).

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

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

Notice of Award

FAIN# UM2HD111102
Federal Award Date
12/01/2023

Recipient Information

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

2. Congressional District of Recipient
02

3. Payment System Identifier (ID)
1596001138A1

4. Employer Identification Number (EIN)
596001138

5. Data Universal Numbering System (DUNS)
790877419

6. Recipient's Unique Entity Identifier
JF2BLNN4PJC3

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

8. Authorized Official
Stacey Patterson

Federal Agency Information

9. Awarding Agency Contact Information
Mahasin Ingram

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

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

Federal Award Information

11. Award Number
5UM2HD111102-02

12. Unique Federal Award Identification Number (FAIN)
UM2HD111102

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

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

15. Assistance Listing Number
93.865

16. Assistance Listing Program Title
Child Health and Human Development Extramural Research

17. Award Action Type
Non-Competing Continuation

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

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

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Teri A. Pailen

30. Remarks

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

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Notice of Award

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

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 5UM2HD111102-02

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

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

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $9,417,285 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to FLORIDA STATE UNIVERSITY in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 31 USC 6305 42 CFR Part 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

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

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number UM2HD111102. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

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

Additional information follows

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

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

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

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

Fiscal Information:

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

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

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

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

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

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

SECTION III – STANDARD TERMS AND CONDITIONS – 5UM2HD111102-02

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the

most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV – HD SPECIFIC AWARD CONDITIONS – 5UM2HD111102-02

Clinical Trial Indicator: Yes

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

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

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

IRB approval verification must be submitted within 60 days of the date of this Notice of Award to the Grants Management Specialist (GMS). Please contact the GMS if the IRB approval will be delayed beyond 60 days. Failure to comply with the above requirements can result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action.

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

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

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

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

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

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

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

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

RISK ASSESSMENT:

Clinical Trial Study/Studies:

416802

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

Clinical Trial Study/Studies:

416804

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

Clinical Trial Study/Studies:

416806

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

Clinical Trial Study/Studies:

416813

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

Clinical Trial Study/Studies:

416814

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

Clinical Trial Study/Studies:

416815

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

SPREADSHEET SUMMARY
AWARD NUMBER: 5UM2HD111102-02

INSTITUTION: FLORIDA STATE UNIVERSITY

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

		6	5	5	9	5

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

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Attachment 7

Human Subjects Data Transfer and Use Terms

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

☒ From Subrecipient to PTE
☒ From PTE to Subrecipient

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

Description of Data:

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

DocuSign Envelope ID: 245909DC-478C-4608-9C27-0377811F25B6

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

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

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

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

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

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

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

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

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

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

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

FDP Subaward Amendment

Awarding Agency: National Institutes of Health (NIH)
Amendment No: 2
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)	(End Date of Latest Budget Period)	Amount Funded This Action	Total Amount of Funds Obligated to Date
Start Date: 01/25/2023	End Date: 03/21/2025	$ 124,590.00	$ 297,653.00

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

Amendment(s) to Original Terms and Conditions
This Amendment revises the above-referenced Subaward Agreement as follows:

☒ **Additional Budget Period**
Additional budget period 12/01/2024 - 03/21/2025 is hereby added to this Subaward.

☐ **No Cost Extension**

☒ **Additional Funding**
Additional funding in the amount of $ 124,590.00 is hereby obligated to this Subaward.

☐ **Deobligation**

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

☐ **Carryover Authorized**

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

☒ **Detailed Budget/Scope of Work/Notice of Award Attached** (Specify if the Budget and Scope of Work are "New", "Revised", or "Supplemental" in dropdown or "Other")
A Notice of Award and Budget is incorporated by attachment to this Amendment.

☒ **Other (See Below)**

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

2. Budget and Budget Justification for Year 3 are attached below and hereby incorporated in Attachment 5.

3. End date of this subaward is 03/21/2025 to comply with the REVISED Notice of Award for FAIN# UM2HD111102 included below, and hereby added to this subaward.

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
		Signed by: Susan Philip 4C9D2F27470A474	04/23/2025 | 6:18
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

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

Budget Type: ☐ Project ☒ Subaward/Consortium **Budget Period: 1** **Start Date:** 12/01/2024 **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		203,700.00	2.40			40,740.00	10,072.00	50,812.00
Project Role:	PD/PI										
	Albert		Liu		203,700.00	1.20			20,370.00	5,093.00	25,463.00
Project Role:	Co-PI										
	Hyman		Scott		2,037,000.00	1.20			20,370.00	5,093.00	25,463.00
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 101,738.00

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) 101,738.00

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)	101,738.00

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)
22.462% of total personnel cost	22.46	101,738.00	22,852.00

Total Indirect Costs	22,852.00

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): Dept of Transportation, Office of Inspector General

I. Total Direct and Indirect Costs

	Funds Requested ($)
Total Direct and Indirect Institutional Costs (G + H)	124,590.00

J. Fee

	Funds Requested ($)

K. Total Costs and Fee

	Funds Requested ($)
Total Costs and Fee (I + J)	124,590.00

L. Budget Justification

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

Year 3 BUDGET JUSTIFICATION
City and County of San Francisco (CCSF)
San Francisco Department of Public Health (SFDPH)

PERSONNEL

Total Personnel: $101,738 in YR3

Personnel costs calculated using the current NIH salary cap of $203,700 and includes fringe

Susan Buchbinder, MD (Principal Investigator): Dr. Buchbinder is Director of Bridge HIV at the San Francisco Department of Public Health and Professor of Medicine, Epidemiology and Biostatistics at the University of California, San Francisco. She provides scientific leadership in the NIH sponsored HIV Vaccine Trials Network and HIV Prevention Trials Network and leads several multi-site HIV prevention efficacy trials, with a focus on advancing integrated prevention strategies in diverse populations of men who have sex with men (MSM) in the US and globally. Most recently, she has focused on the use of mHealth technology for young MSM to increase access to prevention and treatment services for populations at risk for or living with HIV infection, and implementation of prevention strategies. As Principal Investigator (PI) of the PrEP CHOICE proposal, she will be responsible for the overall scientific vision and implementation of the specific aims of this study. Dr. Buchbinder will have responsibility for maintaining the proposed study schedule, ensuring quality control over all aspects of the study, including data analysis, presentations, publications, and dissemination of results. She will lead weekly team meetings. Dr. Buchbinder will serve as primary liaison with the ATN and will oversee all budgetary issues for the project. In addition, throughout the 7-year cycle of the ATN grant, Dr. Buchbinder will serve on the Biomedical Therapeutics team, and contribute to the successful completion of the ATN SLC grant application, generate and review the scientific priorities within the ATN; assist ATN PIs to pursue new scientific partnerships and funding opportunities; oversee the research project teams and protocol development within the Team agenda areas; identify gaps in the scientific agenda of the Team; review manuscripts and discretionary proposals within the Team's area of expertise; participate on at least 80% of scheduled Team calls; participate in bi-annual face-to-face ATN meetings; and participate in other ad hoc leadership meetings, as needed.
Dr. Buchbinder will devote 2.40 Cal Mos to the project in YR3.

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

face ATN meetings; and participate in other ad hoc leadership meetings, as needed. **Dr. Liu will devote 1.20 Cal Mos to the project** in YR3.

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 MSM (Sex Pro). He is currently the Director of the PrEP clinic at Ward 86 and has developed a PrEP Clinical Protocol for use across the public health clinics in San Francisco. Dr. Scott oversees Bridge HIV research associates conducting qualitative focus groups and interviews, will assist with technology development and scientific design of research protocols, and provide clinical guidance, training and safety monitoring regarding administration of various PrEP agents to youth in this study. He will maintain frequent contact with Dr. Buchbinder and the other Co-Investigators through meetings, conference calls and e-mail. He will also work closely with the research team in data analysis, manuscript preparation, and dissemination of results. **Dr. Scott will devote 1.20 Cal Mos to the project in YR3.**

Total Direct Costs: $101,738 YR3

Indirect Costs: Total $22,852 YR3

CCSF indirect costs are calculated at 22.46% of the modified total direct cost. This rate is for the other sponsored activities approved by Department of Health and Human Services (DHHS).

Total Costs: $124,590 YR3.

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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** 03/21/2025	
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	
22. Offset	
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** 03/21/2025	
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.

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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

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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

Fiscal Information:

Payment System Identifier:	1596001138A1
Document Number:	UHD111102A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2025

IC	CAN	2025
HD	8014710	$8,647,748
MH	8472592	$1,000,000
DA	8472628	$2,000,000

NIH Administrative Data:
PCC: MPIDB-DR / **OC**: 41029 / **Released**: 03/24/2025
Award Processed: 03/25/2025 12:22:50 AM

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.)

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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 represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to

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Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

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

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the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

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

TERMINATION

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

CLOSEOUT

"Recipient Institution" may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), as applicable within 120 days of the end of this grant.

The Closeout procedures should occur as expeditiously as possible while maintaining the safety of human subjects. There must be an orderly process to ensure the safety and welfare of participants. The grant close-out must occur within 120 days. The closeout will include:

- Informing all enrolled study participants of the study's termination and what study closure means for them:
    - Options pertaining to receiving further intervention, continuing follow-up, if required
    - Recognition of the value of their data and contribution to research
- If there remain participants that are actively participating in the research, the process and responsibilities will differ depending on the nature of the research.
    - If there is a prospect of direct benefit of the intervention and/or the intervention requires ongoing monitoring for safety and welfare there must be a plan to address these needs.
    - If there are no participants actively participating, or there is no need for ongoing monitoring or care, the protocol may be closed.
- Conduct any necessary final study visits or data collection procedures for enrolled participants.
- Notifying the IRB, DSMB, FDA, and/or other monitoring bodies of the study's closure.

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- Assure all consent forms, case report forms, and source documentation for the study are completed as necessary and are present in the study files.
- Complete all adverse event reporting and reconciliation as per protocol.
- Perform any appropriate statistical analyses of the study data collected to date.
- Prepare a comprehensive final study report summarizing findings, including any deviations from the protocol and GCP compliance.
- Review and clean collected data for accuracy and completeness resulting in a locked dataset, suitable for sharing, as required.
- Confirm final disposition of investigational product(s) and devices. Plan for removal of any implanted devices, if applicable.
- Handle any biospecimens collected and prepare them for sharing, if required.
- Update the study record and status to terminated in ClinicalTrials.gov as appropriate.

APPEALS

NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

****

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

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Monitoring Plan. All NIH-sponsored multi-site clinical trials, NIH-defined Phase III clinical trials and some single site clinical trials that pose potential risk to participants require Data and Safety Monitoring Board (DSMB) oversight. Applicants are expected to establish an independent, external DSMB when required by this policy.

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

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

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

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

RISK ASSESSMENT:

Clinical Trial Study/Studies:

416802

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

Clinical Trial Study/Studies:

416804

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

Clinical Trial Study/Studies:

416806

This Clinical Trial Study or Studies listed above have been determined by NICHD to be considered **LOW** risk. Oversight by NICHD will occur in the standard manner through the annual

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RPPR. An annual update (no additional reports) on the status of the milestones included in Section 6 of the eRA HSS and any additional agreed-upon milestones are due in the RPPR. Information and procedures concerning these requirements are available on the NICHD Policies on Clinical Research site.

Clinical Trial Study/Studies:

416813

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

Clinical Trial Study/Studies:

416814

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

Clinical Trial Study/Studies:

416815

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

SPREADSHEET SUMMARY
AWARD NUMBER: 5UM2HD111102-03 REVISED

INSTITUTION: FLORIDA STATE UNIVERSITY

Budget	Year 3
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
TOTAL FEDERAL DC	$9,626,686
TOTAL FEDERAL F&A	$2,021,062

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TOTAL COST	$11,647,748

Facilities and Administrative Costs	Year 3
F&A Cost Rate 1	54%
F&A Cost Base 1	$3,742,708
F&A Costs 1	$2,021,062

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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)	(End Date of Latest Budget Period)	Amount Funded This Action	Total Amount of Funds Obligated to Date
Start Date: 01/25/2023	End Date: 11/30/2025	-$ 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:	
	Date	Signed by: Susan Philip 4C9D2E27470A474...	Date 09/26/2025 | 4:26 PM PD
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...

FDP Mar 2024

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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

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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**	

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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

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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.

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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

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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.

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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

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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

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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.

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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.

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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	$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

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City and County of San Francisco
Daniel Lurie
Mayor

San Francisco Department of Public Health
Daniel Tsai
Director of Health

Memorandum

To: Honorable Members of the Board of Supervisors

From: San Francisco Department of Public Health

Date: Thursday, December 4, 2025

RE: **Retroactivity re: File 251153**

This Resolution seeks authorization for the Department of Public Health (DPH) to retroactively accept and expend a grant increase in the amount of $62,295, from the National Institutes of Health, through Florida State University for participation in the Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) Scientific Leadership Center.

This grant increase accept and expend is retroactive because DPH received notice of the grant increase after the pre-determined project start date. DPH received notice of the grant increase on September 6, 2025, for a project period of May 21, 2025, through November 30, 2025. The project period was predetermined by the grantor. Upon receiving the notice of grant increase, DPH brought the item to the Controller's Office for review on October 29, 2025. The Controller's Office reviewed and forwarded the packet to the Mayor's Office on November 13, 2025, for introduction on November 18, 2025.

We respectfully request retroactive authorization for these items. Please contact Lily Conover, SFDPH Controller, at lily.conover@sfdph.org for any questions about this request for retroactive authorization.

President, District 8
BOARD of SUPERVISORS

City Hall
1 Dr. Carlton B. Goodlett Place, Room 244
San Francisco, CA 94102-4689
Tel. No. 554-6968
Fax No. 554-5163
TDD/TTY No. 544-5227

RAFAEL MANDELMAN

PRESIDENTIAL ACTION

Date: 12/5/25

To: Angela Calvillo, Clerk of the Board of Supervisors

Madam Clerk,
Pursuant to Board Rules, I am hereby:

☐ Waiving 30-Day Rule (Board Rule No. 3.23)

File No. _____ _____
(Primary Sponsor)

Title. _____

☐ Transferring (Board Rule No 3.3)

File No. _____ _____
(Primary Sponsor)

Title. _____

From: _____ Committee

To: _____ Committee

☒ Assigning Temporary Committee Appointment (Board Rule No. 3.1)

Supervisor: Chen Replacing Supervisor: _____

For: 12/10/25 (Date) Budget & Finance (Committee) Meeting

Start Time: _____ End Time: _____

Temporary Assignment: ○ Partial ◉ Full Meeting

Rafael Mandelman, President
Board of Supervisors

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Daniel L. Lurie
Mayor

TO: **Angela Calvillo, Clerk of the Board of Supervisors**

FROM: **Daniel Tsai**
Director of Health

DATE: **11/7/2025**

SUBJECT: **Grant Accept and Expend**

GRANT TITLE: **Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) Scientific Leadership Center - $235,358**

Attached please find the original and 1 copy of each of the following:

☒ Proposed grant resolution, original signed by Department

☒ Grant information form, including disability checklist

☒ Budget and Budget Justification

☐ Grant application: Not Applicable. No application submitted.

☒ Agreement / Award Letter

☐ Other (Explain):

Special Timeline Requirements:

Departmental representative to receive a copy of the adopted resolution:

Name: Gregory Wong (greg.wong@sfdph.org) Phone: 554-2521

Interoffice Mail Address: Dept. of Public Health, 101 Grove St # 108

Certified copy required Yes ☐ No ☒

OFFICE OF THE MAYOR
SAN FRANCISCO

DANIEL LURIE
MAYOR

TO: Angela Calvillo, Clerk of the Board of Supervisors
FROM: Adam Thongsavat, Liaison to the Board of Supervisors
RE: Accept and Expend Grant Increase - Retroactive - National Institutes of Health - Florida State University - Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) Scientific Leadership Center - $235,358
DATE: November 18, 2025

Resolution retroactively authorizing the Department of Public Health to accept and expend a grant increase from the National Institutes of Health through Florida State University for participation in a program, entitled "Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) Scientific Leadership Center," in the amount of $62,295 for the period May 21, 2025 through November 30, 2025 for a total amount of $235,358 for the total period of January 25, 2023, through November 30, 2025.

Should you have any questions, please contact Adam Thongsavat at adam.thongsavat@sfgov.org

1 DR. CARLTON B. GOODLETT PLACE, ROOM 200
SAN FRANCISCO, CALIFORNIA 94102-4681
TELEPHONE: (415) 554-6141