File No. 241199 **Committee Item No.** _____
Board Item No. 15

COMMITTEE/BOARD OF SUPERVISORS

AGENDA PACKET CONTENTS LIST

Committee: Budget and Finance Committee **Date** _____
Board of Supervisors Meeting **Date** January 14, 2025

Cmte Board

☐	☐	**Motion**
☐	☒	**Resolution**
☐	☐	**Ordinance**
☐	☐	**Legislative Digest**
☐	☐	**Budget and Legislative Analyst Report**
☐	☐	**Youth Commission Report**
☐	☐	**Introduction Form**
☐	☒	**Department/Agency Cover Letter and/or Report**
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☐	☒	**Grant Information Form**
☐	☒	**Grant Budget**
☐	☐	**Subcontract Budget**
☐	☐	**Contract/Agreement**
☐	☐	**Form 126 – Ethics Commission**
☐	☒	**Award Letter**
☐	☐	**Application**
☐	☐	**Public Correspondence**

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

☐	☒	Subaward Amendment No. 1 051823
☐	☒	Subaward Amendment No. 2 082824
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Completed by: Brent Jalipa **Date** January 9, 2025
Completed by: Brent Jalipa **Date** _____

FILE NO. 241199 RESOLUTION NO.

[Accept and Expend Grant - Retroactive - National Institutes of Health - University of Texas Southwestern Medical Center - NIDA Clinical Trials Network: Big South/West Node - $104,508]

Resolution retroactively authorizing the Department of Public Health to accept and expend a grant increase in the amount of $13,431 from the National Institutes of Health through the University of Texas Southwestern Medical Center, for a new total amount of $104,508 for participation in a program, entitled "NIDA Clinical Trials Network: Big South/West Node," for the period of April 1, 2022, through February 28, 2025.

WHEREAS, The National Institutes of Health (NIH) through the University of Texas Southwestern Medical Center (UTS) has agreed to fund the Department of Public Health (DPH) in the amount of $104,508 for participation in a program, entitled "NIDA Clinical Trials Network: Big South/West Node," for the period of April 1, 2022, through February 28, 2025; and

WHEREAS, The funds will be used to fund an eight-week, double-blind, randomized placebo-controlled trial to determine the efficacy of a combination of extended-release medication compared to placebo injections for the treatment of cocaine use disorder (CUD); and

WHEREAS, The primary objective is to evaluate whether assignment of eight weeks of outpatient medication compared to placebo injections reduces urine-verified cocaine use in study Weeks five through eight; and

WHEREAS, The Center on Substance Use and Health (CSUH) will competitively randomize participants into the study with a goal of three to four participants each month over an estimated 17-month recruitment period; and

WHEREAS, CSUH will dedicate staff time and resources to conduct the study with regular reporting to the Lead Team; and

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

WHEREAS, A grant increase of $13,431 was approved for the period of March 1, 2024, through February 28, 2025; and

WHEREAS, A request for retroactive approval is being sought because DPH received the original grant agreement/award letter/memorandum in the amount of $50,881 on May 3, 2023 for a project start date of April 1, 2022, then received an increase in grant funds in the amount of $40,196 on May 18, 2023, for a project start date of March 1, 2023, and received another increase in grant funds in the amount of $13,431 on August 29, 2024, for a project start date of March 1, 2024; and

WHEREAS, The grant budget includes a provision for indirect costs in the amount of $17,200; now, therefore, be it

RESOLVED, That DPH is hereby authorized to retroactively accept and expend a grant in the amount of $104,508 from the NIH through UTS; 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 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/_____

Dr. Grant Colfax

Director of Health

Approved: _____/s/_____

Benjamin McCloskey,

Interim Mayor's Budget Director

Approved: _/s/Jocelyn Quintos for Greg Wagner

Greg Wagner, Controller

File Number: 241199
(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: **NIDA Clinical Trials Network: Big South/West Node**

2. Department: **Department of Public Health**
Center for Public Research

3. Contact Person: **Philip Coffin** Telephone: **415-437-6282**

4. Grant Approval Status (check one):

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

5. Amount of Grant Funding Approved or Applied for: **$104,508**
(April 01, 2022 – February 28, 2023: $50,881
March 01, 2023 – February 29, 2024: $40,196
March 01, 2024 – February 28, 2025: $13,431)

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

7a. Grant Source Agency: **National Institutes of Health (NIH)**
b. Grant Pass-Through Agency (if applicable): **University of Texas Southwestern Medical Center**

8. Proposed Grant Project Summary:
The funds will be used to fund an 8-week, double-blind, randomized placebo-controlled trial to determine the efficacy of a combination of extended-release naltrexone (XR-NTX) and extended-release buprenorphine (XR-BUP) compared to placebo injections (PBO-Inj) for the treatment of cocaine use disorder (CUD). The primary objective is to evaluate whether assignment of 8 weeks of outpatient XR-NTX + XR-BUP compared to PBO-Inj reduces urine-verified cocaine use in study Weeks 5 through 8. The primary outcome measure is the proportion of cocaine-negative urine drug screens (UDS) obtained during Weeks 5 through 8 as measured for the XR-NTX + XR-BUP and PBO-Inj conditions. The secondary objective is to evaluate the effect of assignment to 8 weeks of XR-NTX + XR-BUP compared to PBO-Inj on self-report days of cocaine use, cocaine craving, safety, and treatment effectiveness. The secondary outcome measures are 1) Self-reported days of cocaine use and cocaine craving effects (Visual Analog Scale (VAS)) during Weeks 0-8; 2) Measures of adverse events during Weeks 0-8: number and severity of adverse events; number and outcomes (fatal/non-fatal) of overdose events reported; 3) Measures of Treatment Effectiveness Assessment (TEA) at Week 8.
The Center on Substance Use and Health (CSUH) will competitively randomize participants into the study with a goal of 3-4 participants each month over an estimated 17-month recruitment period. CSUH will dedicate staff time and resources to conduct of the study with regular reporting to the Lead Team.

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

Start-Date: **04/01/2022** End-Date: **02/28/2025**

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? **$17,200** b2. How was the amount calculated? **19.7% of Total Direct 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 March 1, 2024. The Department received the grant increase of $13,431 on August 29, 2024, for the period of March 1, 2024, to February 28, 2025. The AL # for this grant is 93.279.

This grant does not require an ASO amendment, does not create net new position(s), and partially reimburses the Department for one position:

No.	Class	Job Title	FTE	Start Date	End Date
1	2232	Senior Physician Specialist	0.015	03/01/2024	02/28/2025

Project Description: **HD HIV PD196 2425 NIDA Clinical Trails Network: Big South/West Node**
Project ID: **10041200**
Proposal ID: **CTR00004136**
Fund: **11580**
Version ID: **V101**
Authority ID: **10001**
Activity ID: **0001**

****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: 11/22/2024 | 3:41 PM PST

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

Department Head or Designee Approval of Grant Information Form:

Dr. Grant Colfax
(Name)

Director of Health
(Title)

Date Reviewed: 11/23/2024 | 6:48 AM PST

DocuSigned by:
Jenny Louie for Dr. Colfax
40CFE25DD8B4404...
Jenny Louie, COO for

SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH
Center for Public Research
NIDA Clinical Trials Network: Big South/West Node
April 1, 2022 - February 28, 2025

		Year 1 Project: 10040072 4/1/22 - 2/28/23	Year 2 Project: 10040337 3/1/23 - 2/29/24	Year 3 Project: 10041200 3/1/24 - 2/28/25	Total Amount
	Personnel -				-
	Senior Physician Specialist	19,521	9,865	3,288	32,674
					-
					-
	Fringe benefits	7,028	3,551	1,184	11,763
					-
	Rent	17,780	18,818	6,273	42,871
					-
					-
					-
					-
					-
	Indirect Costs	6,552	7,962	2,686	17,200
Total		**50,881**	**40,196**	**13,431**	**104,508**

San Francisco Department of Public Health (SFDPH)
Population Health Division – Center for Public Research
NIDA Clinical Trials Network: Big South/West Node

BUDGET JUSTIFICATION
March 1, 2024 to February 28, 2025

A. PERSONNEL

1. 0.015 2232 – Senior Physician Specialist: Phillip Coffin
Annual Salary $ 221,900 x 0.015 FTE for 12 months = $3,288

B. MANDATORY FRINGE

2. Mandatory Fringe Benefits (@ 36%) = $1,184

Total Salaries	$3,288
Total Fringe	$1,184
TOTAL PERSONNEL:	**$4,472**
C. TRAVEL	**$0**
D. RENT	**$6,273**
E. SUPPLIES	**$0**
F. CONTRACTUAL	**$0**
G. OTHER	**$0**
TOTAL DIRECT COSTS	**$10,745**
H. INDIRECT COSTS	**$2,686**
TOTAL BUDGET:	**$13,431**

FDP Subaward Amendment

Amendment No: 1 | Subaward No: GMO 230401 PO000002962A

Pass-Through Entity (PTE)		Subrecipient	
The University of Texas Southwestern Medical Center	Entity Name	City and County of San Francisco	
subawards@utsouthwestern.edu	Contact Email	eduardo.sida@sfdph.org	
Madhukar Trivedi, MD	Principal Investigator	Phillip Coffin, M.D., M.I.A.	

Project Title: NIDA Clinical Trials Network: Big South/West Node

PTE/Prime Award No.: 5UG1DA020024-19 | Awarding Agency: National Institutes of Health (NIH)

Cumulative Budget Period(s) (Agreement Start Date) Start Date: 04/01/2022	(End Date of Latest Budget Period) End Date: 02/29/2024	Amount Funded This Action	Total Amount of Funds Obligated to Date
		$ 40,196.00	$ 91,077.00

Subrecipient Cost Share ☐ | Subject to FFATA ☐

Amendment(s) to Original Terms and Conditions

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

☒ **Additional Budget Period**

Additional budget period 03/01/2023 - 02/29/2024 is hereby added to this Subaward.

☐ **No Cost Extension**

☒ **Additional Funding**

Additional funding in the amount of $ 40,196.00 is hereby obligated to this Subaward.

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

(If changing carryover restrictions from prior Agreement, PTE must use the bilateral modification template)

☐ **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 Attached** (Select any that apply)

☒ New Budget ☐ Supplemental Budget ☒ Notice of Award

☐ Revised Budget ☐ Carryover Budget

The selected document(s) are hereby incorporated by attachment to this Amendment. The scope of work remains unchanged.

For all other contractual changes, the PTE must use the bilateral modification template

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: Docusigned by: Cheryl Anderson EC40EC947C9C4CD... DS JM Date 5/18/2023

Name: Cheryl L. Anderson, CRA

Title: Director, Pre-Award Administration

The Subrecipient is not required to countersign this amendment. Unilateral acceptance of this modification does not bypass internal approval processes of the Subrecipient. If Subrecipient would like to terminate this action, a request should be directed to PTE's Administrative Contact.

City & County of San Francisco - Dept of Public (CCSF-DPH)

Statement of Work (SOW)

CTN-0109: Randomized, placebo-controlled trial of injectable naltrexone and monthly injectable buprenorphine for cocaine use (CURB-2)

Big South/West Node

Yr18 Period of Performance: 03/01/2023 – 02/29/2024

Dr. Phillip Coffin, City & County of San Francisco - Dept of Public, will be the Site PI for the Center for Substance Use and Health (CSUH), one of twelve study sites to conduct the CTN-0109 CURB-2 study. This is an 8-week, double-blind, randomized placebo-controlled trial to determine the efficacy of a combination of extended-release naltrexone (XR-NTX) and extended-release buprenorphine (XR-BUP) compared to placebo injections (PBO-Inj) for the treatment of cocaine use disorder (CUD). The primary objective is to evaluate whether assignment of 8 weeks of outpatient XR-NTX + XR-BUP compared to PBO-Inj reduces urine-verified cocaine use in study Weeks 5 through 8. The primary outcome measure is the proportion of cocaine-negative urine drug screens (UDS) obtained during Weeks 5 through 8 as measured for the XR-NTX + XR-BUP and PBO-Inj conditions. The secondary objective is to evaluate the effect of assignment to 8 weeks of XR-NTX + XR-BUP compared to PBO-Inj on self-report days of cocaine use, cocaine craving, safety, and treatment effectiveness. The secondary outcome measures are 1) Self-reported days of cocaine use and cocaine craving effects (Visual Analog Scale (VAS)) during Weeks 0-8; 2) Measures of adverse events during Weeks 0-8: number and severity of adverse events; number and outcomes (fatal/non-fatal) of overdose events reported; 3) Measures of Treatment Effectiveness Assessment (TEA) at Week 8.

CSUH will competitively randomize participants into the study with a goal of 3-4 participants each month over an estimated 17-month recruitment period. CSUH will dedicate staff time and resources to conduct of the study with regular reporting to the Lead Team. Dr. Coffin will be responsible for oversight of all local scientific and administrative processes and procedures required for implementation of this study at CSUH, including development of site-specific standard operating procedures (SOPs) for study. He will assign the research staff and assist with their training and supervision and will support the activities of the study physicians.

City & County of San Francisco - Dept of Public Health

Budget Justification

CTN-0109: Randomized, placebo-controlled trial of injectable naltrexone and monthly injectable buprenorphine for cocaine use (CURB-2)

Big South/West Node

Yr19 Period of Performance: 03/01/2023 – 02/29/2024

CTN-0109 CURB-2 CCSF-DPH: Total $40,196 ($32,234 Direct; $7,962 F&A)

CTN-0109 CURB-2 CCSF-DPH PERSONNEL Total $13,416 ($9,865 Salary; $3,551 Fringe)

Person	Role	Cal Mths	Inst Base Salary	Salary	Fringe	Total	# mths
Coffin	Site PI	0.60	$ 197,300	$ 9,865	$ 3,551	$ 13,416	12

CTN-0109 CURB-2 CCSF-DPH OTHER EXPENSE: Total $18,818

CCSF-DPH requires rent expense calculated as $4,704.50 times 4 months.

CTN-0109 CURB-2 CCSF-DPH F&A EXPENSE: Total $7,962

Direct is $32,234. MTDC is $32,234. CCSF-DPH F&A Rate is 24.70%. Total CCSFDPH F&A requested is $7,962.

Recipient Information

1. Recipient Name
UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER, THE
5323 HARRY HINES BLVD

DALLAS, 75390

2. Congressional District of Recipient
30

3. Payment System Identifier (ID)
1756002868A4

4. Employer Identification Number (EIN)
756002868

5. Data Universal Numbering System (DUNS)
800771545

6. Recipient's Unique Entity Identifier
YZJ6DKPM4W63

7. Project Director or Principal Investigator
MADHUKAR H. TRIVEDI, MD (Contact)
Professor
MADHUKAR.TRIVEDI@UTSOUTHWESTERN.EDU
214-648-0181

8. Authorized Official
LaTasha Stevenson
Latasha.Stevenson@UTSouthwestern.edu
212-648-4323

Federal Agency Information

9. Awarding Agency Contact Information
Allison Moyal
Grants Management Specialist
NATIONAL INSTITUTE ON DRUG ABUSE
moyala@mail.nih.gov
3018278036

10. Program Official Contact Information
Ronald Dobbins

NATIONAL INSTITUTE ON DRUG ABUSE
rdobbins@nida.nih.gov
301 443-6697

Federal Award Information

11. Award Number
5UG1DA020024-19

12. Unique Federal Award Identification Number (FAIN)
UG1DA020024

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

14. Federal Award Project Title
NIDA Clinical Trials Network: Big South/West Node

15. Assistance Listing Number
93.279

16. Assistance Listing Program Title
Drug Abuse and Addiction Research Programs

17. Award Action Type
Non-Competing Continuation

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 03/01/2023 **– End Date** 02/29/2024	
20. Total Amount of Federal Funds Obligated by this Action	$8,888,943
20 a. Direct Cost Amount	$7,589,312
20 b. Indirect Cost Amount	$1,299,631
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$8,888,943
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$8,888,943
26. Project Period Start Date 09/01/2005 **– End Date** 02/28/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$32,948,959

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Carol Alderson

30. Remarks

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

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

NATIONAL INSTITUTE ON DRUG ABUSE

SECTION I – AWARD DATA – 5UG1DA020024-19

Principal Investigator(s):
Jennifer Sharpe Potter, PHD
Steven J Shoptaw, PHD
MADHUKAR H. TRIVEDI (contact), MD

Award e-mailed to: grants.mgt@utsouthwestern.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $8,888,943 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UT SOUTHWESTERN MEDICAL CENTER in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 31 USC 6305 42 CFR 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 National Institute On Drug Abuse of the National Institutes of Health under Award Number UG1DA020024. 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,

Carol Alderson
Grants Management Officer
NATIONAL INSTITUTE ON DRUG ABUSE

Additional information follows

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

Salaries and Wages	$1,318,385
Fringe Benefits	$395,519
Personnel Costs (Subtotal)	$1,713,904
Consultant Services	$13,500
Materials & Supplies	$27,623
Travel	$94,041
Other	$206,066
Subawards/Consortium/Contractual Costs	$5,516,178
Publication Costs	$18,000
Federal Direct Costs	$7,589,312
Federal F&A Costs	$1,299,631
Approved Budget	$8,888,943
Total Amount of Federal Funds Authorized (Federal Share)	$8,888,943
TOTAL FEDERAL AWARD AMOUNT	$8,888,943
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$8,888,943

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
19	$8,888,943	$8,888,943
20	$778,990	$778,990

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

Fiscal Information:

Payment System Identifier:	1756002868A4
Document Number:	UDA020024D
PMS Account Type:	P (Subaccount)
Fiscal Year:	2023

IC	CAN	2023	2024
DA	8054627	$3,160,172	$0
DA	8472653	$5,728,771	$778,990

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

NIH Administrative Data:
PCC: CT/RDD / **OC**: 41029 / **Released**: Alderson, Carol 03/01/2023
Award Processed: 03/02/2023 12:12:18 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5UG1DA020024-19

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 – 5UG1DA020024-19

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).

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

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) UG1DA020024. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

This award is not subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170.

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.

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 – DA SPECIFIC AWARD CONDITIONS – 5UG1DA020024-19

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.

This award contains grant-specific restrictions. These restrictions may only be lifted by a revised Notice of Award (NoA).

HUMAN SUBJECTS RESTRICTION - Single IRB (sIRB) REQUIRED
This award is being issued without a currently valid certification of an acceptable Single Institutional Review Board (sIRB) approval for this multi-site project with the following restriction: Only activities that are clearly severable and independent from activities that involve human subjects **related to CTN-0120 and CTN-0132** may be conducted pending NIDA's acceptance of the certification of sIRB approval. Proof of sIRB approval must be submitted within 30 days of approval.

Only activities that are clearly severable and independent from activities that involve human subjects may be conducted until OHRP has approved an Assurance and NIDA has received and accepted the recipient's certification of sIRB approval. No funds may be drawn down from the payment system and no obligations may be made against Federal funds for research involving human subjects for any period not covered by both an OHRP-approved FWA and an sIRB approval consistent with 45 CFR Part 46. 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.

See required elements here - Single IRB for Multi-Site or Cooperative Research | grants.nih.gov

FY2023 FUNDING – REVISED TOTAL COST
The award amount obligated for FY2023 represents an increase from the summary total on the -18 NoA. This increase represents the combined amount of core funds and study funds in accordance with RFA-DA-20-024, as per the email to the AOR dated 11/14/2022. This revised commitment is based upon cost analysis, program priorities and availability of funds.

CTN TERMS
This award is issued as a Cooperative Agreement, a financial assistance mechanism in which substantial NIH scientific and/or programmatic involvement is anticipated in the performance of the activity. This award is subject to the Cooperative Agreement Terms and Conditions of Award detailed in "Section VI. Award Administration Information" section of RFA-DA-20-024, "The National Drug Abuse Treatment Clinical Trials Network (UG1 Clinical Trial Required)", 9/4/2019, which are hereby incorporated by reference as special terms and conditions of this award.

The NIH Project Scientist for this Cooperative Agreement is:

CTN-0090: Yanping Liu
Email: liuyanp@mail.nih.gov
Phone: 301-451-4217

CTN-0108: Geetha Subramaniam
Email: subramaniamga@nida.nih.gov
Phone: 301-480-2593

CTN-0109: Udi Ghitza
Email: ghitzau@mail.nih.gov
Phone: 301-480-2529

CTN-0109-A-1: Udi Ghitza
Email: ghitzau@mail.nih.gov
Phone: 301-480-2529

CTN-0110: Udi Ghitza
Email: ghitzau@mail.nih.gov
Phone: 301-480-2529

CTN-0120: Udi Ghitza
Email: ghitzau@mail.nih.gov
Phone: 301-480-2529

CTN-0132: Udi Ghitza
Email: ghitzau@mail.nih.gov
Phone: 301-480-2529

DATA AND SAFETY MONITORING PLAN
This award is subject to the current Data Safety Monitoring Plan (DSMP) submitted and previously approved by NIDA. Any changes in the DSMP must be reviewed and approved by the Program Official. If changes are approved, the approval will be reflected on the Notice of Award (NoA). If changes are not approved, the Principal Investigator must revise the DSMP to the satisfaction of the Program Official. The Principal Investigator must provide a DSMP for any new trial that is to be conducted under this grant.

DATA AND SAFETY MONITORING BOARD (DSMB)
This award is subject to the NIDA Guidelines for Establishing and Operating a Data and Safety Monitoring Board.

NIH SALARY CAP
None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the current salary cap. See current salary cap levels at NIH's Salary Cap Summary .

PROTECTION OF HUMAN SUBJECTS & sIRB REQUIREMENTS
The recipient is reminded of the requirement for education in the protection of human research participation. This requirement can be satisfied by completing the on-line tutorial Protecting Human Research Participants (http://phrp.nihtraining.com). Additional details on this requirement can be found at NIH Notice NOT-OD-08-054, "Guidance on NIH Office of Extramural Research (OER) on-line tutorial Protecting Human Research Participants (PHRP)."
The recipient is reminded that NIH requires sites engaged in NIH-funded, multi-site research conducted at more than one domestic site to rely upon approval by a single Institutional Review Board (sIRB) as required by the Revised Common Rule (rCR) at 45 CFR Part 46.114 and the NIH sIRB Policy (NOT-OD-16-094), More information on this requirement can be found in the NIHGPS 4.1.15 Human Subjects Protections (nih.gov) and the NIH Notice NOT-OD-16-094, "Final NIH Policy on the Use of a Single Institutional review Board for Multi-Site Research"). Institutional Review Board (IRB) approval(s) is required for each new protocol and performance site prior to implementation of human subjects research. No funds may be drawn down from the payment system and no obligations may be made against Federal funds for research involving human subjects at any site engaged in such research for any period not covered by an Office for Human Research Protections Assurance and an IRB approval consistent with the requirements of 45 CFR Part 46.
Failure to comply with the above requirements may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action. See the NIH Grants Policy Statement, Section 4.1.15 Human Subjects Protections for specific requirements related to the protection of human subjects, which are applicable to and a term and condition of this award.

REBUDGETING
Funding is provided at the projected total cost. Funds may be rebudgeted between direct costs and facilities and administrative (F&A) costs, consistent with applicable cost principles and institutional and policy requirements for prior approval.

PARTICIPATION IN ANNUAL INVESTIGATOR MEETINGS
The NIH HEAL Initiative will require a high level of coordination and sharing between investigators. It is expected that NIH HEAL Initiative recipients will cooperate and coordinate their activities after awards are made by participating in Program Director/Principal Investigator (PD/PI) meetings, including an annual HEAL Investigators Meeting, as well as other activities.

HEAL DATA SHARING PLATFORM REQUIREMENTS

NIH intends to maximize the impact of HEAL Initiative-supported projects through broad and rapid data sharing. As a requirement of the **HEAL Initiative Public Access and Data Sharing Policy** (https://heal.nih.gov/data/public-access-data), and in line with the new **NIH Policy for Data Management and Sharing** (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html), all HEAL Initiative award recipients, regardless of the amount of direct costs requested for any budget or project period, are required to include a Data Management and Sharing Plan outlining how scientific data, accompanying metadata, other relevant data, and associated documentation will be managed and shared. The plan should describe data types, file formats, submission timelines, and standards used in collecting or processing the data. It is expected that data generated by HEAL Initiative-funded projects will be submitted to study-appropriate domain-specific or generalist repositories in consultation with the HEAL Data Stewardship Group to ensure the data is accessible via the HEAL Initiative Data Ecosystem. Recipients shall consult with the HEAL Data Stewardship Group to follow requirements and timelines developed through the HEAL Initiative Data Ecosystem, for example, use of HEAL Data Ecosystem resources including but not limited to recommended repositories, clinical data elements, metadata standards, and data dictionaries.

As a standard term and condition of award all data collected as part of the NIH HEAL Initiative are collected under a Certificate of Confidentiality and entitled to the protections thereof. Recipients who receive Data and/or Materials from this award for performance of activities under this award are required to use the Data and/or Materials only as outlined by the NIH HEAL Initiative, in a manner that is consistent with applicable state and federal laws and regulations, including any informed consent requirements and the terms of the recipient's NIH funding, including 42 U.S.C. 241(d). Failure to adhere to the terms and conditions of the award, NIH may take one or more enforcement actions which include disallowing costs, withholding of further awards, or wholly or partly suspending the grant, pending corrective action.

It is expected that all data collected by award recipients and their collaborators as part of the NIH HEAL Initiative will be accessible via the HEAL Data Ecosystem. Award recipients and their collaborators are required to acknowledge HEAL Initiative support by referencing in the acknowledgement sections of any relevant publication the following terminology “the HEAL Initiative (https://heal.nih.gov.” For more information regarding HEAL Initiative data sharing, visit the HEAL Initiative Data Ecosystem.

HEAL Initiative studies conducting clinical research or research involving human subjects must meet the following additional requirements:

- HEAL Initiative trials that are required to register in clinicaltrials.gov should reference support from and inclusion in the HEAL Initiative by including the standardized terms “the HEAL Initiative (https://heal.nih.gov/)” in the Study Description Section.
- All new HEAL clinical pain studies are required to submit their case-report forms/questionnaires to the HEAL Clinical Data Elements (CDE) Program. The program will create the CDE files containing standardized variable names, responses, coding, and other information. The program will also format the case-report forms in a standardized way that is compliant with accessibility standards under Section 508 of the Rehabilitation Act of 1973 (29 U.S.C § 794 (d)), which “require[s] Federal agencies to make their electronic and information technology accessible to people with disabilities.” HEAL Initiative clinical studies that are using copyrighted questionnaires are required to obtain licenses for use prior to initiating data collection. Licenses must be shared with the HEAL CDE team and the program officer prior to use of copyrighted materials. For additional information, visit the HEAL CDE Program.
- To the extent possible, HEAL awardees are expected to integrate broad data sharing consent language into their informed consent forms.

NIDA TERMS

In conjunction with the Acknowledgment of Federal Funding Requirement (as specified in the NIH Grants Policy Statement, Appropriation Mandates http://grants.nih.gov/policy/nihgps/index.htm), in order to most effectively disseminate research results, advance notice should be given to NIDA that research findings are about to be published so that we may coordinate accurate and timely release to the media. This information will be embargoed until the publication date. Please see

the NIDA Special Considerations Page for guidance on coordination with the NIDA Press Office at https://www.drugabuse.gov/funding/special-considerations-for-nida-funding, or contact the NIDA Press Office at media@nida.nih.gov.

Please see Special Considerations for NIDA Funding Opportunities and Awards at https://www.drugabuse.gov/funding/special-considerations-for-nida-funding

SPREADSHEET SUMMARY
AWARD NUMBER: 5UG1DA020024-19

INSTITUTION: UT SOUTHWESTERN MEDICAL CENTER

Budget	Year 19	Year 20
Salaries and Wages	$1,318,385	$223,379
Fringe Benefits	$395,519	$53,288
Personnel Costs (Subtotal)	$1,713,904	$276,667
Consultant Services	$13,500	
Materials & Supplies	$27,623	$675
Travel	$94,041	$24,330
Other	$206,066	$13,660
Subawards/Consortium/Contractual Costs	$5,516,178	$261,846
Publication Costs	$18,000	
TOTAL FEDERAL DC	$7,589,312	$577,178
TOTAL FEDERAL F&A	$1,299,631	$201,812
TOTAL COST	$8,888,943	$778,990

Facilities and Administrative Costs	Year 19	Year 20
F&A Cost Rate 1	64%	64%
F&A Cost Base 1	$2,030,673	$315,332
F&A Costs 1	$1,299,631	$201,812

FDP Subaward Amendment

Awarding Agency: National Institutes of Health (NIH)
Amendment No: 2
PTE/Prime Award No.: 5UG1DA020024-20
Subaward No: GMO 230401 PO000002962B

Pass-Through Entity (PTE)		Subrecipient
The University of Texas Southwestern Medical Center	Entity Name	City and County of San Francisco
subawards@utsouthwestern.edu	Contact Email	eduardo.sida@sfdph.org
Madhukar Trivedi, MD	Principal Investigator	Phillip Coffin,MD, MIA, FACP, FIDSA

Project Title: NIDA Clinical Trials Network: Big South/West Node

Cumulative Budget Period(s) (Agreement Start Date) Start Date: 04/01/2022 (End Date of Latest Budget Period) End Date: 02/28/2025	Amount Funded This Action	Total Amount of Funds Obligated to Date
	$ 13,431.00	$ 104,508.00

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 03/01/2024 - 06/30/2024 is hereby added to this Subaward.

☐ **No Cost Extension**

☒ **Additional Funding**
Additional funding in the amount of $ 13,431.00 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, Scope of Work, and Budget is incorporated by attachment to this Amendment.

☒ **Other (See Below)**

Purchase Order Number changed from PO# 000002962A to PO# 000002962B

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: Cheryl Anderson EC40EC9A7C9C4CD...	DocuSigned by: Susan Philip 4C9D2E27476A474...
Date: 8/29/2024	Date: August 28, 2024 |
Name: Cheryl L. Anderson, CRA	Name: Grant Colfax, MD
Title: Director, Pre-Award Administration	Title: Director of Health

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

City & County of San Francisco - Dept of Public (CCSF-DPH)

Statement of Work (SOW)

CTN-0109: Randomized, placebo-controlled trial of injectable naltrexone and monthly injectable buprenorphine for cocaine use (CURB-2)

Big South/West Node

Yr20 Period of Performance: 03/01/2024 – 02/28/2025

Dr. Phillip Coffin, City & County of San Francisco - Dept of Public, will be the Site PI for the Center for Substance Use and Health (CSUH), one of twelve study sites to conduct the CTN-0109 CURB-2 study. This is an 8-week, double-blind, randomized placebo-controlled trial to determine the efficacy of a combination of extended-release naltrexone (XR-NTX) and extended-release buprenorphine (XR-BUP) compared to placebo injections (PBO-Inj) for the treatment of cocaine use disorder (CUD). The primary objective is to evaluate whether assignment of 8 weeks of outpatient XR-NTX + XR-BUP compared to PBO-Inj reduces urine-verified cocaine use in study Weeks 5 through 8. The primary outcome measure is the proportion of cocaine-negative urine drug screens (UDS) obtained during Weeks 5 through 8 as measured for the XR-NTX + XR-BUP and PBO-Inj conditions. The secondary objective is to evaluate the effect of assignment to 8 weeks of XR-NTX + XR-BUP compared to PBO-Inj on self-report days of cocaine use, cocaine craving, safety, and treatment effectiveness. The secondary outcome measures are 1) Self-reported days of cocaine use and cocaine craving effects (Visual Analog Scale (VAS)) during Weeks 0-8; 2) Measures of adverse events during Weeks 0-8: number and severity of adverse events; number and outcomes (fatal/non-fatal) of overdose events reported; 3) Measures of Treatment Effectiveness Assessment (TEA) at Week 8.

CSUH will competitively randomize participants into the study with a goal of 3-4 participants each month over an estimated 17-month recruitment period. CSUH will dedicate staff time and resources to conduct of the study with regular reporting to the Lead Team. Dr. Coffin will be responsible for oversight of all local scientific and administrative processes and procedures required for implementation of this study at CSUH, including development of site-specific standard operating procedures (SOPs) for study. He will assign the research staff and assist with their training and supervision and will support the activities of the study physicians.

City & County of San Francisco - Dept of Public Health

Budget Justification

CTN-0109: Randomized, placebo-controlled trial of injectable naltrexone and monthly injectable buprenorphine for cocaine use (CURB-2)

Big South/West Node

Yr20 Period of Performance: 03/01/2024 – 02/28/2025

CTN-0109 CURB-2 CCSF-DPH: Total $13,431 ($10,745 Direct; $2,686 F&A)

CTN-0109 CURB-2 CCSF-DPH PERSONNEL Total $4,472 ($3,288 Salary; $1,184 Fringe)

CTN-0109 CURB-2 CCSF-DPH OTHER EXPENSE: Total $6,273

CCSF-DPH requires rent expense calculated as $1,568.25 times 4 months.

CTN-0109 CURB-2 CCSF-DPH F&A EXPENSE: Total $2,686

Direct is $10,745. MTDC is $10,745. CCSF-DPH F&A Rate is 25%. Total CCSFDPH F&A requested is $2,686.

National Institutes of Health
NATIONAL INSTITUTE ON DRUG ABUSE

Notice of Award
FAIN# UG1DA020024
Federal Award Date
06/11/2024

Recipient Information

1. Recipient Name
THE UNIVERSITY OF TEXAS
SOUTHWESTERN MEDICAL CENTER
5323 HARRY HINES BLVD
DALLAS, TX 75390

2. Congressional District of Recipient
30

3. Payment System Identifier (ID)
1756002868A4

4. Employer Identification Number (EIN)
756002868

5. Data Universal Numbering System (DUNS)
800771545

6. Recipient's Unique Entity Identifier
YZJ6DKPM4W63

7. Project Director or Principal Investigator
MADHUKAR H. TRIVEDI, MD (Contact)
Professor
madhukar.trivedi@utsouthwestern.edu
214-648-0181

8. Authorized Official
LaTasha Stevenson
Latasha.Stevenson@UTSouthwestern.edu
212-648-4323

Federal Agency Information

9. Awarding Agency Contact Information
Allison Moyal
Grants Management Specialist
NATIONAL INSTITUTE ON DRUG ABUSE
moyala@mail.nih.gov
3018278036

10. Program Official Contact Information
Ronald Dobbins

NATIONAL INSTITUTE ON DRUG ABUSE
rdobbins@nida.nih.gov
301 443-6697

Federal Award Information

11. Award Number
5UG1DA020024-20

12. Unique Federal Award Identification Number (FAIN)
UG1DA020024

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

14. Federal Award Project Title
NIDA Clinical Trials Network: Big South/West Node

15. Assistance Listing Number
93.279

16. Assistance Listing Program Title
Drug Abuse and Addiction Research Programs

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 03/01/2024 **– End Date** 02/28/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$3,526,160
20 b. Indirect Cost Amount	$466,673
21. Authorized Carryover	$3,992,833
22. Offset	$0
23. Total Amount of Federal Funds Obligated this budget period	$5,809,886
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$5,809,886
26. Project Period Start Date 09/01/2005 **– End Date** 02/28/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$38,758,845

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Allison Moyal

30. Remarks

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

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

NATIONAL INSTITUTE ON DRUG ABUSE

SECTION I – AWARD DATA – 5UG1DA020024-20 REVISED

Principal Investigator(s):
Jennifer Sharpe Potter, PHD
Steven J Shoptaw, PHD
MADHUKAR H. TRIVEDI (contact), MD

Award e-mailed to: grants.mgt@utsouthwestern.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 UT SOUTHWESTERN MEDICAL CENTER in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 31 USC 6305 42 CFR 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 National Institute On Drug Abuse of the National Institutes of Health under Award Number UG1DA020024. 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,

Allison Moyal
Grants Management Officer
NATIONAL INSTITUTE ON DRUG ABUSE

Additional information follows

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

Salaries and Wages	$1,216,643
Fringe Benefits	$364,387
Personnel Costs (Subtotal)	$1,581,030
Consultant Services	$33,800
Materials & Supplies	$24,660
Travel	$99,068
Other	$269,486
Subawards/Consortium/Contractual Costs	$6,500,452
Federal Direct Costs	$8,508,496
Federal F&A Costs	$1,294,223
Approved Budget	$9,802,719
Total Amount of Federal Funds Authorized (Federal Share)	$5,809,886
Cumulative Authorized Carryover and Offset for this Budget Period	$3,992,833
TOTAL FEDERAL AWARD AMOUNT	$5,809,886
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
20	$5,809,886	$5,809,886

Fiscal Information:

Payment System Identifier:	1756002868A4
Document Number:	UDA020024D
PMS Account Type:	P (Subaccount)
Fiscal Year:	2024

IC	CAN	2024
DA	8042483	$574,889
DA	8472653	$5,234,997

NIH Administrative Data:
PCC: CT/RDD / **OC**: 41029 / **Released**: 06/10/2024
Award Processed: 06/11/2024 12:09:28 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5UG1DA020024-20 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 – 5UG1DA020024-20 REVISED

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

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

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

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

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

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) UG1DA020024. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

This award is not subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170.

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 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.

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 – DA SPECIFIC AWARD CONDITIONS – 5UG1DA020024-20 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.

This award contains grant-specific restrictions. These restrictions may only be lifted by a revised Notice of Award (NoA).

HUMAN SUBJECTS RESTRICTION - Single IRB (sIRB) REQUIRED (CTN-0132)
This award is being issued without a currently valid certification of an acceptable Single Institutional Review Board (sIRB) approval for this multi-site project with the following restriction: Only activities that are clearly severable and independent from activities that involve human subjects **related to CTN-0132** may be conducted pending NIDA's acceptance of the certification of sIRB approval. Proof of sIRB approval must be submitted within 30 days of approval.

Only activities that are clearly severable and independent from activities that involve human subjects may be conducted until OHRP has approved an Assurance and NIDA has received and accepted the recipient's certification of sIRB approval. No funds may be drawn down from the payment system and no obligations may be made against Federal funds for research involving human subjects for any period not covered by both an OHRP-approved FWA and an sIRB approval consistent with 45 CFR Part 46. 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.

See required elements here - Single IRB for Multi-Site or Cooperative Research | grants.nih.gov

REVISION #2 - CARRYOVER APPROVED
This revised award includes a carryover of $3,992,833 ($3,526,160 direct costs; $466,673 F&A costs) from the -18 year to the -20 year. These funds are restricted for the stated purpose(s) listed in the email request dated 5-30-24 from LaTasha Stevenson at UT Southwestern Medical Center and may not be rebudgeted or used for other purposes.

The recipient is reminded that carryover funds are subject to the appropriation in effect when the funds were initially awarded, and salaries must not exceed the applicable salary cap for that fiscal year. For additional information, see the NIH Grants Policy Statement (NIH GPS), and see Section on Salary Cap, Salary Limitation, 4.2.10, and Prior Approval Requirements, 8.1.2.

This revision supersedes Notice of Award (NoA) issued 4-29-24. All other terms below remain applicable.

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This award contains grant-specific restrictions. These restrictions may only be lifted by a revised Notice of Award (NoA).

HUMAN SUBJECTS RESTRICTION - Single IRB (sIRB) REQUIRED (CTN-0132)
This award is being issued without a currently valid certification of an acceptable Single Institutional Review Board (sIRB) approval for this multi-site project with the following restriction: Only activities that are clearly severable and independent from activities that involve human subjects **related to CTN-0132** may be conducted pending NIDA's acceptance of the certification of sIRB approval. Proof of sIRB approval must be submitted within 30 days of approval.

Only activities that are clearly severable and independent from activities that involve human subjects may be conducted until OHRP has approved an Assurance and NIDA has received and accepted the recipient's certification of sIRB approval. No funds may be drawn down from the payment system and no obligations may be made against Federal funds for research involving human subjects for any period not

covered by both an OHRP-approved FWA and an sIRB approval consistent with 45 CFR Part 46. 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.

See required elements here - Single IRB for Multi-Site or Cooperative Research | grants.nih.gov

REVISION #1 - FINAL FY2024 FUNDING LEVEL
This revised award restores funds to the previously committed level for the current budget period. Future year recommended levels remain unchanged.

This revision supersedes Notice of Award (NoA) issued 3-11-24. All other terms below remain applicable.

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FY2024 FUNDING– REVISED TOTAL COST
The award amount obligated for FY2024 represents an increase from the summary total on the -19 NOA. This increase represents the combined amount of core funds and study funds in accordance with RFA-DA-20-024, as per the email to the AOR dated 11-15-23. This revised commitment is based upon cost analysis, program priorities and availability of funds.

CTN TERMS
This award is issued as a Cooperative Agreement, a financial assistance mechanism in which substantial NIH scientific and/or programmatic involvement is anticipated in the performance of the activity. This award is subject to the Cooperative Agreement Terms and Conditions of Award detailed in "Section VI. Award Administration Information" section of RFA-DA-20-024, "The National Drug Abuse Treatment Clinical Trials Network (UG1 Clinical Trial Required)", 9/4/2019, which are hereby incorporated by reference as special terms and conditions of this award.

The NIH Project Scientist for this Cooperative Agreement is:

CTN-0108: Geetha Subramaniam
Email: subramaniamga@nida.nih.gov
Phone: 301-480-2593

CTN-0109: Udi Ghitza
Email: ghitzau@mail.nih.gov
Phone: 301-480-2529

CTN-0109-A-1: Udi Ghitza
Email: ghitzau@mail.nih.gov
Phone: 301-480-2529

CTN-0110: Udi Ghitza
Email: ghitzau@mail.nih.gov
Phone: 301-480-2529

CTN-0120: Udi Ghitza
Email: ghitzau@mail.nih.gov
Phone: 301-480-2529

CTN-0132: Udi Ghitza
Email: ghitzau@mail.nih.gov
Phone: 301-480-2529

DATA AND SAFETY MONITORING PLAN

This award is subject to the current Data Safety Monitoring Plan (DSMP) submitted and previously approved by NIDA. Any changes in the DSMP must be reviewed and approved by the Program Official. If changes are approved, the approval will be reflected on the Notice of Award (NoA). If changes are not approved, the Principal Investigator must revise the DSMP to the satisfaction of the Program Official. The Principal Investigator must provide a DSMP for any new trial that is to be conducted under this grant.

DATA AND SAFETY MONITORING BOARD (DSMB)
This award is subject to the NIDA Guidelines for Establishing and Operating a Data and Safety Monitoring Board.

NIH SALARY CAP
None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the current salary cap. See current salary cap levels at NIH's Salary Cap Summary .

PROTECTION OF HUMAN SUBJECTS & sIRB REQUIREMENTS
The recipient is reminded of the requirement for education in the protection of human research participation. This requirement can be satisfied by completing the on-line tutorial Protecting Human Research Participants (http://phrp.nihtraining.com). Additional details on this requirement can be found at NIH Notice NOT-OD-08-054, "Guidance on NIH Office of Extramural Research (OER) on-line tutorial Protecting Human Research Participants (PHRP)."
The recipient is reminded that NIH requires sites engaged in NIH-funded, multi-site research conducted at more than one domestic site to rely upon approval by a single Institutional Review Board (sIRB) as required by the Revised Common Rule (rCR) at 45 CFR Part 46.114 and the NIH sIRB Policy (NOT-OD-16-094), More information on this requirement can be found in the NIHGPS 4.1.15 Human Subjects Protections (nih.gov) and the NIH Notice NOT-OD-16-094, "Final NIH Policy on the Use of a Single Institutional review Board for Multi-Site Research"). Institutional Review Board (IRB) approval(s) is required for each new protocol and performance site prior to implementation of human subjects research. No funds may be drawn down from the payment system and no obligations may be made against Federal funds for research involving human subjects at any site engaged in such research for any period not covered by an Office for Human Research Protections Assurance and an IRB approval consistent with the requirements of 45 CFR Part 46.
Failure to comply with the above requirements may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action. See the NIH Grants Policy Statement, Section 4.1.15 Human Subjects Protections for specific requirements related to the protection of human subjects, which are applicable to and a term and condition of this award.

REBUDGETING
Funding is provided at the projected total cost. Funds may be rebudgeted between direct costs and facilities and administrative (F&A) costs, consistent with applicable cost principles and institutional and policy requirements for prior approval.

PARTICIPATION IN ANNUAL INVESTIGATOR MEETINGS
The NIH HEAL Initiative will require a high level of coordination and sharing between investigators. It is expected that NIH HEAL Initiative recipients will cooperate and coordinate their activities after awards are made by participating in Program Director/Principal Investigator (PD/PI) meetings, including an annual HEAL Investigators Meeting, as well as other activities.

HEAL DATA SHARING PLATFORM REQUIREMENTS
NIH intends to maximize the impact of HEAL Initiative-supported projects through broad and rapid data sharing. As a requirement of the **HEAL Initiative Public Access and Data Sharing Policy** (https://heal.nih.gov/data/public-access-data), and in line with the new **NIH Policy for Data Management and Sharing**

(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html), all HEAL Initiative award recipients, regardless of the amount of direct costs requested for any budget or project period, are required to include a Data Management and Sharing Plan outlining how scientific data, accompanying metadata, other relevant data, and associated documentation will be managed and shared. The plan should describe data types, file formats, submission timelines, and standards used in collecting or processing the data. It is expected that data generated by HEAL Initiative-funded projects will be submitted to study-appropriate domain-specific or generalist repositories in consultation with the HEAL Data Stewardship Group to ensure the data is accessible via the HEAL Initiative Data Ecosystem. Recipients shall consult with the HEAL Data Stewardship Group to follow requirements and timelines developed through the HEAL Initiative Data Ecosystem, for example, use of HEAL Data Ecosystem resources including but not limited to recommended repositories, clinical data elements, metadata standards, and data dictionaries.

As a standard term and condition of award all data collected as part of the NIH HEAL Initiative are collected under a Certificate of Confidentiality and entitled to the protections thereof. Recipients who receive Data and/or Materials from this award for performance of activities under this award are required to use the Data and/or Materials only as outlined by the NIH HEAL Initiative, in a manner that is consistent with applicable state and federal laws and regulations, including any informed consent requirements and the terms of the recipient's NIH funding, including 42 U.S.C. 241(d). Failure to adhere to the terms and conditions of the award, NIH may take one or more enforcement actions which include disallowing costs, withholding of further awards, or wholly or partly suspending the grant, pending corrective action.

It is expected that all data collected by award recipients and their collaborators as part of the NIH HEAL Initiative will be accessible via the HEAL Data Ecosystem. Award recipients and their collaborators are required to acknowledge HEAL Initiative support by referencing in the acknowledgement sections of any relevant publication the following terminology “the HEAL Initiative (https://heal.nih.gov.” For more information regarding HEAL Initiative data sharing, visit the HEAL Initiative Data Ecosystem.

HEAL Initiative studies conducting clinical research or research involving human subjects must meet the following additional requirements:

- HEAL Initiative trials that are required to register in clinicaltrials.gov should reference support from and inclusion in the HEAL Initiative by including the standardized terms “the HEAL Initiative (https://heal.nih.gov/)” in the Study Description Section.
- All new HEAL clinical pain studies are required to submit their case-report forms/questionnaires to the HEAL Clinical Data Elements (CDE) Program. The program will create the CDE files containing standardized variable names, responses, coding, and other information. The program will also format the case-report forms in a standardized way that is compliant with accessibility standards under Section 508 of the Rehabilitation Act of 1973 (29 U.S.C § 794 (d)), which “require[s] Federal agencies to make their electronic and information technology accessible to people with disabilities.” HEAL Initiative clinical studies that are using copyrighted questionnaires are required to obtain licenses for use prior to initiating data collection. Licenses must be shared with the HEAL CDE team and the program officer prior to use of copyrighted materials. For additional information, visit the HEAL CDE Program.
- To the extent possible, HEAL awardees are expected to integrate broad data sharing consent language into their informed consent forms.

NIDA TERMS

In conjunction with the Acknowledgment of Federal Funding Requirement (as specified in the NIH Grants Policy Statement, Appropriation Mandates

http://grants.nih.gov/policy/nihgps/index.htm), in order to most effectively disseminate research results, advance notice should be given to NIDA that research findings are about to be published so that we may coordinate accurate and timely release to the media. This information will be embargoed until the publication date. Please see the NIDA Special Considerations Page for guidance on coordination with the NIDA Press Office at https://www.drugabuse.gov/funding/special-considerations-for-nida-funding, or contact the NIDA Press Office at media@nida.nih.gov.

Please see Special Considerations for NIDA Funding Opportunities and Awards at https://www.drugabuse.gov/funding/special-considerations-for-nida-funding

SPREADSHEET SUMMARY
AWARD NUMBER: 5UG1DA020024-20 REVISED

INSTITUTION: UT SOUTHWESTERN MEDICAL CENTER

Budget	Year 20
Salaries and Wages	$1,216,643
Fringe Benefits	$364,387
Personnel Costs (Subtotal)	$1,581,030
Consultant Services	$33,800
Materials & Supplies	$24,660
Travel	$99,068
Other	$269,486
Subawards/Consortium/Contractual Costs	$6,500,452
TOTAL FEDERAL DC	$8,508,496
TOTAL FEDERAL F&A	$1,294,223
TOTAL COST	$5,809,886

Facilities and Administrative Costs	Year 20
F&A Cost Rate 1	64%
F&A Cost Base 1	$2,022,224
F&A Costs 1	$1,294,223

UT Southwestern Medical Center | My UTSW

City and County of San Francisco
1 Dr . Carlton B Groodlett Place Room 316
San Francisco, CA 94102

Re: Subaward No GMO230401 and PO0000002962 between UT Southwestern Medical Center and City and County of San Francisco under a National Institutes of Health (NIH)/ National Institute On Drug Abuse Grant No. 5UG1DA020024-18

UT Southwestern PI: Madhukar Trivedi, MD
City and County of San Francisco PI: Phillip Coffin, M.D., M.I.A.

Dear Subrecipient:
On behalf of UT Southwestern, Sponsored Programs Administration is pleased to welcome you as a subrecipient and collaborator on the above referenced sponsored project. UT Southwestern is responsible for the programmatic and financial monitoring of UT Southwestern sponsored award subrecipients.

In addition to the proposed contract, this welcome package provides important information and documentation that is critical to the successful administration and fiscal management of your subaward. The documents enclosed are:

- The proposed contract between your institution and UT Southwestern, containing all relevant budgetary, programmatic, administrative and financial information, terms and conditions, and reporting requirements;
- Require monthly invoices and require that costs are supported by adequate documentation such as vendor invoices, time and attendance records, approved purchase orders, receiving documents, Percentage of Principal Investigator effort, Travel documentation (i.e. receipts, travel itinerary), documentation expenses placed in maintenance and operations category.

A sample subrecipient invoice which your institution may use the sample as a template for billing UT Southwestern for the reimbursement of project expenses. If you opt to use this template, please ensure that your invoices include the same information as provided in the template.

At your earliest convenience, please duly execute the enclosed subaward and return to the attention of the undersigned. Questions of a technical or programmatic nature may be directed to the UT Southwestern principal investigator at madhukar.trivedi@utsouthwestern.edu

We look forward to working with you in facilitating a fruitful and productive collaboration.

Sincerely,
DocuSigned by:
Kenneth Chalk
76D0C4AD64274501...
Kenneth J Chalk
Contracts Specialist Lead
Sponsored Programs Administration
Direct 214-648-0876

FDP Cost Reimbursement Subaward

Federal Awarding Agency: National Institutes of Health (NIH)

Pass-Through Entity (PTE):	**Subrecipient:**
The University of Texas Southwestern Medical Center	City and County of San Francisco
PTE PI: Madhukar Trivedi, MD	Sub PI: Phillip Coffin, M.D., M.I.A.
PTE Federal Award No: 5UG1DA020024-18 REVISED	Subaward No: GMO230401 PO0000002962

Project Title: NIDA Clinical Trials Network: Big South/West Node

Subaward Budget Period: Start: 04/01/2022 End: 02/28/2023	Amount Funded This Action (USD): $ 50,881.00
Estimated Period of Performance: Start: 04/01/2022 End: 02/28/2025	Incrementally Estimated Total (USD): $ 86,968.00

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 Authorized Official Contact and the Subrecipient's Authorized Official 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:
DocuSigned by: Cheryl Anderson EC40EC947C9C4CD... DS JM	DocuSigned by: Greg Wagner 2652F024752845F...
Name: Cheryl L. Anderson, CRA	Name: Grant Colfax, MD
Title: Director, Pre-Award Administration	Title: Director of Health
Date: 5/3/2023	Date: 5/2/2023 11:09:

Approved as to form, David Chiu, City Attorney

By: DocuSigned by: Henry Lifton Henry L. Lifton, Deputy City Attorney

Attachment 1
Certifications and Assurances

Subaward Number:
GMO230401 PO0000002962

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

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

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

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

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

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

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

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

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

Attachment 2
Federal Award Terms and Conditions

Subaward Number: GMO230401 PO0000002962

Required Data Elements

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

Awarding Agency Institute (If Applicable)

Federal Award Issue Date	FAIN	Assistance Listing No.

Assistance Listing Program Title (ALPT)

Key Personnel Per NOA

This Subaward Is:

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

General Terms and Conditions

By signing this Subaward, Subrecipient agrees to the following:

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

Special Terms and Conditions:

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

No additional requirements

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 Shall Grant 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.

Work Involving Human or Vertebrate Animals (Select Applicable Options)

☐ No Human or Vertebrate Animals

IRB Exempt and determination will be provided upon request

☒ Human Subjects Exempt

☐ 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) Not Applicable

This section left intentionally blank

NIH Terms and Conditions

The Clinical Trial Indicator in Section IV of the PTE's NOA is stated as: No ?

Multiple PIs (MPI)

This subaward is not subject to an MPI Leadership Plan. ?

Certificate of Confidentiality:

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

Additional Terms

Attachment 3A
Pass-Through Entity (PTE) Contacts

Subaward Number: GMO230401 PO0000002

PTE Information

Entity Name: The University of Texas Southwestern Medical Center

Legal Address: 5323 Harry Hines Blvd.
Dallas, TX 75390-9020

Website: https://www.utsouthwestern.net/intranet/administration/sponsored-programs/

PTE Contacts

Central Email: subawards@utsouthwestern.edu

Principal Investigator Name: Madhukar Trivedi, MD

Email: madhukar.trivedi@utsouthwestern.edu Telephone Number: 214-648-0188

Administrative Contact Name: Kenneth J Chalk

Email: subawards@utsouthwestern.edu Telephone Number: 214-648-0860

COI Contact email (if different to above): conflictofinterest@utsouthwestern.edu

Financial Contact Name: Nell Cryer, Post Award Director

Email: Postawardbilling@utsouthwestern.edu Telephone Number: 214-648-0860

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

Authorized Official Name: Cheryl L. Anderson, CRA,Director, Pre-Award Administration

Email: subawards@utsouthwestern.edu Telephone Number: 214-648-0860

PI Address:

5323 Harry Hines Blvd.
Dallas, TX 75390-9119

Administrative Address:

5323 Harry Hines Blvd.
Dallas, TX 75390-9020

Invoice Address:

UT Southwestern Medical Center
ATTN: Sponsored Programs Administration
5323 Harry Hines Blvd
Dallas, TX 75390-9020
Or EMAIL INVOICES TO: AccountsPayable@UTSouthwestern.edu

Attachment 3B

Research Subaward Agreement

Subrecipient Contacts

Subaward Number: GMO230401 PO0000002962

Subrecipient Information for FFATA reporting

Entity's UEI/DUNS Name: CITY & COUNTY OF SAN FRANCISCO

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: Phillip Coffin, M.D., M.I.A.

Email: phillip.coffin@sfdph.org Telephone Number: (510) 407-2603

Administrative Contact Name: Eduardo Sida

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

Financial Contact Name: Sajid Shaikh

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

Invoice Email: sajid.shaikh@sfdph.org

Authorized Official Name: Greg Wagner

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

Legal Address:

101 Grove Street
San Francisco, CA 94103

Administrative Address:

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

Payment Address:

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

Attachment 3B-2

Highest Compensated Officers

Subaward Number: GMO230401 PO0000002962

Subrecipient:

Institution Name: City and County of San Francisco

PI Name: Phillip Coffin, M.D., M.I.A.

Highest Compensated Officers

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

Officer 1 Name:

Officer 1 Compensation:

Officer 2 Name:

Officer 2 Compensation:

Officer 3 Name:

Officer 3 Compensation:

Officer 4 Name:

Officer 4 Compensation:

Officer 5 Name:

Officer 5 Compensation:

Attachment 4
Reporting and Prior Approval Terms

Subaward Number: GMO230401 PO0000002962

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 Administrative Contact 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 Administrative Contact.

☒ 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 Administrative Contact 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 Administrative Contact.

Other Reports:

☐ In accordance with 37 CFR 401.14, Subrecipient agrees to notify both the Federal Awarding Agency via iEdison and PTE's Administrative Contact 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 Administrative Contact 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:

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

Additional Technical and Reporting Requirements:

Require monthly invoices

Require that Subrecipient maintain record retention policies in accordance with 2 CFR 200.333 to ensure costs are supported by adequate documentation such as vendor invoices, time and attendance records, approved purchase orders, receiving documents , Percentage of Principal Investigator effort, Travel documentation (i.e. receipts, travel itinerary), documentation expenses placed in maintenance and operations category.

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

Subaward Number: GMO230401 PO0000002962

Statement of Work

○ Below ◉ Attached, 1 pages

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

Budget Information

Indirect Information Indirect Cost Rate (IDC) Applied	24.678 %	**Cost Sharing**	No
Rate Type:	Modified Total Direct Costs	If Yes, include Amount: $	

Budget Details

○ Below ◉ Attached, 3 pages

Budget Totals

Direct Costs	$ 44,329.00
Indirect Costs	$ 6,552.00
Total Costs	$ 50,881.00

All amounts are in United States Dollars

City and County of San Francisco Department of Public Health (CCSF-DPH) Statement of Work (SOW)
CTN-0109: Randomized, placebo-controlled trial of injectable naltrexone and monthly injectable buprenorphine for cocaine use disorder (CURB-2)
Big South/West Node
Yr18 Period of Performance: 04/01/2022 – 02/28/2023

Dr. Phillip Coffin, City and County of San Francisco Department of Public Health, will be the Site PI for the Center for Substance Use and Health (CSUH), one of twelve study sites to conduct the CTN-0109 CURB-2 study. This is an 8-week, double-blind, randomized placebo-controlled trial to determine the efficacy of a combination of extended-release naltrexone (XR-NTX) and extended-release buprenorphine (XR-BUP) compared to placebo injections (PBO-Inj) for the treatment of cocaine use disorder (CUD). The primary objective is to evaluate whether assignment of 8 weeks of outpatient XR-NTX + XR-BUP compared to PBO-Inj reduces urine-verified cocaine use in study Weeks 5 through 8. The primary outcome measure is the proportion of cocaine-negative urine drug screens (UDS) obtained during Weeks 5 through 8 as measured for the XR-NTX + XR-BUP and PBO-Inj conditions. The secondary objective is to evaluate the effect of assignment to 8 weeks of XR-NTX + XR-BUP compared to PBO-Inj on self-report days of cocaine use, cocaine craving, safety, and treatment effectiveness. The secondary outcome measures are 1) Self-reported days of cocaine use and cocaine craving effects (Visual Analog Scale (VAS)) during Weeks 0-8; 2) Measures of adverse events during Weeks 0-8: number and severity of adverse events; number and outcomes (fatal/non-fatal) of overdose events reported; 3) Measures of Treatment Effectiveness Assessment (TEA) at Week 8.

CSUH will competitively randomize participants into the study with a goal of 3-4 participants each month over an estimated 17-month recruitment period. CSUH will dedicate staff time and resources to conduct of the study with regular reporting to the Lead Team. Dr. Coffin will be responsible for oversight of all local scientific and administrative processes and procedures required for implementation of this study at CSUH, including development of site-specific standard operating procedures (SOPs) for study. He will assign the research staff and assist with their training and supervision and will support the activities of the study physicians.

Program Director/Principal Investigator (Last, First, Middle): CCSF-DPH: Coffin, Phillip O.

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY	FROM 04/01/2022	THROUGH 02/28/2023

List PERSONNEL *(Applicant organization only)*
Use Cal, Acad, or Summer to Enter Months Devoted to Project
Enter Dollar Amounts Requested *(omit cents)* for Salary Requested and Fringe Benefits

NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths	INST.BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
Coffin	PD/PI	1.15			203,700	19,521	7,028	26,549
SUBTOTALS →						19,521	7,028	26,549

CONSULTANT COSTS none	0
EQUIPMENT *(Itemize)* none	0
SUPPLIES *(Itemize by category)*	
TRAVEL none	0
INPATIENT CARE COSTS none	0
OUTPATIENT CARE COSTS none	0
ALTERATIONS AND RENOVATIONS *(Itemize by category)* none	0
OTHER EXPENSES *(Itemize by category)* Rent	17,780
CONSORTIUM/CONTRACTUAL COSTS — DIRECT COSTS	0
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD *(Item 7a, Face Page)*	**$** 44,329
CONSORTIUM/CONTRACTUAL COSTS — FACILITIES AND ADMINISTRATIVE COSTS	0
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD	**$** 44,329

City and County of San Francisco Dept of Public Health (CCSF-DPH)

Budget Justification

CTN-0109: Randomized, placebo-controlled trial of injectable naltrexone and monthly injectable buprenorphine for cocaine use disorder (CURB-2)

Western States Node

Yr18 Period of Performance 04/01/2022 – 02/28/2023

CTN-0109 CURB-2 CCSF-DPH: Total $50,881 ($44,329 Direct; $6,552 F&A)

CTN-0109 CURB-2 CCSF-DPH PERSONNEL Total $26,549 ($19,521 Salary; $7,028 Fringe)

Site Principal Investigator, Phillip O. Coffin, MD, MIA, FACP, FIDSA (1.15 calendar months)

Dr. Coffin will serve as the study site principal investigator (PI) for the Center for Substance Use and Health (CSUH). He will be responsible for oversight of all local scientific and administrative processes and procedures required for implementation of the CURB-2 study, including development of site-specific standard operating procedures (SOPs) for study. He will assign the research staff and assist with their training and supervision and will support the activities of the study physicians. Dr. Coffin's salary here is based on the current NIH salary cap.

CTN-0109 CURB-2 CCSF-DPH OTHER EXPENSE: Total $17,780

CCSF-DPH requires rent expense calculated as (PHFE FTE + CCSF FTE) * Square Feet * # of months * $1.93. For this budget (3.2 + 0.20) * 250 * 11 * $1.93 = $17,780

CTN-0109 CURB-2 CCSF-DPH F&A EXPENSE: Total $6,552

Direct is $44,329. MTDC is $26,549 (Salaries & Wages). CCSF-DPH F&A Rate is 24.678%. Total CCSF-DPH F&A requested is $6,552.

Program Director/Principal Investigator (Last, First, Middle): CCSF-DPH: Coffin, Phillip O.

CHECKLIST

TYPE OF APPLICATION *(Check all that apply.)*

☐ NEW application. *(This application is being submitted to the PHS for the first time.)*

☐ RESUBMISSION of application number: _____
(This application replaces a prior unfunded version of a new, renewal, or revision application.)

☐ RENEWAL of grant number: _____
(This application is to extend a funded grant beyond its current project period.)

☒ REVISION to grant number: UG1DA020024
(This application is for additional funds to supplement a currently funded grant.)

☐ CHANGE of program director/principal investigator.

Name of former program director/principal investigator: _____

☐ CHANGE of Grantee Institution. Name of former institution: _____

☐ FOREIGN application ☐ Domestic Grant with foreign involvement List Country(ies) Involved:

INVENTIONS AND PATENTS *(Renewal appl. only)* ☐ No ☐ Yes

If "Yes," ☐ Previously reported ☐ Not previously reported

1. PROGRAM INCOME ***(See instructions.)***
All applications must indicate whether program income is anticipated during the period(s) for which grant support is request. If program income is anticipated, use the format below to reflect the amount and source(s).

Budget Period	Anticipated Amount	Source(s)
04/01/2022-02/28/2023	$0	n/a

2. ASSURANCES/CERTIFICATIONS ***(See instructions.)***
In signing the application Face Page, the authorized organizational representative agrees to comply with the policies, assurances and/or certifications listed in the application instructions when applicable. Descriptions of individual assurances/certifications are provided in the NIH Grants Policy Statement, Section 4: Public Policy Requirements, Objectives and Other Appropriation Mandates. If unable to certify compliance, where applicable, provide an explanation and place it after this page.

3. FACILITIES AND ADMINSTRATIVE COSTS (F&A)/ INDIRECT COSTS. See specific instructions.

☐ HHS Agreement dated: _____ ☐ No Facilities And Administrative Costs Requested.

☐ HHS Agreement being negotiated with _____ Regional Office.

☐ No HHS Agreement, but rate established with _____ Date _____

CALCULATION* *(The entire grant application, including the Checklist, will be reproduced and provided to peer reviewers as confidential information.)*

a. Initial budget period:	Amount of base $	26,549	x Rate applied	24.678	% = F&A costs	$	6,552
b. 02 year	Amount of base $		x Rate applied		% = F&A costs	$	
c. 03 year	Amount of base $		x Rate applied		% = F&A costs	$	
d. 04 year	Amount of base $		x Rate applied		% = F&A costs	$	
e. 05 year	Amount of base $		x Rate applied		% = F&A costs	$	
					TOTAL F&A Costs	$	6,552

*Check appropriate box(es):

☐ Salary and wages base ☐ Modified total direct cost base ☒ Other base *(Explain)*

☐ Off-site, other special rate, or more than one rate involved *(Explain)*

Explanation *(Attach separate sheet, if necessary.):*

Salaries and Benefits

Subaward Number:
GMO230401 PO0000002962

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.

Recipient Information

1. Recipient Name
UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER, THE
5323 HARRY HINES BLVD

DALLAS, 75390

2. Congressional District of Recipient
30

3. Payment System Identifier (ID)
1756002868A4

4. Employer Identification Number (EIN)
756002868

5. Data Universal Numbering System (DUNS)
800771545

6. Recipient's Unique Entity Identifier
YZJ6DKPM4W63

7. Project Director or Principal Investigator
MADHUKAR H. TRIVEDI, MD (Contact)
Professor
MADHUKAR.TRIVEDI@UTSOUTHWESTERN.EDU
214-648-0181

8. Authorized Official
LaTasha Stevenson
Latasha.Stevenson@UTSouthwestern.edu
212-648-4323

Federal Agency Information

9. Awarding Agency Contact Information
Allison Moyal
Grants Management Specialist
NATIONAL INSTITUTE ON DRUG ABUSE
moyala@mail.nih.gov
3018278036

10. Program Official Contact Information
Ronald Dobbins

NATIONAL INSTITUTE ON DRUG ABUSE
rdobbins@nida.nih.gov
301 443-6697

Federal Award Information

11. Award Number
5UG1DA020024-18

12. Unique Federal Award Identification Number (FAIN)
UG1DA020024

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

14. Federal Award Project Title
NIDA Clinical Trials Network: Big South/West Node

15. Assistance Listing Number
93.279

16. Assistance Listing Program Title
Drug Abuse and Addiction Research Programs

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 03/01/2022 **– End Date** 02/28/2023	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$6,635,445
20 b. Indirect Cost Amount	$403,417
21. Authorized Carryover	$7,038,862
22. Offset	$0
23. Total Amount of Federal Funds Obligated this budget period	$781,644
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$781,644
26. Project Period Start Date 09/01/2005 **– End Date** 02/28/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$24,060,016

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Carol Alderson

30. Remarks

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

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

NATIONAL INSTITUTE ON DRUG ABUSE

SECTION I – AWARD DATA – 5UG1DA020024-18 REVISED

Principal Investigator(s):
Jennifer Sharpe Potter, PHD
Steven J Shoptaw, PHD
MADHUKAR H. TRIVEDI (contact), MD

Award e-mailed to: grants.mgt@utsouthwestern.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 UT SOUTHWESTERN MEDICAL CENTER in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 31 USC 6305 42 CFR 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 National Institute On Drug Abuse of the National Institutes of Health under Award Number UG1DA020024. 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,

Carol Alderson
Grants Management Officer
NATIONAL INSTITUTE ON DRUG ABUSE

Additional information follows

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

Salaries and Wages	$1,323,348
Fringe Benefits	$393,126
Personnel Costs (Subtotal)	$1,716,474
Consultant Services	$10,000
Materials & Supplies	$14,771
Travel	$95,536
Other	$52,631
Subawards/Consortium/Contractual Costs	$7,386,462
Federal Direct Costs	$9,275,874
Federal F&A Costs	$1,426,546
Approved Budget	$10,702,420
Total Amount of Federal Funds Authorized (Federal Share)	$781,644
Cumulative Authorized Carryover and Offset for this Budget Period	$9,920,776
TOTAL FEDERAL AWARD AMOUNT	$781,644
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTAL FEDERAL AWARD AMOUNT YEAR (18) (for this Document Number)	
AWARD NUMBER	**TOTAL FEDERAL AWARD AMOUNT**
5UG1DA020024-18	$781,644
3UG1DA020024-18S1	$2,533,716
TOTAL	**$3,315,360**

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
18	$781,644	$3,315,360
19	$778,990	$3,939,162
20	$778,990	$1,720,672

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

Fiscal Information:

Payment System Identifier: 1756002868A4
Document Number: UDA020024D
PMS Account Type: P (Subaccount)
Fiscal Year: 2022

IC	CAN	2022	2023	2024
DA	8472653	$781,644	$778,990	$778,990

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

NIH Administrative Data:
PCC: CT/RDD / **OC**: 41029 / **Released**: Alderson, Carol 01/11/2023
Award Processed: 01/13/2023 12:01:18 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5UG1DA020024-18 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 – 5UG1DA020024-18 REVISED

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

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

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

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

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

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) UG1DA020024. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

This award is not subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170.

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.

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 – DA SPECIFIC AWARD CONDITIONS – 5UG1DA020024-18 REVISED

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

REVISION #5 - CARRYOVER APPROVED
This revised award includes a carryover of $7,038,862 ($5,335,735 for CTN-109 and $1,703,127 for CTN-0110) from the -17 year to the -18 year. These funds are restricted for the stated purpose(s) listed in the eRA submitted requests dated 11-10-22 from LaTasha Stevenson and dated 11-20-22 from Jamie Maiden at UT Southwestern Medical Center and may not be rebudgeted or used for other purposes.

This revision supersedes Notice of Award (NoA) issued 9-24-22. All other terms below remain applicable.

****

This award contains grant-specific restrictions. These restrictions may only be lifted by a revised Notice of Award.

REVISION #4 - ADDITIONAL PROTOCOL EXPENSES APPROVED
This revised award approves expenditure of additional funds in the amount of $272,408 Total Costs (Direct Costs: $272,408; F&A: $0) to support CTN-0109. These funds are restricted for stated purpose in the request dated 8/12/22 from LaTasha Stevenson/UT Southwestern Medical Center, and may not be used for any other purpose without Grants Management Branch, NIDA approval.

This revision supersedes Notice of Award (NoA) issued on 6/30/22. All other terms below remain applicable.

REVISION #3 - TERM CORRECTION

This award has been revised to correct a typo in revision #1 referenced below, referring to the carryover of funds from year -16 to year -18. This revision supersedes Notice of Award (NoA) issued 5/31/2022. All other terms below remain applicable.

This revision supersedes Notice of Award (NoA) issued 5/31/22. All other terms below remain applicable.

REVISION #2 - CARRYOVER APPROVED
This revised award includes a carryover of $891,682 ($745,283 direct costs; $146,399 F&A costs) from the -16 year to the -18 year to support CTN-0108. These funds are restricted for the stated purpose(s) listed in the email request dated 12/29/2021 from LaTasha Stevenson/UT Southwestern Medical Center and may not be rebudgeted or used for other purposes.

This revised award includes a carryover of $721,308 ($430,066 direct costs; $291,242 F&A costs) from the -16 year to the -18 year to support CTN-0109. These funds are restricted for the stated purpose(s) listed in the email request dated 12/29/2021 from LaTasha Stevenson/UT Southwestern Medical Center and may not be rebudgeted or used for other purposes.

This revised award includes a carryover of $247,952 ($151,190 direct costs; $96,762 F&A costs) from the -16 year to the -18 year to support CTN-0109-A-1. These funds are restricted for the stated purpose(s) listed in the email request dated 12/29/2021 from LaTasha Stevenson/UT Southwestern Medical Center and may not be rebudgeted or used for other purposes.

RESTRICTED FUNDING FOR TO BE NAMED ACTIVITIES
This award provides additional funding in the amount of $17,597 to support clinical trial-related activities for CTN-0109-A-1 pursuant to request dated 12/29/2021 from LaTasha Stevenson/UT Southwestern Medical Center, pending administrative approval. The AOR must submit the following items in consideration of access to these funds:

- Identifying information for each new associated site(s)
- Budget(s) for all site(s)
- Budget justification for all site(s)

The information above must be submitted to Jennifer Schermerhorn (email: schermerhornj@mail.nih.gov, phone: 301-827-6704), Grants Management Specialist and Ronald Dobbins (email: rdobbins@mail.nih.gov, phone: 301-827-5242), Program Officer. These funds are restricted and may not be rebudgeted or used for any other purpose without NIDA awarding unit approval. The NIDA will notify the recipient via a revised Notice of Award (NoA) when these NIH administrative requirements have been met.

This revision supersedes Notice of Award (NoA) issued 5/27/2022. All other terms below remain applicable.

REVISION #1 - CARRYOVER APPROVED
This revised award includes a carryover of $703,416 ($419,156 direct costs; $284,260 F&A costs) from the -16 year to the -18 year. These funds are restricted for the stated purpose(s) listed in the email request dated 2/3/2022 from LaTasha Stevenson/UT Southwestern Medical Center and may not be rebudgeted or used for other purposes.

RESTRICTED FUNDING FOR TO BE NAMED ACTIVITIES
This award provides additional funding in the amount of $27,551 to support clinical trial-related activities pursuant to request dated 2/3/2022 from LaTasha Stevenson/UT Southwestern Medical Center, pending administrative approval. The AOR must submit the following items in consideration of access to these funds:

- Identifying information for each new associated site(s)
- Budget(s) for all site(s)
- Budget justification for all site(s)

The information above must be submitted to Jennifer Schermerhorn (email: schermerhornj@mail.nih.gov, phone: 301-827-6704), Grants Management Specialist and Ronald Dobbins (email: rdobbins@mail.nih.gov, phone: 301-827-5242), Program Officer. These funds are restricted and may not be rebudgeted or used for any other purpose without NIDA awarding unit approval. The NIDA will notify the recipient via a revised Notice of Award (NoA) when these NIH administrative requirements have been met.

This revision supersedes Notice of Award (NoA) issued 3/1/2022. All other terms below remain applicable.

HUMAN SUBJECTS RESTRICTED- DELAYED ONSET
RESTRICTION: The present award is being made without a currently valid certification of Institutional Review Board (IRB) approval for this project with the following restriction: Only activities that are clearly severable and independent from activities that involve human subjects may be conducted under this award until the project has received IRB approval consistent with 45 CFR Part 46 and certification of IRB approval has been submitted to and accepted by NIDA. **This term of award is applicable to CTN studies: -0109, -0110, -0120 and -0132.**

No funds may be drawn down from the payment system and no obligations may be made against Federal funds for research involving human subjects by the grantee or any other site engaged in such research for any period not covered by an OHRP-approved Assurance and IRB approval consistent with 45 CFR Part 46.

Failure to comply with the above requirements may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action.

See the NIH Grants Policy Statement, section on Human Subjects Protections http://grants.nih.gov/policy/nihgps/index.htm for specific requirements related to the protection of human subjects, which are applicable to this term and condition of award.

CTN TERMS
This award is issued as a Cooperative Agreement, a financial assistance mechanism in which substantial NIH scientific and/or programmatic involvement is anticipated in the performance of the activity. This award is subject to the Cooperative Agreement Terms and Conditions of Award detailed in “Section VI. Award Administration Information” section of RFA-DA-20-024, “The National Drug Abuse Treatment Clinical Trials Network (UG1 Clinical Trial Required)”, 9/4/2019, which are hereby incorporated by reference as special terms and conditions of this award.

The NIH Project Scientist for this Cooperative Agreement is:

- Innovatively Increasing PCP Prescribing of Buprenorphine: Measurement Based Care and Integrated Electronic Solution (MBC4OUD) (CTN-0090); Project Scientist - Yanping Liu (email: liuyanp@mail.nih.gov; phone: 301-451-4217)
- Transcranial Magnetic Stimulation for the Treatment of Cocaine/Methamphetamine Use Disorder (CTN-0108); Project Scientist - Geetha Subramaniam (phone: 301-480-2593; email: subramaniamga@nida.nih.gov)
- Randomized, placebo-controlled trial of injectable naltrexone and monthly injectable buprenorphine for cocaine use disorder (CURB-2) (CTN-0109); Project Scientist - Udi Ghitza (phone: 301-480-2529; email: ghitzau@mail.nih.gov)
- Innovative Development of Research Engagement Manual (I-DREM): Strategies to Enhance Recruitment and Retention of Black Individuals in CTN-0109 CURB-2 (CTN-0109-A-1); Project Scientist - Udi Ghitza (phone: 301-480-2529; email: ghitzau@mail.nih.gov)
- Randomized, placebo-controlled trial of injectable naltrexone and monthly injectable buprenorphine for methamphetamine use disorder (MURB) (CTN-0110); Project Scientist - Udi Ghitza (phone: 301-480-2529; email: ghitzau@mail.nih.gov)
- R-MIST: Remote Methadone Ingestion Surveillance Trial (CTN-0120); Project Scientist - Udi Ghitza (phone: 301-480-2529; email: ghitzau@mail.nih.gov)

- Ketamine for Methamphetamine use Disorder (KMD) Study (CTN-0132); Project Scientist - Udi Ghitza (phone: 301-480-2529; email: ghitzau@mail.nih.gov)

This award is subject to the current Data Safety Monitoring Plan (DSMP) submitted and previously approved by NIDA. Any changes in the DSMP must be reviewed and approved by the Program Official. If changes are approved, the approval will be reflected on the Notice of Award. If changes are not approved, the Principal Investigator must revise the DSMP to the satisfaction of the Program Official. The Principal Investigator must provide a DSMP for any new trial that is to be conducted under this grant.

DATA AND SAFETY MONITORING BOARD (DSMB)
This award is subject to the NIDA Guidelines for Establishing and Operating a Data and Safety Monitoring Board.

PROTECTION OF HUMAN SUBJECTS
The grantee is reminded of the requirement for education in the protection of human research participation. This requirement can be satisfied by completing the on-line tutorial Protecting Human Research Participants (http://phrp.nihtraining.com). Additional details on this requirement can be found at NIH Notice NOT-OD-08-054, "Guidance on NIH Office of Extramural Research (OER) on-line tutorial Protecting Human Research Participants (PHRP)."

The grantee is reminded that IRB approval(s) are required for each new protocol and performance site prior to implementation of human subjects research. No funds may be drawn down from the payment system and no obligations may be made against Federal funds for research involving human subjects at any site engaged in such research for any period not covered by an Office for Human Research Protections Assurance and an IRB approval consistent with the requirements of 45 CFR Part 46.

Failure to comply with the above requirements may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action. See the NIH Grants Policy Statement, Section for Human Subjects under Public Policy Requirements http://grants.nih.gov/policy/nihgps/index.htm for specific requirements related to the protection of human subjects, which are applicable to and a term and condition of this award.

REBUDGETING
Funding is provided at the projected total cost. Funds may be rebudgeted between direct costs and F&A costs, consistent with applicable cost principles and institutional and policy requirements for prior approval.

NIH SALARY CAP
None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the current salary cap. See current salary cap levels at NIH's Salary Cap Summary .

NIDA TERMS
In conjunction with the Acknowledgment of Federal Funding Requirement (as specified in the NIH Grants Policy Statement, Appropriation Mandates- http://grants.nih.gov/policy/nihgps/index.htm, in order to most effectively disseminate research results, advance notice should be given to NIDA that research findings are about to be published so that we may coordinate accurate and timely release to the media. This information will be embargoed until the publication date. Please see the NIDA Special Considerations Page for guidance on coordination with the NIDA Press Office at https://www.drugabuse.gov/funding/special-considerations-for-nida-funding, or contact the NIDA Press Office at media@nida.nih.gov.

Please see Special Considerations for NIDA Funding Opportunities and Awards at https://www.drugabuse.gov/funding/special-considerations-for-nida-funding.

SPREADSHEET SUMMARY

AWARD NUMBER: 5UG1DA020024-18 REVISED

INSTITUTION: UT SOUTHWESTERN MEDICAL CENTER

Budget	Year 18	Year 19	Year 20
Salaries and Wages	$1,323,348	$223,379	$223,379
Fringe Benefits	$393,126	$53,288	$53,288
Personnel Costs (Subtotal)	$1,716,474	$276,667	$276,667
Consultant Services	$10,000		
Materials & Supplies	$14,771	$675	$675
Travel	$95,536	$24,330	$24,330
Other	$52,631	$13,660	$13,660
Subawards/Consortium/Contractual Costs	$7,386,462	$261,846	$261,846
TOTAL FEDERAL DC	$9,275,874	$577,178	$577,178
TOTAL FEDERAL F&A	$1,426,546	$201,812	$201,812
TOTAL COST	$781,644	$778,990	$778,990

Facilities and Administrative Costs	Year 18	Year 19	Year 20
F&A Cost Rate 1	64%	64%	64%
F&A Cost Base 1	$2,228,978	$315,332	$315,332
F&A Costs 1	$1,426,546	$201,812	$201,812

UT Southwestern Medical Center | My UTSW

Sample Invoice

UTSW #:
UTSW PI: Purchase Order Number:
Sub PI: GMO Number:

Award #: Performance Period:
Grant #: Billing Period:

Project Title:
Please indicate the UTSW Acct# as reference with your payment:

Voucher #: **Current Period**

Category Totals	Cumulative Cost to Date
Salaries & Fringes	
Fringe Benefits	
Supplies	
Other Expenses	
Equipment	
Subtotal	
Indirect Cost	
Non-Overhead Bearing Expenses Tuitions & Stipends	
Total	

Amount Reimbursable

PLEASE SEND INVOICES TO:

UT Southwestern Medical Center
ATTN: Sponsored Programs Administration
5323 Harry Hines Blvd.
Dallas, TX 75390-9020

Or EMAIL INVOICES TO: AccountsPayable@UTSouthwestern.edu

For questions, please contact: AccountsPayable@UTSouthwestern.edu

I certify that all payments requested are for appropriate purposes and in accordance with the agreements set forth in the applications and award documents.

Signed by Certifying Official_____

DocuSign

Certificate Of Completion

Envelope Id: 130AB192A031447BAFC7463843741C73 Status: Completed

Subject: NIH/NIDA_Trivedi_SUB202302-0019_City and County of San Francisco_GMO230401 PO0000002962

Source Envelope:

Document Pages: 25 Signatures: 2 Envelope Originator:

Certificate Pages: 2 Initials: 1 Kenneth Chalk

AutoNav: Enabled 5323 Harry Hines Blvd

EnvelopeId Stamping: Enabled Dallas, TX 75390

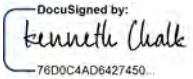
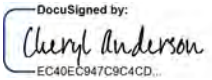
Time Zone: (UTC-06:00) Central Time (US & Canada) kenneth.chalk@utsouthwestern.edu

IP Address: 129.112.109.41

Record Tracking

Status: Original Holder: Kenneth Chalk Location: DocuSign

5/3/2023 3:12:49 PM kenneth.chalk@utsouthwestern.edu

Signer Events	Signature	Timestamp
Kenneth Chalk kenneth.chalk@utsouthwestern.edu Grants and Contracts Specialist UT Southwestern Medical Center Security Level: Email, Account Authentication (None) **Electronic Record and Signature Disclosure:** Not Offered via DocuSign	DocuSigned by:  76D0C4AD6427450... Signature Adoption: Pre-selected Style Using IP Address: 129.112.109.41	Sent: 5/3/2023 3:15:58 PM Viewed: 5/3/2023 3:16:06 PM Signed: 5/3/2023 3:24:48 PM
Jamie Maiden Jamie.maiden@utsouthwestern.edu Asst. Director UT Southwestern Medical Center Security Level: Email, Account Authentication (None) **Electronic Record and Signature Disclosure:** Not Offered via DocuSign	DS  Signature Adoption: Pre-selected Style Using IP Address: 199.165.154.173	Sent: 5/3/2023 3:24:52 PM Viewed: 5/3/2023 3:25:23 PM Signed: 5/3/2023 3:25:42 PM
Cheryl Anderson cheryl.anderson@utsouthwestern.edu Director, Pre-Award Administration, Sponsored Programs Administration UT Southwestern Medical Center Security Level: Email, Account Authentication (None) **Electronic Record and Signature Disclosure:** Not Offered via DocuSign	DocuSigned by:  EC40EC947C9C4CD... Signature Adoption: Pre-selected Style Using IP Address: 129.112.109.41	Sent: 5/3/2023 3:25:47 PM Viewed: 5/3/2023 3:26:33 PM Signed: 5/3/2023 3:26:49 PM

In Person Signer Events	Signature	Timestamp

Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp
Angela Casey-Willingham Angela.Casey-Willingham@UTSouthwestern.edu Security Level: Email, Account Authentication (None) **Electronic Record and Signature Disclosure:** Not Offered via DocuSign	COPIED	Sent: 5/3/2023 3:26:53 PM
Zoie Choate Zoie.Choate@UTSouthwestern.edu Security Level: Email, Account Authentication (None) **Electronic Record and Signature Disclosure:** Not Offered via DocuSign	COPIED	Sent: 5/3/2023 3:26:53 PM
Eduardo Sida eduardo.sida@sfdph.org Security Level: Email, Account Authentication (None) **Electronic Record and Signature Disclosure:** Not Offered via DocuSign	COPIED	Sent: 5/3/2023 3:26:53 PM Viewed: 5/3/2023 4:17:57 PM

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	5/3/2023 3:15:58 PM
Certified Delivered	Security Checked	5/3/2023 3:26:33 PM
Signing Complete	Security Checked	5/3/2023 3:26:49 PM
Completed	Security Checked	5/3/2023 3:26:53 PM

Payment Events	Status	Timestamps

London N. Breed
Mayor

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

FROM: **Dr. Grant Colfax**
Director of Health

DATE: **12/11/2024**

SUBJECT: **Grant Accept and Expend**

GRANT TITLE: **NIDA Clinical Trials Network: Big South/West Node - $104,508**

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 ☒

From:	Trejo, Sara (MYR)
To:	BOS Legislation, (BOS)
Cc:	Paulino, Tom (MYR); Wong, Greg (DPH); Validzic, Ana (DPH); Neukrug, Sarah (DPH); Chiong, Christina (DPH)
Subject:	Mayor -- Resolution -- NIDA Clinical Trials Network A&E
Date:	Tuesday, December 10, 2024 2:43:44 PM
Attachments:	DPH A&E - NIDA Clinical Trials Network - $104,508.pdf 1322 Board Cover Memo.docx 1322 Grant Resolution.doc 1322 GRIF.doc 1322 All Years Budgets.xlsx 1322 Budget Justification.doc 1322 FE_Amendment #2_GMO 230401 PO000002962B_.cleaned.pdf 1322 FE_Amendment#1_GMO 230401 PO000002962A.pdf 1322 NIHNIDA_Trivedi_SUB202302-0019_City_and_Coun.cleaned Award.pdf RE New Proposed Legislation from DPH (.msg

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Hello Clerks,

Attached is a Resolution retroactively authorizing the Department of Public Health to accept and expend a grant increase in the amount of $13,431 from the National Institutes of Health through the University of Texas Southwestern Medical Center for a total amount of $104,508 for participation in a program, entitled “NIDA Clinical Trials Network: Big South/West Node,” for the period of April 1, 2022, through February 28, 2025.

Best regards,

Sara Trejo
Legislative Aide
Office of the Mayor
City and County of San Francisco