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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:

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.

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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.

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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.

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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.

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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

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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

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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

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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.

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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
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

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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

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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

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