

File Number: _____
(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):

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? 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):

- | | | |
|--|---|--|
| <input checked="" type="checkbox"/> Existing Site(s) | <input type="checkbox"/> Existing Structure(s) | <input type="checkbox"/> Existing Program(s) or Service(s) |
| <input type="checkbox"/> Rehabilitated Site(s) | <input type="checkbox"/> Rehabilitated Structure(s) | <input type="checkbox"/> New Program(s) or Service(s) |
| <input type="checkbox"/> New Site(s) | <input type="checkbox"/> 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

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(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

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Jenny Louie, COO for