Research Subaward Agreement Amendment Number 2						
Pass-through Entit	ty (PTE)	Subred	cipie	nt	
Institution/Organization ("PTE")			Institution/O	rganizat	ion ("Subrecipie	ent")
Entity Name: Oregon Health & S	cience Univ	ersity	Entity Name	e: City &	& County of Sa	n Francisco,
Email Address: spasub@ohsu.ec	du		Department of Public Health			
Principal Investigator: Todd Korthuis		Email Address: sajid.shaikh@sfdph.org				
		Principal Inv	vestigat	tor: Phillip Cof	fin	
Project Title: Western States Node of the National Drug Abuse Treatment Clinical Trials Network						
PTE Federal Award No. 5UG1DA015815-21			Federal Awarding Agency: DHHS NIH NIDA			
Subaward Period of Performance: Amount F		⁻ unded This A	ction:	Subaward N	0:	
Start Date: 06/01/2020 End Date: \$26,410				1017225_SF	DPH	
02/28/2023						
Effective Date of Amendment:	Total Amo	unt of Fede	ral Funds	Subje	ect to FFATA:	Automatic Carryover:
03/01/2022	Obligated t	to Date: \$8	1,610	_ Υε	es 🖂 No	🗌 Yes 🔀 No

Amendment(s) to Original Terms and Conditions

This Amendment revised the above-referenced Research Subaward Agreement as follows:

The Period of Performance is hereby extended through 02/28/2023.

The Current Budget Period is from 03/21/2022 through 02/28/2023.

Funds for the Current Budget Period are hereby awarded in the amount of \$26,410 per the Budget in Attachment 5.2.

Applicable terms and conditions in Attachment 6.2, the Prime Award, is hereby incorporated by reference.

Attachment 3A, PTE Contacts are updated as follows: Administrative Contact: Name: Subout Grants & Contracts Administrator Ph: 503-494-7784 Email: <u>spasub@ohsu.edu</u>

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]
Michael Padden Digitally signed by Michael Padden Date: 2022.09.09 10:27:41 -07'00'	Date:	DocuSigned by: Gryg Wagner Dat 19377729752949F	9/7/2022 3:: e:	28:17 PDT
Grants & Contracts Administrator		Title:		

Approved as to :	form, David Chiu, City Attorney
Bittenry lifton	form, David Chiu, City Attorney Henry L. Lifton, Deputy City Attorney
6D6CB58424584B1	
9/6/2022	11:30:07 PDT

San Francisco Department of Public Health (SFDPH) Population Health Division – Center for Public Research Western States Node of the National Drug Abuse Treatment Clinical Trials Network **BUDGET JUSTIFICATION**

March 1, 2022 to February 28, 2023

Α. PERSONNEL **B**. **MANDATORY FRINGE**

1. 0.05 2232 - Senior Physician Specialist: Phillip Coffin Annual Salary \$199,300 x 0.05 FTE for 12 month = \$9,965 Mandatory Fringe Benefits (@, 35%) = \$3,488\$13,423

Dr Coffin will work with the PIs to ensure the success of the next iteration of the Western States Node. Dr Coffin will complete all required forms, participate in regular calls, assist with the development of CTN concepts and protocols, and be prepared to act as a site in future CTN protocols.

	Total Salaries Total Fringe	\$9,865 \$3,488
TOTA	AL PERSONNEL:	\$13,423
C.	TRAVEL	\$0
D.	EQUIPMENT	\$0
E.	SUPPLIES	\$0
F.	CONTRACTUAL	\$11,012

Margarita Martin, Project Manager (0.6 cal mos/5%). Ms. Martin is responsible for contract management related to this project, project-specific materials purchases and production and travel arrangements for Dr. Coffin

G. **OTHER** \$600 Fund requested to cover the cost of rent for both PHFE staff and SFDPH staff. Rent calculated based FTE at a rate of \$2/sqft/mo x 250 sqft/person x 12 months. Cost of rent is not included in indirect rate. TOTAL DIRECT COSTS \$25,065

H. **INDIRECT COSTS 10% of total direct costs)** \$1,345

\$26,410

TOTAL BUDGET:

Department of Health and Human Services



National Institutes of Health NATIONAL INSTITUTE ON DRUG ABUSE Notice of Award FAIN# UG1DA015815 Federal Award Date 03/04/2022

Recipient Information	Federal Award Information		
1. Recipient Name OREGON HEALTH & SCIENCE UNIVERSITY 3181 SW SAM JACKSON PARK RD	11. Award Number 5UG1DA015815-21		
PORTLAND, OR 97239 2. Congressional District of Recipient	12. Unique Federal Award Identification Number (FAIN) UG1DA015815		
03 3. Payment System Identifier (ID) 1931176109A1	13. Statutory Authority 42 USC 241 31 USC 6305 42 CFR 52		
4. Employer Identification Number (EIN) 931176109	14. Federal Award Project Title Western States Node of the National Drug Abuse Treatment Clinical	Trials Network	
5. Data Universal Numbering System (DUNS) 096997515	15. Assistance Listing Number 93.279		
6. Recipient's Unique Entity Identifier NPSNT86JKN51	16. Assistance Listing Program Title Drug Abuse and Addiction Research Programs		
7. Project Director or Principal Investigator Philip Todd Korthuis, MD (Contact)	17. Award Action Type Non-Competing Continuation		
Associate Professor Of Medicine korthuis@ohsu.edu 503-494-8044	18. Is the Award R&D? Yes		
	Summary Federal Award Financial Informatio	n	
8. Authorized Official	19. Budget Period Start Date 03/01/2022 – End Date 02/28/2023 20. Total Amount of Federal Funds Obligated by this Action	\$747,413	
Elizabeth Sobolewski	20 a. Direct Cost Amount	\$566,359	
salvatie@ohsu.edu 503-418-5498	20 b. Indirect Cost Amount	\$181,054	
503-418-5498	21. Authorized Carryover	\$0	
	22. Offset	\$0	
Federal Agency Information	23. Total Amount of Federal Funds Obligated this budget period	\$747,413	
9. Awarding Agency Contact Information	24. Total Approved Cost Sharing or Matching, where applicable	\$0	
Jennifer L Schermerhorn	25. Total Federal and Non-Federal Approved this Budget Period	\$747,413	
NATIONAL INSTITUTE ON DRUG ABUSE	26. Project Period Start Date 09/30/2002 – End Date 02/28/2025		
schermerhornj@mail.nih.gov	27. Total Amount of the Federal Award including Approved Cost	\$4,708,343	
301-827-6704	Sharing or Matching this Project Period		
10. Program Official Contact Information			
Ronald Dobbins	28. Authorized Treatment of Program Income Additional Costs		
NATIONAL INSTITUTE ON DRUG ABUSE			
rdobbins@nida.nih.gov	29. Grants Management Officer - Signature		
301 443-6697	Amy Connolly		

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.

Notice of Award



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



NATIONAL INSTITUTE ON DRUG ABUSE

SECTION I – AWARD DATA – 5UG1DA015815-21

Principal Investigator(s): Keith N. Humphreys, PHD Philip Todd Korthuis (contact), MD

Award e-mailed to: orserv@ohsu.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of \$747,413 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to OREGON HEALTH & SCIENCE UNIVERSITY 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 UG1DA015815. 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/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,

Amy Connolly Grants Management Officer NATIONAL INSTITUTE ON DRUG ABUSE

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)	
Salaries and Wages	\$201,547
Fringe Benefits	\$69,140
Personnel Costs (Subtotal)	\$270,687
Consultant Services	\$36,000
Travel	\$26,598
Subawards/Consortium/Contractual Costs	\$231,074
Publication Costs	\$2,000
Federal Direct Costs	\$566,359
Federal F&A Costs	\$181,054
Approved Budget	\$747,413
Total Amount of Federal Funds Authorized (Federal Share)	\$747,413
TOTAL FEDERAL AWARD AMOUNT	\$747,413
AMOUNT OF THIS ACTION (FEDERAL SHARE)	\$747,413

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)				
YR	THIS AWARD	CUMULATIVE TOTALS		
21	\$747,413	\$747,413		
22	\$744,065	\$744,065		
23	\$743,195	\$743,195		

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

Fiscal Information:

Payment System Identifier:	1931176109A1
Document Number:	UDA015815E
PMS Account Type:	P (Subaccount)
Fiscal Year:	2022

IC	CAN	2022	2023	2024
DA	8472653	\$747,413	\$744,065	\$743,195

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: Connolly, Amy 03/03/2022 Award Processed: 03/04/2022 12:05:51 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5UG1DA015815-21

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 – 5UG1DA015815-21

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

- a. The grant program legislation and program regulation cited in this Notice of Award.
- b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- c. 45 CFR Part 75.
- d. National Policy Requirements and all other requirements described in the NIH Grants Policy

Statement, including addenda in effect as of the beginning date of the budget period.

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

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

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

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

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

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS 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) UG1DA015815. 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: <u>http://publicaccess.nih.gov/</u>.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of <u>Public Law</u> <u>110-85</u>), the "responsible party" must register "applicable clinical trials" on the <u>ClinicalTrials.gov Protocol</u> <u>Registration System Information Website</u>. NIH encourages registration of all trials whether required under the law or not. For more information, see <u>http://grants.nih.gov/ClinicalTrials_fdaaa/</u> 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 <u>http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm</u>).

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 - 5UG1DA015815-21

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.

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 <u>RFA-DA-20-024</u>, "The <u>National Drug Abuse Treatment Clinical Trials Network (UG1 Clinical Trial Required)</u>", 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:

- Medication Treatment for Opioid Use Disorder in Expectant Mothers (MOMs): A Pragmatic Randomized Trial Comparing Extended-Release and Daily Buprenorphine Formulations (CTN-0080); Project Scientist - Carmen Rosa (phone: 301-480-2548; email: <u>crosa@nida.nih.gov</u>)
- Inpatient versus Outpatient Treatment Outcomes for People with Opioid Use Disorder (CTN-0086); Project Scientist - Udi Ghitza (phone: 301-480-2529; email: ghitzau@nida.nih.gov)
- Exemplar Hospital Initiation Trial to Enhance Treatment Engagement (EXHIT ENTRE) (CTN-0098); Project Scientist - Udi Ghitza (phone: 301-480-2529; email: <u>ghitzau@nida.nih.gov</u>)
- Subthreshold Opioid Use Disorder Prevention (STOP) Trial (CTN-0101); Project Scientist
 Geetha Subramaniam (phone: 301-480-2593; email: <u>subramaniamga@nida.nih.gov</u>)
- Assessment and Design of a Cost-Effective Collaborative MOUD Delivery System (CTN-0124); Project Scientist - Udi Ghitza (phone: 301-480-2529; email: <u>ghitzau@nida.nih.gov</u>)
- Integrative Data Analysis of CTN Studies to Examine the Impact of Psychosocial Treatments for Black People who use Cocaine (CTN-0125); Project Scientist - Xiaoming Wang (email: <u>wangx19@mail.nih.gov</u>; phone: 301-827-6332)

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 <u>NIDA Guidelines for Establishing and Operating a Data and Safety</u> <u>Monitoring Board.</u>

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 (<u>http://phrp.nihtraining.com</u>). Additional details on this requirement can be found at NIH Notice <u>NOT-OD-08-054</u>, "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 <u>Salary Cap Summary</u>.

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.gov or contact the NIDA Press Office at media@nida.nih.gov.

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

SPREADSHEET SUMMARY AWARD NUMBER: 5UG1DA015815-21

INSTITUTION: OREGON HEALTH & SCIENCE UNIVERSITY

Budget	Year 21	Year 22	Year 23
Salaries and Wages	\$201,547	\$201,547	\$201,547
Fringe Benefits	\$69,140	\$69,140	\$69,140
Personnel Costs (Subtotal)	\$270,687	\$270,687	\$270,687
Consultant Services	\$36,000	\$36,000	\$36,000
Travel	\$26,598	\$24,424	\$23,859
Subawards/Consortium/Co	\$231,074	\$231,074	\$231,074
ntractual Costs			
Publication Costs	\$2,000	\$2,000	\$2,000
TOTAL FEDERAL DC	\$566,359	\$564,185	\$563,620
TOTAL FEDERAL F&A	\$181,054	\$179,880	\$179,575
TOTAL COST	\$747,413	\$744,065	\$743,195

Facilities and Administrative Costs	Year 21	Year 22	Year 23
F&A Cost Rate 1	54%	54%	54%
F&A Cost Base 1	\$335,285	\$333,111	\$332,546
F&A Costs 1	\$181,054	\$179,880	\$179,575