Research Subaward Agreement						
	Amendment Number 1					
Pass-through Entit	Pass-through Entity (PTE)			Subrecipient		
Institution/Organization ("PTE")			Institution/O	rganizat	ion ("Subrecipie	ent")
Entity Name: Oregon Health & S	Science Unive	ersity	Entity Name	e: City 8	& County of Sa	n Francisco,
Email Address: spasub@ohsu.ed	du		Department of Public Health			
Principal Investigator: Todd Kort	thuis		Email Address: sajid.shaikh@sfdph.org			
			Principal Investigator: Phillip Coffin			
Project Title: Western States No	de of the Na	ntional Drug	g Abuse Treat	ment C	linical Trials N	etwork
PTE Federal Award No. 5UG1DA	A015815-20		Federal Awa	arding A	Agency: DHHS	NIH NIDA
Subaward Period of Performanc	Amount F	unded This A	ction:	Subaward N	0:	
Start Date: 06/01/2020 End Date: \$26,262			1017225_SFDPH		DPH	
02/28/2022						
Effective Date of Amendment:	Total Amo	ount of Federal Funds Subject to FFATA: Automatic Cari			Automatic Carryover:	
03/01/2021	Obligated t	to Date: \$5	5,200	Ye	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 02/28/2022.

The Current Budget Period is from 03/01/2021 through 02/28/2022.

Funds for the Current Budget Period are hereby awarded in the amount of \$26,262 per the Budget in Attachment 5.1.

Applicable terms and conditions in Attachment 6.1, the Prime Award, is hereby incorporated by reference.

Attachment 3A, PTE Contacts is hereby updated to replace the Invoice Address and the Authorized Official, as follows:

Invoice Address:

Oregon Health & Science University
Office of Proposal and Award Management
3181 SW Sam Jackson Park Road
Portland, OR 97329-3098

Authorized Official:

Lisa Fitzpatrick, Grants & Contracts Manager, OPAM

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 Subrecipie	nt	
Jen Michaud Date: 03/03/2021 Subout Grants & Contracts Administrator	Docusigned by: Gry Wagner 28527524752949F Name: Greg Wagner, CFO Title:	3/2/2021 1: ate:	40 PM PST

Subaward 1017225_SFDPH, Amendment 1 - ATTACHMENT 5.1 - BUDGET (1 page)

Personnel	Role	Base	Мо	Effort	C-M	Salary	% OPE	\$ OPE	Total Cost
Coffin, Phillip MD		\$197,300	12	5%	0.60	\$9,865	0.350	\$3,453	\$13,318.00
Total Salary						\$9,865		\$3,453	\$13,318.00
Subcontract - San Francisco Publ	ic Health		Qty	Cost					Total
Heluna Health	Project Mana	ger							\$11,012.00
Travel			Qty	Cost					Total
CTN/Steering Committee meetings			0						\$0.00
National conferences			0						\$0.00
Conference registration			0						\$0.00
Sub-Total									\$0.00
			PHF						
Other			FTE	CCSF FTE	Sq FT	\$	Months		Total
Rent			0.05	250	\$2	12			\$600
Sub-Total									\$600.00
Total Direct Costs									\$24,930.00
MTDC									\$24,930.00
Indirect Rate		10%							\$1,332.00
Total		. • / •							\$26,262

Notice of Award FAIN# UG1DA015815 Federal Award Date 02/22/2021

Recipient Information

1. Recipient Name

OREGON HEALTH & SCIENCE UNIVERSITY 3181 SW SAM JACKSON PARK RD

PORTLAND, OR 97239

- 2. Congressional District of Recipient
- 3. Payment System Identifier (ID) 1931176109A1
- **4. Employer Identification Number (EIN)** 931176109
- 5. Data Universal Numbering System (DUNS) 096997515
- 6. Recipient's Unique Entity Identifier
- 7. Project Director or Principal Investigator Philip Todd Korthuis, MD (Contact) Associate Professor Of Medicine korthuis@ohsu.edu (503) 494-8044
- 8. Authorized Official

Jon Geselle geselle@ohsu.edu 503-494-1291

Federal Agency Information

9. Awarding Agency Contact Information
Jennifer L Schermerhorn

NATIONAL INSTITUTE ON DRUG ABUSE schermerhornj@mail.nih.gov 301-827-6704

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

5UG1DA015815-20

12. Unique Federal Award Identification Number (FAIN)

UG1DA015815

13. Statutory Authority

42 USC 241 31 USC 6305 42 CFR 52

14. Federal Award Project Title

Western States Node of the National Drug Abuse Treatment Clinical Trials Network

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 03/01/2021 – End Date 02/28/2022	
20. Total Amount of Federal Funds Obligated by this Action	\$755,924
20 a. Direct Cost Amount	\$576,832
20 b. Indirect Cost Amount	\$179,092
21. Authorized Carryover	\$0
22. Offset	\$0
23. Total Amount of Federal Funds Obligated this budget period	\$755,924
24. Total Approved Cost Sharing or Matching, where applicable	\$0
25. Total Federal and Non-Federal Approved this Budget Period	\$755,924
26. Project Period Start Date 09/30/2002 – End Date 02/28/2025	
27. Total Amount of the Federal Award including Approved Cost	\$3,029,533
Sharing or Matching this Project Period	

28. Authorized Treatment of Program Income

Additional Costs

29. Grants Management Officer - Signature

Pamela G. Fleming

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.

Notice of Award



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



NATIONAL INSTITUTE ON DRUG ABUSE

SECTION I – AWARD DATA – 5UG1DA015815-20

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 \$755,924 (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.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,

Pamela G. Fleming
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	\$23,964
Subawards/Consortium/Contractual Costs	\$245,181
Publication Costs	\$1,000
Federal Direct Costs	\$576,832
Federal F&A Costs	\$179,092
Approved Budget	\$755,924
Total Amount of Federal Funds Authorized (Federal Share)	\$755,924
TOTAL FEDERAL AWARD AMOUNT	\$755,924
	4 4
AMOUNT OF THIS ACTION (FEDERAL SHARE)	\$755,924

	SUMMARY TOTALS FOR ALL YEARS (for this Document Number)					
YR	THIS AWARD	CUMULATIVE TOTALS				
20	\$755,924	\$755,924				
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: 2021

IC	CAN	2021	2022	2023	2024
DA	8472653	\$755.924	\$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: Fleming, Pamela 02/19/2021

Award Processed: 02/22/2021 12:12:43 AM

SECTION II - PAYMENT/HOTLINE INFORMATION - 5UG1DA015815-20

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 - 5UG1DA015815-20

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

- 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: http://publicaccess.nih.gov/.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of <u>Public Law 110-85</u>), the "responsible party" must register "applicable clinical trials" on the <u>ClinicalTrials.gov Protocol 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</u> fdaaa/

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

DocuSign Envelope ID: 752A91D8-8C5E-4165-9F23-D616FF78C87B 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV - DA SPECIFIC AWARD CONDITIONS - 5UG1DA015815-20

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 RFA-DA-15-008, "The <a href="National Drug Abuse Treatment Clinical Trials Network (UG1)," 07/03/2014, 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: crosa@nida.nih.gov)
- Exemplar Hospital Initiation Trial to Enhance Treatment Engagement (EXHIT ENTRE) (CTN-0098); Project Scientist - Udi Ghitza (phone: 301-480-2529; email: ghitzau@nida.nih.gov)
- Subthreshold Opioid Use Disorder Prevention (STOP) Trial (CTN-0101); Project Scientist
 Geetha Subramaniam (phone: 301-480-2593; email: subramaniamga@nida.nih.gov)
- Rural Expansion of Medication Treatment for Opioid Use Disorder (CTN-0102); Project Scientist - Yanping Liu (phone: 301-451-4217; email: liuyanp@nida.nih.gov)
- Surmounting Withdrawal to Initiate Fast Treatment with Naltrexone (SWIFT): Improving
 the Real-World Effectiveness of Injection Naltrexone for Opioid Use Disorder (CTN0097); Project Scientist Udi Ghitza (phone: 301-480-2529; email: ghitzau@nida.nih.gov)
- Optimizing Retention, Duration and Discontinuation Strategies for Opioid Use Disorder Pharmacotherapy (CTN-0100); Project Scientist - David Liu (phone: 301-480-2535; email: <u>dliu@nida.nih.gov</u>)
- Comparing Treatments for HIV-Positive Opioid Users in an Integrated Care Effectiveness Study (CHOICES) (CTN-0055); Project Scientist - Raul Mandler (phone: 301-480-2541; email: mandlerr@nida.nih.gov) and Udi Ghitza (phone: 301-480-2529; email: ghitzau@nida.nih.gov)
- Comparing Treatments for HIV-Infected Opioid Users in an Integrated Care Effectiveness Study (CHOICES); Scale-Up (CTN-0067); Project Scientist - Landhing Moran (phone: 301-827-0642; email: lmoran@nida.nih.gov)
- Selection Bias-Free Estimation of the Impact of Drug-Focused 12-step Mutual Help Groups (CTN-0085); Project Scientist - Udi Ghitza (phone: 301-480-2529; email: ghitzau@nida.nih.gov)
- 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)
- A Foundation to Examine Reasons for Discontinuation for Buprenorphine Care in the Veterans Health Administration (CTN-0087); Project Scientist - Udi Ghitza (phone: 301-480-2529; email: ghitzau@nida.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

DATA AND SAFETY MONITORING BOARD (DSMB)

This award is subject to the <u>NIDA Guidelines for Establishing and Operating a Data and Safety 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 (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 finds 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. Any press notification should be coordinated with the NIDA Press Officer who can be reached at (301) 443-6245.

The National Institute on Drug Abuse (NIDA) encourages data harmonization to increase comparability, collaboration, and scientific yield of research on drug abuse. Towards that end, NIDA strongly encourages human-subject studies to incorporate a series of measures from the Substance Abuse and Addiction Core and Specialty collections, which are available in the PhenX Toolkit at http://www.phenxtoolkit.org. For more information about NIDA's data harmonization efforts, please see NOT-DA-12-008 at http://grants.nih.gov/grants/guide/notice-files/NOT-DA-12-008.html.

SPREADSHEET SUMMARY

AWARD NUMBER: 5UG1DA015815-20

INSTITUTION: OREGON HEALTH & SCIENCE UNIVERSITY

Budget	Year 20	Year 21	Year 22	Year 23
Salaries and Wages	\$201,547	\$201,547	\$201,547	\$201,547
Fringe Benefits	\$69,140	\$69,140	\$69,140	\$69,140
Personnel Costs	\$270,687	\$270,687	\$270,687	\$270,687

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Consultant Services	\$36,000	\$36,000	\$36,000	\$36,000
Travel	\$23,964	\$26,598	\$24,424	\$23,859
Subawards/Consortium/	\$245,181	\$231,074	\$231,074	\$231,074
Contractual Costs				
Publication Costs	\$1,000	\$2,000	\$2,000	\$2,000
TOTAL FEDERAL DC	\$576,832	\$566,359	\$564,185	\$563,620
TOTAL FEDERAL F&A	\$179,092	\$181,054	\$179,880	\$179,575
TOTAL COST	\$755 924	\$747 413	\$744 065	\$743 195