DocuSign Envelope ID: 32DF2D74-7B8D-4458-9DDC-68C8E59315AF

FDP Cost Reimbursement Research Subaward Agreement		
Federal Awarding Agency: National Institutes of Health (NIH)		
Pass-Through Entity (PTE):	Subrecipient:	
Oregon Health & Science University	City & County of San Francisco, Department of Public Health	
PTE PI: Philip Todd Korthuis	Sub PI: Phillip Coffin	
PTE Federal Award No: 2UG1DA015815-19	Subaward No: 1017225_SFDPH	
Project Title: Western States Node of the National Drug Abuse	Treatment Clinical Trials Network	
Subaward Period of Performance (Budget Period):Start:06/01/2020End:02/28/2021	Amount Funded This Action (USD): \$28,938.00	
Estimated Project Period (if incrementally funded):Start:06/01/2020End:02/28/2025	Incrementally Estimated Total (USD): \$139,187.00	
 PTE hereby awards a cost reimbursable subaward, as des budget for this Subaward are as shown in Attachment 5. In independent entity and not an employee or agent of PTE. Subrecipient shall submit invoices not more often than mo 	n its performance of Subaward work, Subrecipient shall be an nthly and not less frequently than quarterly for allowable costs	
and 2 CFR 200.305. All invoices shall be submitted using		
 A final statement of cumulative costs incurred, including content of costs incurred, including content of costs shall constitute Subrecipient's All payments shall be considered provisional and are subjustment is necessary as a result of an adverse autores and the subrecipient of an adverse autores autores autores and the subrecipient of an adverse autores autores	t 3A, <u>not later than</u> 60 days after the Budget Period end date. s final financial report. ect to adjustment within the total estimated cost in the event	
 Matters concerning the technical performance of this Subal Investigator as shown in Attachments 3A and 3B. Technic Matters concerning the request or negotiation of any change Subaward, and any changes requiring prior approval, shal shown in Attachments 3A and 3B. Any such change made party's Authorized Official, as shown in Attachments 3A and 	al reports are required as shown in Attachment 4. I ges in the terms, conditions, or amounts cited in this I be directed to each party's Administrative Contact, as to this Subaward requires the written approval of each	
,	d of Performance and budget Unilaterally Ifter receipt unless otherwise indicated by Subrecipient when hown in Attachment 3B.	
 8. Each party shall be responsible for its negligent acts or on officers, or directors, to the extent allowed by law. 9. Either party may terminate this Subaward with 30 days wr Contact, as shown in Attachments 3A and 3B. PTE shall p Uniform Guidance, 2 CFR 200, or 45 CFR Part 75 Appendix 	bay Subrecipient for termination costs as allowable under	
certifies that it will perform the Statement of Work in accor applicable terms of the Federal Award, including the appro	. The parties further agree that they intend this Subaward to	
By an Authorized Official of Pass-through Entity:	DocuSigned by: Official of Subrecipient:	
Elizabeth Williams 9/10/2020	Comas Magin 08.18.2020	
Name: Elizabeth Williams, M.S. Date	Name: Tomas Aragon Date	
Title: Award Operations Manager	Title: Director of PHD	

Attachment 1

Certifications and Assurances

Subaward Number:

1017225_SFDPH

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 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 200.213 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

Per 2 CFR 200.501- 200.521, Subrecipient certifies that it will provide notice of any adverse findings which impact this Subaward and will provide access to records as required by parts 2 CFR 200.336, 200.337, and 200.201 as applicable. If Subrecipient is not subject to the Single Audit Act, then Subrecipient will provide notice of the completion of any required audits and provide access to such audits upon request.

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 pilot 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.

Attachment 2

Federal Award Terms and Conditions

Subaward Number

1017225_SFDPH

Required Data Elements

The data elements required by Uniform	Federal Award Issue Date FAIN	CFDA No.
Guidance are incorporated in the attached Federal Award.		
This Subaward lay	CFDA Title	
This Subaward Is:		
Research & Development Subject to FFATA	Key Personnel Per NOA	4

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/grants/policy/nihgps/nihgps.pdf

- 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/policy/notices.htm

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 Principal Investigator 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 200.33 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

Multiple Pls (MPI)

This subaward is not subject to an MPI Leadership Plan.

Special Terms and Conditions:

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.

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.

Data Sharing and Access (Check if applicable):

Subrecipient agrees to comply with the Federal Awarding Agency's data sharing and access requirements as reflected in the NOA (or in the special terms below) and the Data Management/Sharing Plan submitted to the Federal Awarding Agency and attached.

DocuSign Envelope ID: 32DF2D74-7B8D-4458-9DDC-68C8E59315AF

Promoting Objectivity in Research (COI):

Subrecipient must designate herein which entity's Financial Conflicts of Interest policy (COI) will apply: PTE

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	e Animals (Select Applicable Options) Image: No Human or Vertebrate Animals
	This section left intentionally blank.
Human Subjects Data (Select One)	Not Applicable
	This section left intentionally blank

Additional Terms

Applicable terms and conditions of the PTE Award, Attachment 6, are hereby incorporated as a part of this Agreement.

Attachment 3A

Pass-Through Entity (PTE) Contacts

Subaward Number:

1017225_SFDPH

PTE Information			
Entity Name:	Oregon Health & Science University		
Legal Address:	Office of Proposal & Award Management 3181 SW Sam Jackson Park Road Mail Code: L106OPAM Portland, OR 97239-3098		
Website:	https://www.ohsu.edu/xd/research/administra	tion/proposal-and-award-management/index.cfm	
PTE Contacts			
Central Emai	l: spasub@ohsu.edu		
Principal Investiga	ator Name: Philip Todd Korthuis		
Email:	Email: korthuis@ohsu.edu Telephone Number: 503.494.8044		
Administrative Co	ntact Name: Jen Michaud, Subout Grants & C	ontracts Administrator	
Email:	michauj@ohsu.edu	Telephone Number: 503.494.2379	
COI Contact email (if different to above): integrity@ohsu.edu			
Financial Contact	Name: Subout Administrator		
Email:	spasub@ohsu.edu	Telephone Number: 503.494.7784	
Email invoices? Yes No Invoice email (if different): spasub@ohsu.edu			
Authorized Official	I Name: Elizabeth Williams, M.S., Award	Operations Manager	
Email:	spasub@ohsu.edu	Telephone Number: 503.494.7784	
PI Address:			

3181 SW Sam Jackson Park Road Portland, OR 97239-3098

Administrative Address:

Office of Proposal & Award Management 3181 SW Sam Jackson Park Road Mail Code: L106OPAM Portland, OR 97239-3098

Invoice Address:

Office of Proposal & Award Management 0691 SW Bancroft Street Mail Code: L106OPAM Portland, OR 97239

Attachment 3B

Subaward Number:

1017225_SFDPH

Subrecipient Contacts Subrecipient Information for FFATA reporting Entity's DUNS Name: City & County of San Francisco, Department of Public Health Institution Type: County Government EIN No.: 94-6000417 Currently registered in SAM.gov: () Yes (No No DUNS: 103717336 Exempt from reporting executive compensation: (•) Yes(No (if no, complete 3Bpg2) Parent DUNS: N/A This section for U.S. Entities: Zip Code Look-up Zip Code+4: Congressional District: CA-012 94102-6012 Place of Performance Address 25 Van Ness Avenue San Francisco, CA 94102-6012 **Subrecipient Contacts** Central Email: Website: Principal Investigator Name: Phillip Coffin Telephone Number: 415.437.6282 Email: phillip.coffin@sfdph.org Administrative Contact Name: Sajid Shaikh sajid.shaikh@sfdph.org Telephone Number: 415.279.8833 Email: Financial Contact Name: Same as Administrative Contact Email: Telephone Number: Invoice/Payment Email: Authorized Official Name: **Tomas Aragon** Email: tomas.aragon@sfdph.org Telephone Number: 415.787.2583 Legal Address: **101 Grove Street** San Francisco, CA 94102-4505 Administrative Address: 1380 Howard Street San Francisco, CA 94130-2614

Payment Address:

Same as Administrative Address

Attachment 3B-2

Subaward Number: 1017225_SFDPH

Highest Compensated Officers

Subrecipient:

Institution Name:	City & County of San Francisco, Department of Public Health	
PI Name:	Phillip Coffin	

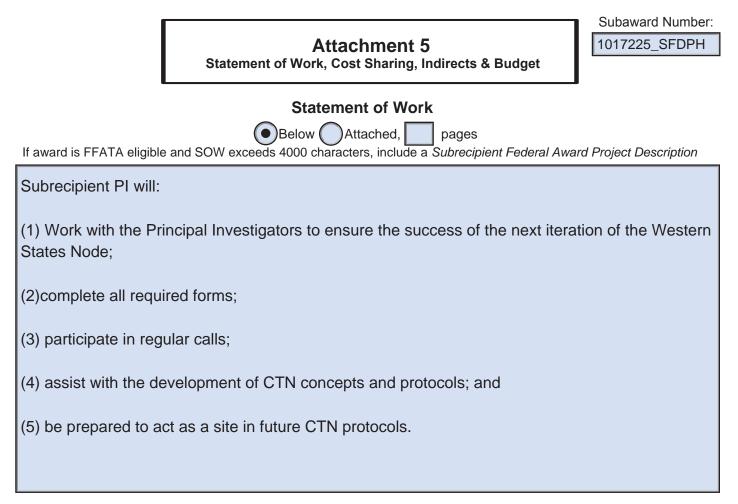
Highest Compensated Officers

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:	

				-	Subay	ward N	umber:
		achme				225_SI	
	Reporting an	d Prior A	pproval Terms				
Sub	recipient agrees to submit the following reports (F	PTE conta	cts are identified in Atta	chment	t 3A):		
Тес	hnical Reports:						
	Monthly technical/progress reports will be submit of the end of the month.	tted to the	PTE's Principal Investiga	tor	within	15	days of
	Quarterly technical/progress reports will be subr the PTE's Principal Investigator	nitted with	in 30 days after the end	d of eac	h projec	t quarte	er to
	Annual technical / progress reports will be subm to the PTE's Principal Investigator . Such re updated other support for key personnel, certific research of any new key personnel, and annual	eport shall ation of ap	also include a detailed	budget he conc	for the r	next Bu	Idget Period,
	A Final technical/progress report will be submitte end of the Project Period or after termination of		1 0		within 6	30	days of the
	Technical/progress reports on the project as ma to satisfy its reporting obligations to the Federal			vestigate	or	in orde	er for the PTE
Pric	r Approvals:						
	Carryover:						
	Carryover is restricted for this subaward by the:	Federa	Awarding Agency				
	Submit carryover requests to the Principal Invest	igator					
Othe	er Reports:						
	In accordance with 37 CFR 401.14, Subrecipien days after Subrecipient's inventor discloses inve for patent matters. The Subrecipient will submit specific forms to the PTE's Principal Investigator included as part of the PTE's final invention repo	ention(s) ir a final inve withi	writing to Subrecipient ention report using Fede n 60 days of the end of	s perso eral Awa the Proj	nnel res arding Ag	gency	
	A negative report is required: Upon Requ	uest					
	Property Inventory Report (only when required b	by Federal	Awarding Agency), spe	ecific rec	quiremer	nts belo	ow.

Other Special Reporting Requirements:



Indirect Information Indirect Cost Rate (IDC) Applied 10 %	Cost Sharing No
Rate Type: de minimis rate of 10%	If Yes, include Amount: \$
Budget Details Below Attached, 1 pages	
	Budget Totals
	Direct Costs \$ 26,359.00
	Indirect Costs \$ 2,580.00
	Total Costs \$ 28,938.00
	All amounts are in United States Dollars

Budget Information

Heluna Health June 1, 2020 - Feb 28, 2021 % OPE \$ OPE Effort C-M Personnel Role Base Мо Salary Total Cost Coffin, Phillip MD PI Costs in sub \$197,300 9 7% 0.67 \$10,951 0.35 \$3,833 \$14,784 Total Salary \$10,951 \$3,833 \$14,784 Subcontract - San Francisco Public Health Qty Cost Total Heluna Health \$11,012 Travel Qty Cost Total Sub-Total \$0 PHFE CCSF Sq Other FTE FTE FT \$ Months Total \$563 \$2 Rent 0.05 0.075 250 9 Sub-Total \$563 Total Direct Costs \$26,359 MTDC \$25,796 Indirect Rate 10% \$2,580 Total \$28,938

Subaward 1017225_SFDPH - ATTACHMENT 5 - BUDGET

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.

Cooperative Agreement

Notice of Award

Federal Award Date: 05/29/2020



National Institutes of Health

NATIONAL INSTITUTE ON DRUG ABUSE

Department of Health and Human Services

Grant Number: 2UG1DA015815-19 **FAIN:** UG1DA015815

Principal Investigator(s):

Keith N. Humphreys, PHD Philip Todd Korthuis (contact), MD

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

Franco, Amy A Grants & Contracts Admin - S 3181 SW Sam Jackson Park Rd L1060PAM Portland, OR 972393098

Award e-mailed to: orserv@ohsu.edu

Period Of Performance: Budget Period: 06/01/2020 – 02/28/2021 Project Period: 09/30/2002 – 02/28/2025

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$915,318 (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 grantee when funds are drawn down or otherwise obtained 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 contact the individual(s) referenced in Section IV.

Sincerely yours,

Jennifer J. Cho Grants Management Officer NATIONAL INSTITUTE ON DRUG ABUSE

Additional information follows

SECTION I – AWARD DATA – 2UG1DA015815-19

Award Calculation (U.S. Dollars)	
Salaries and Wages	\$234,628
Fringe Benefits	\$81,052
Personnel Costs (Subtotal)	\$315,680
Consultant Services	\$48,000
Materials & Supplies	\$1,500
Travel	\$30,938
Other	\$15,624
Subawards/Consortium/Contractual Costs	\$252,202
Publication Costs	\$2,000
Federal Direct Costs	\$665,944
Federal F&A Costs	\$249,374
Approved Budget	\$915,318
Total Amount of Federal Funds Obligated (Federal Share)	\$915,318
TOTAL FEDERAL AWARD AMOUNT	\$915,318
	\$910,310
	\$045.040

AMOUNT OF THIS ACTION (FEDERAL SHARE)

\$915,318

SUMMARY TOTALS FOR ALL YEARS		
YR	THIS AWARD	CUMULATIVE TOTALS
19	\$915,318	\$915,318
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:

CFDA Name:	Drug Abuse and Addiction Research Programs
CFDA Number:	93.279
EIN:	1931176109A1
Document Number:	UDA015815E
PMS Account Type:	P (Subaccount)
Fiscal Year:	2020

IC	CAN	2020	2021	2022	2023	2024
DA	8472653	\$915,318	\$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: 41027 / Released: PFLEMING 05/21/2020 Award Processed: 05/29/2020 12:29:06 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 2UG1DA015815-19

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 - TERMS AND CONDITIONS - 2UG1DA015815-19

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).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VI 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</u> <u>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_fdaaa/</u>

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 Special Terms and Conditions – 2UG1DA015815-19

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.

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.

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 <u>http://grants.nih.gov/policy/nihgps/index.htm</u> for specific requirements related to the protection of human subjects, which are applicable to this term and condition of award.

FY2020 FUNDING

The award amount for the current year is based upon IRG/Council recommendations, cost analysis, program priorities and availability of funds.

ADDITIONAL PROTOCOL EXPENSES INCLUDED

This award provides additional funds in the amount of \$109,131 Total Costs to support CTN-0067. These funds are restricted for stated purpose, in request dated 4/23/2020, from Elizabeth Salvatierra/Oregon Health & Science University, and may not be used for any other purpose, without Grants Management Branch, NIDA approval.

BUDGET PERIOD

This award is funded at the recommended level adjusted to a 9-month budget period.

Future year anniversary dates for this grant will be **March** 1 and the Research Performance Progress Report (RPPR) is due on **January** 1.

MULTIPLE PI

The following principal investigators (PIs) are associated with this project:

- Philip Korthuis (Oregon Health & Science University)
- Keith Humphreys (Stanford University)

Dr. Korthuis is the contact PI for correspondence purposes. As this grant has multiple Principal Investigators (PIs), all NIH Grant policies regarding multiple PIs, including, but, not limited to all prior approval requirements, must be followed accordingly, see NIH Grants Policy Statement,

section on Multiple Program Director/Principal Investigators, found at http://grants.nih.gov/policy/nihgps/index.htm.

CTN TERMS

This award is issued as a Cooperative Agreement, a financial assistance mechanisms 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-15-008</u>, "The <u>National Drug Abuse Treatment Clinical Trials Network (UG1)</u>," 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: Landhing Moran (CTN-0067) Email: <u>Imoran@nida.nih.gov</u> Phone: 301-827-0642

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.

CONSORTIUM ACTIVITY

This award includes funds awarded for consortium activities. Consortia are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS), Section on Consortium Agreements - <u>http://grants.nih.gov/policy/nihgps/index.htm</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.

DATA AND SAFETY MONITORING BOARD (DSMB)

This award is subject to the <u>NIDA Guidelines for Establishing and Operating a Data and</u> <u>Safety Monitoring Board</u>

DATA AND SAFETY MONITORING

This award is subject to the Data and Safety Monitoring Plan (DSMP) submitted and approved by NIDA, via application, dated 11/11/2019. 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, via revision. 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.

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. 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.

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Jennifer L Schermerhorn Email: schermerhornj@mail.nih.gov Phone: 301-827-6704

Program Official: Ronald Dobbins Email: rdobbins@nida.nih.gov Phone: 301 443-6697 Fax: 301-443-2317

SPREADSHEET SUMMARY

GRANT NUMBER: 2UG1DA015815-19

INSTITUTION: OREGON HEALTH & SCIENCE UNIVERSITY

Budget	Year 19	Year 20	Year 21	Year 22	Year 23
Salaries and Wages	\$234,628	\$201,547	\$201,547	\$201,547	\$201,547
Fringe Benefits	\$81,052	\$69,140	\$69,140	\$69,140	\$69,140
Personnel Costs (Subtotal)	\$315,680	\$270,687	\$270,687	\$270,687	\$270,687
Consultant Services	\$48,000	\$36,000	\$36,000	\$36,000	\$36,000
Materials & Supplies	\$1,500				
Travel	\$30,938	\$23,964	\$26,598	\$24,424	\$23,859
Other	\$15,624				
Subawards/Consortium/Contractual	\$252,202	\$245,181	\$231,074	\$231,074	\$231,074
Costs					
Publication Costs	\$2,000	\$1,000	\$2,000	\$2,000	\$2,000
TOTAL FEDERAL DC	\$665,944	\$576,832	\$566,359	\$564,185	\$563,620
TOTAL FEDERAL F&A	\$249,374	\$179,092	\$181,054	\$179,880	\$179,575
TOTAL COST	\$915,318	\$755,924	\$747,413	\$744,065	\$743,195

Facilities and Administrative Costs	Year 19	Year 20	Year 21	Year 22	Year 23
F&A Cost Rate 1	54%	54%	54%	54%	54%
F&A Cost Base 1	\$423,725	\$331,651	\$335,285	\$333,111	\$332,546
F&A Costs 1	\$228,812	\$179,092	\$181,054	\$179,880	\$179,575

F&A Cost Rate 2	32%		
F&A Cost Base 2	\$64,255		
F&A Costs 2	\$20,562		