

Research Subaward Agreement Amendment Number 3			
Pass-through Entity (PTE)		Subrecipient	
Institution/Organization ("PTE") Entity Name: Oregon Health & Science University Email Address: spasub@ohsu.edu Principal Investigator: Todd Korthuis		Institution/Organization ("Subrecipient") Entity Name: City & County of San Francisco, Department of Public Health Email Address: sajid.shaikh@sfdph.org Principal Investigator: Phillip Coffin	
Project Title: Western States Node of the National Drug Abuse Treatment Clinical Trials Network			
PTE Federal Award No. 5UG1DA015815-22		Federal Awarding Agency: DHHS NIH NIDA	
Subaward Period of Performance: Start Date: 06/01/2020 End Date: 29-FEB-2024	Amount Funded This Action: \$28,327.00	Subaward No: 1017225_SFDPH	
Effective Date of Amendment: 01-MAR-2023	Total Amount of Federal Funds Obligated to Date: \$109,937.00	Subject to FFATA: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Automatic Carryover: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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 29-FEB-2024.

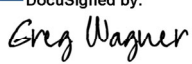
The Current Budget Period is from 01-MAR-2023 through 29-FEB-2024.

Funds for the Current Budget Period are hereby awarded in the amount of \$28,327.00 per the Budget in Attachment 5.3.

Applicable terms and conditions in Attachment 6.3, the Prime Award, is hereby incorporated by reference.

Dr. Grant Colfax, Director of Health, retroactively approves the original agreement dated August 18, 2020. Deputy City Attorney, Henry L. Lifton, retroactively approves as to form the original agreement and Amendment No. 1.

All other terms and conditions of this Subaward Agreement remain in full force and effect.

By an Authorized Official of PTE Dawn M. Geoppinger Digitally signed by Dawn M. Geoppinger Date: 2023.04.03 11:33:56 -07'00' Name: Grants & Contracts Administrator Date: _____	By an Authorized Official of Subrecipient DocuSigned by:  28527524752949F... Date: 4/3/2023 9:59:42 PDT Name: Grant Colfax, MD Title: Director of Health
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Approved as to form, David Chiu, City Attorney

By: 
 6D6CB58424584B1...
 Henry L. Lifton, Deputy City Attorney

**DETAILED BUDGET FOR INITIAL BUDGET PERIOD
DIRECT COSTS ONLY**

FROM
03/01/2023

THROUGH
02/29/2024

List PERSONNEL (*Applicant organization only*)
Use Cal, Acad, or Summer to Enter Months Devoted to Project
Enter Dollar Amounts Requested (*omit cents*) for Salary Requested and Fringe Benefits

NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths	INST.BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
Coffin, Phillip	Co-Investigator	0.6			\$203,700	\$10,185	\$3,667	\$13,852
SUBTOTALS						\$10,185	\$3,667	\$13,852

CONSULTANT COSTS	
EQUIPMENT (<i>Itemize</i>)	
SUPPLIES (<i>Itemize by category</i>)	
TRAVEL	
INPATIENT CARE COSTS	
OUTPATIENT CARE COSTS	
ALTERATIONS AND RENOVATIONS (<i>Itemize by category</i>)	
OTHER EXPENSES (<i>Itemize by category</i>)	

CONSORTIUM/CONTRACTUAL COSTS Heluna Health (PHFE) \$11,012	DIRECT COSTS	\$11,012
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD (<i>Item 7a, Face Page</i>)		\$ 24,864
CONSORTIUM/CONTRACTUAL COSTS – 25% MTDC x \$13,852	FACILITIES AND ADMINISTRATIVE COSTS	\$3,463
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD		\$ 28,327



Recipient Information	Federal Award Information																										
<p>1. Recipient Name OREGON HEALTH & SCIENCE UNIVERSITY 3181 SW SAM JACKSON PARK RD PORTLAND, 97239</p> <p>2. Congressional District of Recipient 03</p> <p>3. Payment System Identifier (ID) 1931176109A1</p> <p>4. Employer Identification Number (EIN) 931176109</p> <p>5. Data Universal Numbering System (DUNS) 096997515</p> <p>6. Recipient's Unique Entity Identifier NPSNT86JKN51</p> <p>7. Project Director or Principal Investigator Philip Todd Korthuis, MD (Contact) Associate Professor Of Medicine korthuis@ohsu.edu 503-494-8044</p> <p>8. Authorized Official Elizabeth Sobolewski salvatie@ohsu.edu 503-418-5498</p>	<p>11. Award Number 5UG1DA015815-22</p> <p>12. Unique Federal Award Identification Number (FAIN) UG1DA015815</p> <p>13. Statutory Authority 42 USC 241 31 USC 6305 42 CFR 52</p> <p>14. Federal Award Project Title Western States Node of the National Drug Abuse Treatment Clinical Trials Network</p> <p>15. Assistance Listing Number 93.279</p> <p>16. Assistance Listing Program Title Drug Abuse and Addiction Research Programs</p> <p>17. Award Action Type Non-Competing Continuation (REVISED)</p> <p>18. Is the Award R&D? Yes</p>																										
<p>Federal Agency Information</p> <p>9. Awarding Agency Contact Information Allison Moyal Grants Management Specialist NATIONAL INSTITUTE ON DRUG ABUSE moyala@mail.nih.gov 3018278036</p> <p>10. Program Official Contact Information Ronald Dobbins NATIONAL INSTITUTE ON DRUG ABUSE rdobbins@nida.nih.gov 301 443-6697</p>	<table border="1" style="width:100%; border-collapse: collapse; margin-bottom: 10px;"> <thead> <tr style="background-color: #e1eef6;"> <th colspan="2" style="text-align: center; padding: 5px;">Summary Federal Award Financial Information</th> </tr> </thead> <tbody> <tr style="background-color: #e1eef6;"> <td colspan="2" style="padding: 5px;">19. Budget Period Start Date 03/01/2023 – End Date 02/29/2024</td> </tr> <tr> <td style="padding: 5px;">20. Total Amount of Federal Funds Obligated by this Action</td> <td style="text-align: right; padding: 5px;">\$0</td> </tr> <tr> <td style="padding: 5px;"> 20 a. Direct Cost Amount</td> <td style="text-align: right; padding: 5px;">\$28,088</td> </tr> <tr> <td style="padding: 5px;"> 20 b. Indirect Cost Amount</td> <td style="text-align: right; padding: 5px;">\$10,074</td> </tr> <tr> <td style="padding: 5px;">21. Authorized Carryover</td> <td style="text-align: right; padding: 5px;">\$38,162</td> </tr> <tr> <td style="padding: 5px;">22. Offset</td> <td style="text-align: right; padding: 5px;">\$0</td> </tr> <tr> <td style="padding: 5px;">23. Total Amount of Federal Funds Obligated this budget period</td> <td style="text-align: right; padding: 5px;">\$178,971</td> </tr> <tr> <td style="padding: 5px;">24. Total Approved Cost Sharing or Matching, where applicable</td> <td style="text-align: right; padding: 5px;">\$0</td> </tr> <tr> <td style="padding: 5px;">25. Total Federal and Non-Federal Approved this Budget Period</td> <td style="text-align: right; padding: 5px;">\$178,971</td> </tr> <tr> <td colspan="2" style="padding: 5px;">-----</td> </tr> <tr style="background-color: #e1eef6;"> <td colspan="2" style="padding: 5px;">26. Project Period Start Date 09/30/2002 – End Date 02/28/2025</td> </tr> <tr> <td style="padding: 5px;">27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period</td> <td style="text-align: right; padding: 5px;">\$5,882,863</td> </tr> </tbody> </table> <p>28. Authorized Treatment of Program Income Additional Costs</p> <p>29. Grants Management Officer - Signature Carol Alderson</p>	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	\$0	20 a. Direct Cost Amount	\$28,088	20 b. Indirect Cost Amount	\$10,074	21. Authorized Carryover	\$38,162	22. Offset	\$0	23. Total Amount of Federal Funds Obligated this budget period	\$178,971	24. Total Approved Cost Sharing or Matching, where applicable	\$0	25. Total Federal and Non-Federal Approved this Budget Period	\$178,971	-----		26. Project Period Start Date 09/30/2002 – End Date 02/28/2025		27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	\$5,882,863
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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.																											



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

Notice of Award



NATIONAL INSTITUTE ON DRUG ABUSE

SECTION I – AWARD DATA – 5UG1DA015815-22 REVISED

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 revises this award (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,

Carol Alderson
Grants Management Officer
NATIONAL INSTITUTE ON DRUG ABUSE

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	\$222,379
Fringe Benefits	\$82,056
Personnel Costs (Subtotal)	\$304,435
Consultant Services	\$3,750
Materials & Supplies	\$2,600
Travel	\$36,510
Other	\$1,200
Subawards/Consortium/Contractual Costs	\$989,704
Publication Costs	\$2,000
Federal Direct Costs	\$1,340,199
Federal F&A Costs	\$184,926
Approved Budget	\$1,525,125
Total Amount of Federal Funds Authorized (Federal Share)	\$178,971
Cumulative Authorized Carryover and Offset for this Budget Period	\$1,346,154
TOTAL FEDERAL AWARD AMOUNT	\$178,971
AMOUNT OF THIS ACTION (FEDERAL SHARE)	\$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	THIS AWARD	CUMULATIVE TOTALS
22	\$178,971	\$178,971
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: 2023

IC	CAN	2023	2024
DA	8058361	\$178,971	
DA	8472653		\$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: Alderson, Carol 03/07/2023
 Award Processed: 03/08/2023 12:10:36 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5UG1DA015815-22 REVISED

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 – 5UG1DA015815-22 REVISED

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 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) 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 [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 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.

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 – 5UG1DA015815-22 REVISED

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.

REVISION #1 - CARRYOVER APPROVED

This revised award includes a carryover of \$38,162 (\$28,088 direct costs; \$10,074 F&A costs) from the -20 year to the -22 year. These funds are restricted for the stated purpose(s) listed in the eRA-submitted request dated 2-21-23 from Elizabeth Sobolewski at Oregon Health & Science University and may not be rebudgeted or used for other purposes.

The recipient is reminded that carryover funds are subject to the appropriation in effect when the funds were initially awarded, and salaries must not exceed the applicable [salary cap](#) for that fiscal year. For additional information, see the [NIH Grants Policy Statement \(NIH GPS\)](#), and see Section on Salary Cap, Salary Limitation, 4.2.10, and Prior Approval Requirements, 8.1.2.

This revision supersedes Notice of Award (NoA) issued 2-28-23. All other terms below remain applicable.

HUMAN SUBJECTS RESOLVED for CTN-0125 and CTN-0136

This award reflects NIDA's acceptance of the certification of Institutional Review Board (IRB) approval for the recipient and releases the restriction on the Notice of Award issued on 5-31-22 and 9-9-22. Accordingly, the special condition prohibiting research involving human subjects is removed as of the effective date of the IRB approval. See the NIH Grants Policy Statement, section on Human Subjects Protections <http://grants.nih.gov/policy/nihgps/index.htm> for specific requirements related to the protection of human subjects, which are applicable to this term and condition of award.

This revision supersedes Notice of Award (NoA) issued on MM/DD/YY. All other terms below remain applicable.

FUNDING ADJUSTMENT

Funds in the amount of \$1,307,992 have been used as an offset to this award in accordance with the unobligated balance reported on the -20 year Federal Financial Report. Funds in the amount of \$178,971 are being awarded to cover costs associated with HEAL studies only.

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-0101: Geetha Subramaniam
Email: subramaniamga@nida.nih.gov
Phone: 301-480-2593

CTN-0125: Xiaoming Wang
Email: wangx19@mail.nih.gov
Phone: 301-827-6332

CTN-0136: Jeremiah Bertz
Email: Jeremiah.bertz@nih.gov
Phone: 301-433-6697

CTN-0139: Geetha Subramaniam
Email: subramaniamga@nida.nih.gov
Phone: 301-480-2593

DATA 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 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:** 5UG1DA015815-22 REVISED**INSTITUTION:** OREGON HEALTH & SCIENCE UNIVERSITY

Budget	Year 22	Year 23
Salaries and Wages	\$222,379	\$201,547
Fringe Benefits	\$82,056	\$69,140
Personnel Costs (Subtotal)	\$304,435	\$270,687
Consultant Services	\$3,750	\$36,000
Materials & Supplies	\$2,600	
Travel	\$36,510	\$23,859
Other	\$1,200	
Subawards/Consortium/Contractual Costs	\$989,704	\$231,074
Publication Costs	\$2,000	\$2,000
TOTAL FEDERAL DC	\$1,340,199	\$563,620
TOTAL FEDERAL F&A	\$184,926	\$179,575
TOTAL COST	\$1,78,971	\$743,195

Facilities and Administrative Costs	Year 22	Year 23
F&A Cost Rate 1	54%	54%
F&A Cost Base 1	\$330,762	\$332,546
F&A Costs 1	\$178,611	\$179,575
F&A Cost Rate 2	32%	
F&A Cost Base 2	\$19,733	
F&A Costs 2	\$6,315	