

March 24, 2022

Board of County Commissioners
Clackamas County

Approval of an amendment to the Research Subaward Agreement with Oregon Health Science University (OHSU) for Institutional Review Board (IRB) study. Total value is up to \$219,419.00. Funding through Oregon Health and Science University.

County General Funds are not involved.

Purpose/Outcomes	The purpose of this amendment is to continue Clackamas Health Centers (CHC) participation in an IRB focused study on opioid treatment in Criminal Justice System (CJS) involved adults.
Dollar Amount and Fiscal Impact	OSHU will pay CHC up to \$219,419.00 over a period of four years. This amendment is for year two in the amount of \$61,747.00. No County General Funds are involved. No matching funds required
Funding Source	Oregon Health and Science University
Duration	August 1, 2021 – July 31, 2022
Previous Board Action	March 22, 2022 issues; July 8, 2021 Agenda Item – A6:070821-A6.
Strategic Plan Alignment	1. Improve Community Safety and Health. 2. Ensure safe, healthy and secure communities.
Counsel Review	1. February 3, 2022 2. KR
Procurement Review	1. Was the item processed through Procurement? yes <input type="checkbox"/> no <input checked="" type="checkbox"/> 2. This was a direct procurement
Contact Person	Deborah Cockrell, Health Center Director – 503-742-5495
Contract No.	10057_01

BACKGROUND:

Clackamas Health Centers (CHC) of the Health, Housing and Human Services Department requests the approval of amendment #1 to agreement #10057 with OHSU for the purpose of participating in an IRB study focused on opioid addictions.

The National Institutes of Health will award grants from the Justice Community Opioid Innovation Network (JCOIN) to support research on quality addiction treatment for opioid use disorder (OUD) in criminal justice settings nationwide. OSHU will be part of the JCOIN network and sponsor CHC as a participant in this study. OSHU will be accessing CHC patients currently incarcerated with the Corrections Department.

The total amount of this amendment is \$61,747.00. The total amount of the agreement will be up to \$219,419.00 over a period of four years. No County General Funds are involved. The agreement is effective August 1, 2021 through July 31, 2022. This agreement is retro-active due to receiving late from OSHU.

RECOMMENDATION:

Staff recommends approval of this contract, and authorizes the Chair to sign on behalf of the County.

Healthy Families. Strong Communities.

2051 Kaen Road, Oregon City, OR 97045 • Phone (503) 650-5697 • Fax (503) 655-8677

Clackamas.us/h3s

Respectfully submitted,

Rodney Cook

Rodney A. Cook, Director
Health, Housing & Human Services Department

Research Subaward Agreement Amendment Number 1			
Pass-through Entity (PTE)		Subrecipient	
Institution/Organization ("PTE") Entity Name: Oregon Health & Science University Email Address: spasub@ohsu.edu Principal Investigator: Elizabeth Waddell		Institution/Organization ("Subrecipient") Entity Name: Clackamas County Email Address: healthcentercontracts@clackamas.us; rhoward@clackamas.us Principal Investigator: Andrew Suchocki	
Project Title: Long-acting buprenorphine vs. naltrexone opioid treatments in CJS-involved adults			
PTE Federal Award No. 5U01DA047982-03 via Subaward 18-A0-00-1001703 from NYU		Federal Awarding Agency: DHHS NIH via NYU	
Subaward Period of Performance: Start Date: 08/001/2020 End Date: 07/31/2022		Amount Funded This Action: \$61,747	Subaward No: 1013969_CLACKAMAS
Effective Date of Amendment: 08/01/2021	Total Amount of Federal Funds Obligated to Date: \$77,356	Subject to FFATA: <input checked="" type="checkbox"/> Yes <input 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 07/31/2022.

The Current Budget Period is from 08/01/2021 through 07/31/2022.

Funds for the Current Budget Period are hereby awarded in the amount of \$61,747 per 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, as follows:

Website: <http://www.ohsu.edu/xd/research/administration/proposal-and-award-management/index.cfm>

Administrative Contact Email: michauj@ohsu.edu, cc: spasub@ohsu.edu

COI Contact Email: coir@ohsu.edu

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

By an Authorized Official of PTE _____ Date: _____ Jen Michaud Subout Grants & Contracts Administrator	By an Authorized Official of Subrecipient _____ Date: _____ Name: Title:
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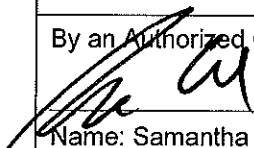
Approved as to form: *Kathleen Rastetter*
2/3/2022

Exit CJS Program
Clackamas Health Centers

YR 3 (08/01/2021 - 07/31/2022)				
Personnel				
Employee	Hr/wk	Salary	Fringe	Total
SUCHOCKI, ANDREW	4.00	19,930	8,338	28,268
KING, JENNIFER	4.00	16,171	9,609	25,780
KING, LESLIE	1.00	2,318	1,604	3,922
CLOTEAUX, SABRINA	1.00	2,744	1,033	3,777
Total Personnel		41,163	20,584	61,747

Materials & Services				
Desc	# of Clients	Units Per Client	Cost per Unit	Total Cost
Meds				-
Testing				-
Total Materials & Services				-

Grand Total	61,747.00
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Subaward Agreement Amendment							
Institution/Organization ("University") Name: New York University, on behalf of its Grossman School of Medicine Address: Sponsored Programs Administration One Park Avenue, 6 th FL New York, NY 10016	Institution/Organization ("Collaborator") Name: Oregon Health & Science University Address: 3181 SW Sam Jackson Park Road Portland, OR 97239-3911 DUNS No. 096997515 EIN No.: 931176109A1						
Prime Award No. 1U01DA047982-01 REVISED	Subaward No. 18-A0-00-1001703						
FAIN: U01DA047982	Project # 111675						
Awarding Agency: NIH/NIDA	CFDA No. 93.279						
University Principal Investigator Dr. Joshua Lee	Collaborator Principal Investigator Dr. Elizabeth Waddell						
Effective Date of Amendment 8/1/2021	Amendment #4						
Project Title: Long-acting buprenorphine vs. naltrexone opioid treatments in CJS-involved adults							
Amendment(s) to Original Terms and Conditions							
<p>This Amendment # 4 (this "Amendment") to the subaward agreement (as amended from time to time, the "Subaward Agreement") between University and Collaborator, relating to work to be performed by Collaborator for the period beginning 8/1/2021 for the above-identified project, amends the Subaward Agreement as set forth below. All capitalized terms used but not defined herein shall have the meanings assigned to such terms in the Subaward Agreement.</p>							
<ol style="list-style-type: none"> 1. The end date of the period of performance under the Subaward Agreement is extended from 7/31/2021 to 7/31/2022. 2. This Amendment authorizes funds in the amount of \$298,868 for direct costs and \$34,128 for indirect costs incurred during the period beginning on the Effective Date through 7/31/2022. The total costs awarded under this Amendment for such period are \$332,996. The allowability of costs will be determined in accordance with applicable OMB and DHHS cost principles. In accordance with the foregoing, the following text and Attachment 1 hereto sets forth the budget for the period of performance of this Amendment: 							
<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border-top: 1px solid black;">Direct Costs</td> <td style="border-top: 1px solid black; text-align: right;">\$298,868</td> </tr> <tr> <td style="border-top: 1px solid black;">Indirect Cost</td> <td style="border-top: 1px solid black; text-align: right;">\$34,128</td> </tr> <tr> <td style="border-top: 1px solid black;">TOTAL COSTS</td> <td style="border-top: 1px solid black; text-align: right;">\$332,996</td> </tr> </table>		Direct Costs	\$298,868	Indirect Cost	\$34,128	TOTAL COSTS	\$332,996
Direct Costs	\$298,868						
Indirect Cost	\$34,128						
TOTAL COSTS	\$332,996						
<ol style="list-style-type: none"> 3. All other terms and conditions of the Subaward Agreement remain in full force and effect. 4. By signing this Amendment, an authorized official of Collaborator certifies, to the best of his/her knowledge and belief, that all certifications, representations and assurances set forth in the Subaward Agreement remain true and complete as of the date of his/her signature below. 							
By an Authorized Official of University:  Name: Samantha Ebel, Date: 11/18/21 Title: Associate Director, OSR Contracts	By an Authorized Official of Collaborator: Jon Geselle <small>Digitally signed by Jon Geselle Date: 2021.11.18 15:14:10 -0500</small> Name: Jon Geselle Date: 11/18/2021 Title: Grants & Contracts Administrator						

**Attachment# 1
BUDGET**

Subaward # 18-A0-00-1001703

Between

New York University, on behalf of its Grossman School of Medicine
And
Oregon Health & Science University

Detailed Budget / Budget Justification

Below or Attached 6 pages

Direct Costs	\$298,868
Indirect Cost	\$34,128
TOTAL COSTS	\$332,996

F&A Rate Applied 32% on Total Direct Costs (TDC) or Modified Total Direct Costs (MTDC) or Other

Cost Sharing: Yes, Amount \$
 No

GENERAL TERMS OF PAYMENT:

This subaward is made only for the purposes stated in this Subaward Agreement and it is understood that the funds provided under this Subaward Agreement will be used for such purposes substantially in accordance with the budget/schedule above and/or attached hereto. University shall not reimburse Collaborator for costs in excess of the budget/schedule above and/or attached hereto. Payments to Collaborator are contingent upon submission of required reports (see Attachment 4) and adherence to the agreed-upon statement of work.

DETAILED BUDGET FOR NEXT BUDGET PERIOD – DIRECT COSTS ONLY	FROM 08/01/2021	THROUGH 07/31/2022	GRANT NUMBER U01DA047982-03
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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	SALARY REQUESTED	FRINGE BENEFITS	TOTALS
Waddell, Elizabeth	PD/PI	.84			9,033	3,359	12,392
Kunkel, Lynn	Protocol Manager	.60			5,386	2,104	7,490
Hart, Elijah	Outreach Coordinator	6.0			16,671	4,297	20,968
Nichols, Ceilidh	Regulatory Specialist	.24			1,301	516	1,817
SUBTOTALS					32,391	10,276	42,667

CONSULTANT COSTS
 None requested

EQUIPMENT (*Itemize*)
 None requested

SUPPLIES (*Itemize by category*)
 Operating Supplies = \$500

500

TRAVEL
 None requested

INPATIENT CARE COSTS

OUTPATIENT CARE COSTS

ALTERATIONS AND RENOVATIONS (*Itemize by category*)
 None requested

OTHER EXPENSES (*Itemize by category*)
 Telecommunication = \$900
 Participant incentives = \$1,780; Lab Test = \$1,000; Study Medications = \$500

4,180

SUBTOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD **\$ 47,347**

CONSORTIUM/CONTRACTUAL COSTS	DIRECT COSTS	251,521
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CONSORTIUM/CONTRACTUAL COSTS	FACILITIES AND ADMINISTRATIVE COSTS	18,977
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TOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD (*Item 8a, Face Page*) **\$ 317,845**

Program Director/Principal Investigator (Last, first, middle): Waddell, Elizabeth Subaward: 18-AO-00-1001703

GRANT NUMBER
U01DA047982-03

CHECKLIST

1. PROGRAM INCOME (See instructions.)

All applications must indicate whether program income is anticipated during the period(s) for which grant support is requested. If program income is anticipated, use the format below to reflect the amount and source(s).

Budget Period	Anticipated Amount	Source(s)
8/1/2021 - 7/31/2022	0.00	

2. ASSURANCES/CERTIFICATIONS (See instructions.)

In signing the application Face Page, the authorized organizational representative agrees to comply with the policies, assurances and/or certifications listed in the application instructions when applicable. Descriptions of individual assurances/certifications are provided in Part III of the PHS 398, and listed in Part I, 4.1 under Item 14. If unable to certify compliance, where applicable, provide an explanation and place it after the Progress Report (Form Page 5).

3. FACILITIES AND ADMINISTRATIVE (F&A) COSTS

Indicate the applicant organization's most recent F&A cost rate established with the appropriate DHHS Regional Office, or, in the case of for-profit organizations, the rate established with the appropriate PHS Agency Cost Advisory Office.

F&A costs will *not* be paid on construction grants, grants to Federal organizations, grants to individuals, and conference grants. Follow any additional instructions provided for Research Career Awards, Institutional National Research Service Awards, Small Business Innovation Research/Small Business Technology Transfer Grants, foreign grants, and specialized grant applications.

DHHS Agreement dated: 12/10/2018 No Facilities and Administrative Costs Requested.

No DHHS Agreement, but rate established with _____ Date _____

CALCULATION*

Entire proposed budget period: Amount of base \$ 47,347 x Rate applied 32.00 % = F&A costs \$ 15,152

Add to total direct costs from Form Page 2 and enter new total on Face Page, Item 8b.

*Check appropriate box(es):

Salary and wages base Modified total direct cost base Other base (Explain)

Off-site, other special rate, or more than one rate involved (Explain)

Explanation (Attach separate sheet, if necessary.):

BUDGET JUSTIFICATION

OHSU Subaward: 18-AO-00-1001703

Oregon Health Science University
August 1, 2021 – July 31, 2022
Revised budget

The following budget justification is provided as a revision to the budget that was previously submitted for year 3. This justification accommodates the reduced funding that was provided in the Notice of Grant Award. In order to fully implement the trial, access to previous carryforward funds will be needed.

A. Senior/Key Personnel

Elizabeth Needham Waddell, MA, PhD, MPI (0.84 cal mons for year 3; 7% FTE) Elizabeth Needham Waddell, PhD is an Associate Professor in the Oregon Health & Science University-Portland State University School of Public Health and the OHSU School of Medicine. She works closely with addiction medicine and behavioral health service providers to identify best practices for integration and to develop a greater understanding of the barriers and facilitators of effective treatment for adults cycling through jail and prison. She is principal investigator on a CDC research grant "Reducing Overdose after Release from Incarceration" (ROAR), which combines medications for addiction treatment with support from certified recovery mentors for women as they are released from prison. The project's evaluation includes a first-time linkage of Oregon's Corrections and Health Authority datasets to assess overdose risk among justice-involved adults. She is an MPI on the New York University Hub of NIDA's Justice Community Opioid Innovation Network (JCOIN), leading the Oregon sites of a national trial comparing extended release buprenorphine and extended release naltrexone in a sample of justice involved adults. She is co-Investigator on the Western States Node of the NIDA Clinical Trials network and two NIH studies focused on barriers to treatment among people who currently inject drugs: "Peer-Based Retention of people who Use Drugs in Rural Research" and the "Oregon HIV/Hepatitis and Opioid Prevention and Engagement (OR-HOPE) Study." Dr. Waddell is an NIH New Investigator and is directly supported and mentored by Dr. David Farabee (MPI, NYU).

As Principal Investigator Dr. Waddell will oversee the recruitment of persons with opiate use disorder (OUD) within the Clackamas County Jail and the Washington County Jail; she will also oversee the design of the study with the MPIs and investigators, utilizing her experience as a researcher in the field to collect demographic and clinical information relevant to the study persons with OUD seeking medications for addictions treatment (MAT) within the criminal justice system. In collaboration with Study Clinicians from CODA and Clackamas County Health Centers, Dr. Waddell is responsible for recruitment, baseline and follow-up clinical characteristic assessments, staff supervision, project development, implementation, progress monitoring, and adherence to protocol. She will meet with all staff on a weekly or bi-weekly basis to coordinate study activities and track observance to project timelines. She will hold weekly meetings through Webex, or in-person with Oregon staff, and participate in all national study meetings with the NYU JCOIN Hub. Dr. Waddell and the MPIs will be responsible for writing interim progress reports, interpreting the data and preparing posters, presentations, and manuscripts.

B. Other Personnel

Lynn Kunkel, MS, CCRP, Protocol Manager (0.60 CM in year 3; 5% FTE) will work in conjunction with Dr. Waddell to oversee all study management and quality assurance activities for the project, including clinical trials management and posting. Ms. Kunkel coordinates and assists in all activities associated with implementing the study, will chair weekly meetings to monitor the study, will coordinate all training activities, and serve as the primary liaison between the OHSU team, Corrections Health, and CODA. She will work with Dr. Waddell to develop a Manual of Operations to ensure protocol adherence, training staff, and monitoring study progress. Ms. Kunkel is a CTN Good Research Practice trainer and received a Certified Clinical Research Professional (CCRP) certificate in 2007.

Ceilidh Nichols, BS, CCRP, Regulatory Specialist (0.24 CM in year 3; 2% FTE) will serve as the OHSU Regulatory and Compliance Specialist for the study. As such she will work closely with the Protocol Manager and the PI to develop and maintain the Manual of Operations, maintaining the regulatory binders and managing IRB submissions. The Regulatory Specialist will work to comply with local, state and federal regulatory guidelines. Ms. Nichols received her Certified Clinical Research Professional (CCRP) certificate in 2017.

Elijah Hart, Outreach Coordinator (6.00 CM in year 3; 50% FTE) will work closely with the site Research Coordinator in Clackamas County to establish strong relationships with participants and will contact participants to remind them of upcoming appointments, check in with them and update locator information. For participants that are hard to find, the OC will be responsible for monitoring databases (Death Index, Arrest records, etc), conducting street outreach and other activities to locate participants to re-engage them back into the study. In some situations, the OC may be asked to administer research measures and collect urine toxicology samples. The OC will assist the MPI, Protocol Director and Research Coordinator in carrying out all aims of the project.

C. Equipment

N/A

D. Travel

N/A

E. Participant/Trainee Support Costs

N/A

F. Other Direct Costs

Other (\$4,680)

- **Materials and Supplies (\$500)** – Funds are requested to support miscellaneous supplies for the project. Supplies may include printer paper and ink to print out study related, file folders, and other such materials.
- **Participant incentives (\$1,780)** – participants will receive monetary compensation for their time and travel for each of their research visits. Participants will be seen twice pre-release but will not be receiving compensation while they're in locked facilities.
- **Study Medications (\$500)** – participants who are randomized to the Sublocade® or XR Buprenorphine group (N=67) who are not opioid tolerant (meaning have not used opioids in >30 days) will require induction and stabilization with sublingual buprenorphine prior to starting the XR Buprenorphine for a period of up to 14 days; in addition both the XR BUP and the XR NTX groups will receive Narcan® (naloxone) kits prior to discharge to prevent overdose (N=67 per each group total of 132).
- **Lab Tests (\$1,000)**- Funds are requested to support the following lab tests required by the protocol:
 - **Urine Toxicology:** Urine toxicology screens will be used throughout the study to screen each participant for the presence of illicit drug use. Toxicology screenings will be conducted at the time of each research interview. All participants will undergo urine toxicology screens at each research visit.
 - **Pregnancy Tests:** Pregnancy tests are needed to check for pregnancy during the study period as pregnancy is an exclusion criterion.
- **Research Staff Mobile Phones (\$900):** Funds are requested to maintain mobile phones for study staff. Imperative to the implementation of this study is the continuous communication between the study staff members, participants and the drug treatment centers. A cell phones is requested for the OHSU Outreach Coordinator.

Subawards (\$270,499 in year 3): Subawards will be established with CODA, Inc. and Clackamas County Health Centers.

G. Indirect Costs

The F&A rate approved for on-campus activity, used in this proposal, is 32%.

The Modified Total Direct Costs (MTDC) used for calculating F&A recovery include all project expenditures except capital equipment (>\$5,000), subcontract amounts after the first \$25,000 and tuition.

The Department of Health and Human Services, acting as the cognizant agency of the federal government, approved a facilities and administration (F&A) cost rate agreement for Oregon Health & Science University (OHSU) on December 10, 2018. The Department of Health and Human Services Representative to this agreement is Arif M. Karim, phone 415-437-7820.

Institutional Status: Oregon Health & Science University (OHSU) is a public corporation chartered by the State of Oregon pursuant to Section 353.020 of the Oregon Revised Statutes. OHSU operates under OMB's Uniform Guidance.

Scope of Work (SOW)

Project Title: Long-acting buprenorphine vs. naltrexone opioid treatments in CJS-involved adults

As a subcontractor to NYU School of Medicine all personnel (PI, Co-I, Other Personnel) listed at our study site will work closely with our Department of Corrections collaborators to contribute to all phases of this project in order to successfully carryout all aims detailed in the full proposal. Dr. Waddell and her team will be responsible for recruitment, baseline and follow-up clinical characteristic assessments, staff supervision, project development, implementation, progress monitoring, and adherence to protocol.

Attachment 3B
Research Subaward Agreement
Subrecipient Contacts

Subaward Number:

Subrecipient Place of Performance for FFATA reporting

Name:

Address:

City: State: Zip Code+4: Zip Code Look-up

EIN No.: DUNS: Parent DUNS:

Institution Type: Congressional District:

Is Subrecipient currently registered in SAM.gov? Yes No

Is Subrecipient exempt from reporting executive compensation? Yes No If no, complete 3B, page 2

Subrecipient Administrative Contact

Name:

Address:

City: State: Zip Code:

Telephone: Email:

Subrecipient Principal Investigator

Name:

Address:

City: State: Zip Code:

Telephone: Email:

Subrecipient Financial Contact

Name:

Address:

City: State: Zip Code:

Telephone: Email:

Central email: Is this the remittance address? Yes No

Remittance Address (if different):

Subrecipient Authorized Official

Name:

Address:

City: State: Zip Code:

Telephone: Email:

Central email: