



Heluna Health
EMPOWERING POPULATION
HEALTH INITIATIVES SINCE 1969

13300 Crossroads Parkway North, Suite 450 | City of Industry, CA | 91746
Phone: 800.201.7320 | Fax: 562.205.2453 | www.helunahhealth.org

[SUBCONTRACT/SUBAWARD] AGREEMENT BETWEEN

HELUNA HEALTH

AND

CITY AND COUNTY OF SAN FRANCISCO

This [Subcontract/Sub-Award] Agreement (this "Agreement") is made and entered into as of June 1, 2021 by and between PUBLIC HEALTH FOUNDATION ENTERPRISES, INC., DBA Heluna Health, a 501(c)(3) California nonprofit corporation (hereinafter referred to as "HELUNA HEALTH"), and the party identified in Section 1 below (hereinafter be referred to as "Subcontractor/Subawardee."

RECITALS

- A. HELUNA HEALTH has been granted an award by National Institute on Drug Abuse (the "Funding Agency"), under contract number 1U01DA051080-02; Federal Award Identification Number (FAIN) U01DA051080; and Catalog of Federal Domestic Assistance (CFDA) number 93.279 under which HELUNA HEALTH and its subcontractors and subawardees will collaborate on the program.
- B. Subcontractor/Subawardee has expertise in the necessary area(s) which their expertise can assist HELUNA HEALTH to perform its obligations under the Funding Award Agreement; and
- C. HELUNA HEALTH desires to engage the services of Subcontractor/Subawardee to assist HELUNA HEALTH in the performance of certain of its obligations under the Funding Award Agreement as set forth herein.
- D. The Parties understand and agree that any funding amount above \$1,000,000, that constitutes revenue to the City requires formal approval by the San Francisco Board of Supervisors acting in its sole discretion under San Francisco Charter Section 9.118.

AGREEMENT

1. IDENTITIES OF PARTIES

SUBCONTRACTOR/SUBAWARDEE:

Legal Name of Subcontractor/Subawardee: City and County of San Francisco

DBA of Subcontractor/Subawardee: San Francisco Department of Public Health

Type of Entity: Sole Proprietorship; Partnership; Corporation;

Limited Liability Company; Government

State of Organization (if an entity): California

Address: 101 Grove Street, Room 402

City/State/Zip: San Francisco, CA 94102

Business Telephone: (415) 554-2778

Social Security or Employer Identification Number: 94-60000417

License Number and Expiration Date, if any: N/A

Email Address: Sajid.shaikh@sfdph.org

Name of Principal Investigator/Project Coordinator: Phillip Coffin

Phone Number of Principal Investigator/Project Coordinator: (415) 437-6282

Is Subcontractor/Subawardee required to file a Single Audit with the Federal Government? (Required for parties who receive Federal funds in the aggregate amount of \$500,000 or more):

[X] Yes [] No

**If yes, has Subcontractor/Subawardee filed the required Single Audit? [X] Yes [] No
(If yes, submit copy to HELUNA HEALTH prior to signing this Agreement)**

HELUNA HEALTH:

Heluna Health

Address and Phone #: 13300 Crossroads Parkway North, Suite 450, City of Industry, CA, 91746-3505; (562) 699-7320

Program Name: Mirtazapine for Methamphetamine Use Disorder: Drug-drug Interaction Study

Program/CID #: 0760.0102

Project Director Name: Phillip Coffin

Project Director Phone #: (415) 437-6282

Project Director Email Address: Phillip.coffin@sfdph.org

Contracts Manager Name: Veronica Reyes

Contracts Manager Email Address: VReyes@helunahealth.org

2. SCOPE OF SERVICES

(a) Services. Subcontractor/Subawardee shall perform the services, duties and obligations set forth in the Statement of Work ("SOW") attached as Exhibit A hereto, which is made a part hereof and incorporated herein by reference (the "Services"). The Services relate Exhibit C, if attached hereto. Subcontractor/Subawardee shall perform the Services in accordance with the specifications, timetables and requirements set forth in the SOW and this Agreement. HELUNA HEALTH may, in its discretion, provide to Subcontractor/Subawardee a copy of the Funding Award Agreement or the relevant sections thereof. If Subcontractor/Subawardee is provided with a copy of the Funding Award Agreement or the relevant sections thereof, Subcontractor/Subawardee shall carefully review them and shall

perform the Services in accordance with the specifications, timetables and requirements set forth therein.

(b) Location(s) of Services. Subcontractor/Subawardee shall perform the Services at the following location(s):

25 Van Ness Avenue, Suite 200
San Francisco, CA 94102

(c) Subcontractor/Subawardee Principal Investigator/Project Coordinator. Subcontractor/Subawardee shall appoint the Principal Investigator/Project Coordinator (the "PI") identified above to be primary point of contact with HELUNA HEALTH with respect to the Services and to have primary responsibility within Subcontractor's/Subawardee's organization for the performance of the (technical or programmatic) aspects of the Services. Subcontractor/Subawardee shall not replace or reassign the PI without HELUNA HEALTH's prior written approval.

(d) HELUNA HEALTH Project Director. The HELUNA HEALTH Project Director identified above shall be primarily responsible on behalf of HELUNA HEALTH for the overall direction of the Services, including review and approval of Subcontractor's/Subawardee's performance of the Services. HELUNA HEALTH will notify Subcontractor/Subawardee if HELUNA HEALTH replaces or reassigns such Project Director.

(e) Performance Reporting. If requested by HELUNA HEALTH or the Funding Agency, Subcontractor/Subawardee shall submit a final technical or performance report, annual performance report, and quarterly performance reports. The final report shall be due 30 days after expiration or termination of this Agreement; annual reports and quarterly reports shall be due 30 days after the reporting period. Subcontractor/Subawardee shall also provide any other reports as may be requested by HELUNA HEALTH. Performance reports shall include a comparison of actual accomplishments with goals and objectives established for the period, findings of the PI, or both, as requested by HELUNA HEALTH. Where possible, quantitative output data should be related to cost data for computation of unit costs. Other pertinent information will include, when appropriate, the reasons why established goals were not met and an analysis. Subcontractor/Subawardee shall immediately notify HELUNA HEALTH of developments that have a significant impact on the performance of the Services hereunder and of any problems, delays, or adverse conditions that materially impair its ability to meet the objectives of the Services, including providing a statement of the action taken or contemplated and any assistance needed to resolve the situation.

3. COMPLIANCE WITH FUNDING AWARD AGREEMENT AND LAWS AND REGULATIONS; FLOW DOWN PROVISIONS

(a) Compliance with Funding Contract. Subcontractor/Subawardee shall comply with, and shall ensure that all of its personnel and lower-tier subcontractors comply with, all of

the rules, requirements and restrictions set forth in the Funding Award Agreement, if attached hereto as Exhibit C, that are applicable to Subcontractor/Subawardee and Subcontractor's/Subawardee's activities.

(b) Flow Down Provisions. Without limiting the generality of Section 3(a) above, Subcontractor/Subawardee shall comply with, and shall ensure that all of its personnel and lower-tier subcontractors comply with, all of the flow-down provisions of the Funding Award Agreement applicable to Subcontractor/Subawardee, if attached as Exhibit C (the "Flow Down Provisions"). Subcontractor/Subawardee represents and warrants that it has carefully reviewed all of the Flow Down Provisions, if attached as Exhibit C, and is able to comply with all of the Flow Down Provisions. In the event that the requirements set forth in the Flow Down Provisions are greater than the requirements set forth in this Agreement, or in the event of any conflict between the provisions of this Agreement and the Flow Down Provisions, the Flow Down Provisions shall control and Subcontractor/Subawardee shall comply with the requirements set forth in the Flow Down Provisions in accordance with Section 2(a).

(c) Laws and Regulations. Subcontractor/Subawardee shall also comply with all state and federal statutes and regulations applicable to Subcontractor/Subawardee, the Services or the Funding Award Agreement, in performing its obligations under this Agreement. Without limiting the generality of the foregoing, Subcontractor shall:

(i) unless exempt, comply with the requirements under 45 CFR Part 74, and the Public Health Service Grants Policy Statement;

(ii) unless exempt, comply with Executive Order 11246 entitled "Equal Employment Opportunity" as amended by Executive Order 11375 and as supplemental in Dept. of Labor regulations (41 CFR Part 60);

(iii) comply with (and not violate) all statutes, laws, rules and regulations relating to non-discrimination against any employees or applicants for employment, including, without limitation, Title VII of the Civil Rights Act of 1964, The Americans with Disabilities Act Amendments Act of 2008, and the California Fair Employment and Housing Act (if Subcontractor/Subawardee is located within California), and shall take affirmative action to ensure that all employment related decisions are made in conformance with all such statutes, laws, rules and regulations; and

(iv) unless it is exempt from doing so, comply with 45 CFR Part 76, Appendix B-Certification Regarding Debarment, Suspension, and Ineligibility, Voluntary Exclusion-Lower Tier Covered Transactions.

(d) HIPAA Business Associate Agreement. If the Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA") is applicable to the Services, Subcontractor/Subawardee shall execute and deliver HELUNA HEALTH's standard Business Associate Agreement as required by HIPAA.

(e) Lower-tier Subcontractors/Subawardees. Subcontractor/Subawardee shall incorporate all of the terms and conditions of this Agreement into all lower-tier subcontracts that Subcontractor/Subawardee may enter into in connection with this Agreement, and shall ensure that all such lower-tier subcontractors/subawardees and their personnel comply with all of the requirements of this Agreement applicable to Subcontractor/Subawardee, and all of the rules, requirements and restrictions set forth in the Funding Award Agreement, if attached as Exhibit C, including the Flow Down Provisions, that are applicable to such lower-tier subcontractors'/subawardees' activities.

4. PAYMENT FOR SERVICES

(a) Budget. The total compensation and reimbursements payable to Subcontractor/Subawardee hereunder shall be as set forth in the detailed budget for the Services attached hereto as Exhibit B (the "Budget"), which is made a part hereof and incorporated herein by reference. The maximum amount payable to Subcontractor/Subawardee hereunder shall not exceed the maximum amount set forth in the Budget.

(b) Must Stay Within Budget Time Periods. Subcontractor/Subawardee shall be compensated only for Services actually performed by Subcontractor/Subawardee and within the appropriate time period set forth in the Budget.

(c) Approval of Services by HELUNA HEALTH. All Services must be completed to the satisfaction of HELUNA HEALTH in order to be entitled to payment hereunder.

(d) Funds Available to HELUNA HEALTH. HELUNA HEALTH shall not be obligated to make payment under this Agreement unless the corresponding funds are disbursed to HELUNA HEALTH under the Funding Award Agreement.

(e) Billing of Expenses and Costs. All expenses and costs shall be billed in accordance with the approved budget. Expenses incurred after the expiration or termination of this Agreement shall be disallowed. Subcontractor/Subawardee shall submit its final invoice no later than 30 days after the date of expiration of the term or termination of this Agreement.

(f) Budget Modifications. The Budget may be modified only by written agreement of HELUNA HEALTH and Subcontractor/Subawardee and the prior written approval of the Funding Agency.

5. INVOICING PROCEDURES

(a) Approval by Funding Agency. If required under the Funding Award Agreement, attached hereto as Exhibit C, Subcontractor/Subawardee must first submit all timesheets and invoices to the Funding Agency for approval by the Funding Agency. After the Funding Agency

has approved a timesheet and invoice submitted by Subcontractor/Subawardee, Subcontractor/Subawardee shall submit the same to HELUNA HEALTH.

(b) Address for Invoices. Subcontractor/Subawardee shall send all timesheets and invoices to the attention of the HELUNA HEALTH Project Director at the address set forth in Section 1 above.

(c) Invoicing Period. All invoices shall be submitted not more frequently than monthly, in arrears and must be submitted to HELUNA HEALTH within 30 days after the end of the applicable month or within 15 days after approval by the Funding Agency (if applicable), whichever is later. All final invoices must be received within 30 days of the expiration or termination of this Agreement or within such earlier time period as HELUNA HEALTH may require. If any invoices are not submitted within such time periods, Subcontractor/Subawardee waives (in HELUNA HEALTH's discretion) all rights to payment under such invoices.

(d) Formatting and Requirements of Invoices. All invoices shall be submitted in the form attached hereto as Exhibit D, as it may be modified by HELUNA HEALTH from time to time.

6. TERM AND TERMINATION

(a) Term. Unless earlier terminated as provided herein, the term of this Agreement shall be from **June 1, 2021 to May 31, 2022** the "Term").

(b) Termination Without Cause. Reserved.

(c) Termination for Cause. With reasonable cause, either party may terminate this Agreement effective immediately upon the giving of written notice of termination for cause. Reasonable cause shall include:

- i. A material violation or breach of this Agreement by the other party which is not cured within 15 days after written notice from the terminating party;
- ii. Any act of the other party that exposes the terminating party to liability to others for personal injury or property damage or any other harm, damage or injury; or
- iii. If either party receives notice from the Funding Agency of the cancellation or termination of, or reduction of funding under, the Funding Award Agreement affecting the Services.

(d) Termination for Lack of Funding. HELUNA HEALTH may terminate this Agreement if for any reason the funding available under the Funding Award Agreement is withdrawn, limited, or impaired.

(e) Cessation Upon Termination. On the effective date of termination, Subcontractor/Subawardee shall cease all further Services under this Agreement, and

Subcontractor/Subawardee shall cancel as many outstanding obligations as possible and not incur any additional obligations.

(f) Payment After Termination. Subject to the terms and conditions set forth in this Agreement, upon termination of this Agreement, provided, that HELUNA HEALTH has received the corresponding funds from the Funding Agency under the Funding Award Agreement , HELUNA HEALTH shall pay for any reasonable non-cancellable obligations properly incurred by Subcontractor/Subawardee under this Agreement and in accordance with the Budget prior to termination, and shall pay any amounts due to Subcontractor/Subawardee and properly invoiced under this Agreement for Services performed prior to termination; provided, that if HELUNA HEALTH has terminated this Agreement for reasonable cause under Section 6(c) above, then HELUNA HEALTH shall have the right to offset and deduct from any payments due to Subcontractor/Subawardee hereunder any damages or losses incurred by HELUNA HEALTH as a result of such violation or breach.

(g) Return of Materials. Reserved.

(h) Surviving Provisions. The provisions of Sections 7 through 16, and any other sections that by their nature should or are intended to survive the expiration or termination of this Agreement shall survive and the parties shall continue to comply with the provisions of this Agreement that survive.

7. REPRESENTATIONS AND WARRANTIES. Subcontractor/Subawardee represents, warrants and covenants to HELUNA HEALTH as follows:

(a) Licenses and Permits. Subcontractor/Subawardee maintains and shall maintain during all relevant times under this Agreement all applicable federal, state and local business and other licenses, including any professional licenses or certificates, industrial permits and/or licenses, industry specific licenses, licenses required by the state(s) and/or locality(s) in which it does business, fictitious business names, federal tax identification numbers, insurance, and anything else required of Subcontractor/Subawardee as a business operator.

(b) Qualifications and Performance. Subcontractor/Subawardee (i) has the experience and skill to perform the Services hereunder, (ii) shall perform the Services in a good and workman like manner and in accordance with generally accepted professional standards and in an expeditious and economical manner consistent with sound professional practices, and (iii) is adequately financed to meet any financial obligation it may be required to incur hereunder.

(c) Not Debarred. Neither Subcontractor/Subawardee nor its principals or personnel are presently, nor will any of them be during the term of this Agreement, debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or funding agency.

8. INDEPENDENT CONTRACTOR STATUS

(a) Independent Contractor. Nothing in this Agreement is intended to place the parties in the relationship of employer-employee, partners, joint venturers, or in anything other than an independent contractor relationship. It is the parties' intention that Subcontractor/Subawardee shall be an independent contractor and not HELUNA HEALTH's employee or agent, and in conformity therewith, that Subcontractor/Subawardee shall retain sole and absolute discretion and judgment in the manner and means of carrying out Subcontractor/Subawardee's Services hereunder. Subcontractor/Subawardee is under the control of HELUNA HEALTH as to the results of Subcontractor/Subawardee's Services only, and not as to the means by which such results are accomplished.

(b) No Power to Bind HELUNA HEALTH. Without limiting the generality of the foregoing paragraph, this Agreement does not designate Subcontractor/Subawardee as the agent or legal representative of HELUNA HEALTH for any purpose whatsoever. Subcontractor/Subawardee is not granted any right or authority to assume or create any obligation or responsibility, or to make any promise or commitment regarding any work, on behalf of or in the name of HELUNA HEALTH or to bind it in any manner, or to make any contract or agreement on behalf of or in the name of HELUNA HEALTH, without the prior written consent from HELUNA HEALTH management. No sales, invoices nor orders for goods or services shall be valid and binding upon HELUNA HEALTH (whether as the provider or the recipient) unless and until accepted by HELUNA HEALTH, at its sole and absolute discretion, through its established channels. HELUNA HEALTH shall not be liable for any obligation incurred by Subcontractor/Subawardee.

(c) No Withholding. Except for tax withholdings that are required by law, neither federal, nor state, nor local income tax nor payroll taxes of any kind shall be withheld or paid by HELUNA HEALTH on behalf of Subcontractor/Subawardee or the employees of Subcontractor/Subawardee. Subcontractor/Subawardee and its personnel shall not be treated as employees or HELUNA HEALTH with respect to the Services performed hereunder for federal or state tax purposes or for any other purposes.

(d) No Employee Benefits. Neither Subcontractor/Subawardee nor its personnel shall be eligible for, and shall not participate in, any of HELUNA HEALTH's retirement, health, or other fringe benefit plans.

(e) Workers' Compensation. No workers' compensation insurance shall be obtained by HELUNA HEALTH concerning Subcontractor/Subawardee or Subcontractor's/Subawardee's personnel. Subcontractor/Subawardee shall comply with all workers' compensation laws concerning Subcontractor/Subawardee and its personnel.

(f) Taxes. Subcontractor/Subawardee understands that Subcontractor/Subawardee is responsible to pay, according to law, Subcontractor's/Subawardee's income taxes. If Subcontractor/Subawardee is not an entity, Subcontractor/Subawardee further understands

that Subcontractor/Subawardee may be liable for self-employment (social security) tax, to be paid by Subcontractor/Subawardee according to law. Subcontractor/Subawardee shall be solely responsible for the payment of all federal, state and local income taxes, social security taxes, federal and state unemployment insurance and similar taxes and all other assessments, taxes, contributions or sums payable with respect to Subcontractor/Subawardee or its employees as a result of or in connection with the Services performed by Subcontractor/Subawardee hereunder. Subcontractor/Subawardee represents and warrants and covenants that it shall report all income earned as a result of this Agreement and pay all federal, state and local income and self-employment taxes and other assessments required to be paid under applicable law. Subcontractor/Subawardee agrees to defend, indemnify and hold HELUNA HEALTH harmless from any and all claims made by federal, state and local taxing authorities on account of Subcontractor's/Subawardee's failure to pay any such federal, state or local income and self-employment taxes or other assessments due as a result of Subcontractor's/Subawardee's Services hereunder.

(g) Sub-Tier Subcontractors/Subawardees. Subcontractor/Subawardee shall have control over the manner and means of Subcontractor/Subawardee's performance under this Agreement. However, HELUNA HEALTH is engaging Subcontractor/Subawardee for Subcontractor's/Subawardee's unique skills, knowledge, abilities and other attributes. Any lower-tier subcontractors/subawardees who are approved by HELUNA HEALTH must execute all agreements and documents required by HELUNA HEALTH prior to performing any work. Subcontractor/Subawardee shall ensure that all lower-tier subcontractors/subawardees comply with all of the terms and provisions of this Agreement and shall be responsible and liable for all acts and omissions of all lower-tier subcontractors/subawardees as if they were the acts or omissions of Subcontractor/Subawardee.

9. OWNERSHIP OF WORK PRODUCT

(a) Ownership of Work Product. Subcontractor/Subawardee owns all work product developed under this Agreement.

(b) No Infringement. Subcontractor/Subawardee represents and warrants that any Work Product developed by Subcontractor/Subawardee and shall not infringe or violate any patents, copyrights, trademarks, trade secrets or other proprietary rights of any third party.

(c) No Harmful Code. With respect to the website and any computer programs or software code ("Software") included in the Services hereunder, Subcontractor/Subawardee represents and warrants that: (i) the Software and its media shall contain no computer instructions or inappropriate functions whose purpose or result is to disrupt, damage or interfere with HELUNA HEALTH's or its affiliates' or their customers' use of or access to the Software or any of their data, programs or computer or telecommunications facilities and (ii) unless expressly authorized in writing by HELUNA HEALTH, such Software shall not contain any mechanism which electronically notifies Subcontractor/Subawardee of any fact or event, nor contain any key, node lock, time-out, logic bomb or other function, implemented by any means,

which may restrict HELUNA HEALTH's or its affiliates' or customers' use of or access to the Software or any other programs, data or equipment.

10. PUBLICATIONS

(a) Right to Publish Works. Subcontractor/Subawardee may, with HELUNA HEALTH's and the Funding Agency's prior written consent, publish articles written by Subcontractor/Subawardee in connection with the Services performed by Subcontractor/Subawardee hereunder. Subcontractor/Subawardee shall submit all such articles for review by HELUNA HEALTH and the Funding Agency at least 60 days prior to the proposed publication date.

(b) Acknowledgment in Publications. On any publication approved by HELUNA HEALTH and the Funding Agency as described above, Subcontractor/Subawardee shall place an acknowledgment of federal government support, and shall include a disclaimer, as appropriate, as follows: "The contents of this publication are solely the responsibility of the authors and do not necessarily represent the official views of Heluna Health. or **[Name of Funding Agency]**".

(c) Use of HELUNA HEALTH's or Funding Agency's Name. Subcontractor/Subawardee shall not use in any manner HELUNA HEALTH's name, logo or trademarks without HELUNA HEALTH's prior written consent. Subcontractor/Subawardee shall not use in any manner the Funding Agency's name, logo or trademarks without the Funding Agency's prior written consent.

11. INDEMNIFICATION

HELUNA HEALTH hereby agrees to indemnify, hold harmless and defend Subcontractor/Subawardee, its officers, directors, agents, contractors and employees from any and all claims, causes of action, costs, demands, expenses (including attorney's fees and costs), losses, damages, injuries, and liabilities arising from (i) any accident, death, or injury whatsoever or however caused to any person or property arising out of the intentional action or negligence of HELUNA HEALTH, (ii) HELUNA HEALTH's violation of any federal, state or local law or regulation or (iii) the breach by HELUNA HEALTH of any its representations, warranties or agreements under this Agreement.

12. INSURANCE

(a) Required Coverages. Subcontractor/Subawardee shall, unless otherwise agreed in writing by HELUNA HEALTH, maintain: (i) Workers' Compensation insurance, (ii) Professional Liability Insurance and Commercial General Liability Insurance (including broad form contractual and automobile liability coverage), with minimum limits of ONE MILLION DOLLARS (\$1,000,000) combined single limit per occurrence, and (iii) Automobile Liability on each automobile owned by him/her/it or his/her/its agents, subcontractors/subawardees or employees, which is used at any time to carry out Subcontractor's/Subawardee's duties hereunder, with minimum limits

of \$100,000 per person and \$300,000 per occurrence for bodily injury. If higher or additional coverages are required under the Flow Down Provisions, attached as Exhibit C, Subcontractor/Subawardee shall procure such coverages. A program of self-insurance is acceptable.

13. CONFIDENTIALITY

(a) Sunshine Ordinance. HELUNA HEALTH acknowledges that this Agreement and all records related to its formation, and the performance of Services, and HELUNA HEALTH's payment are subject to the California Public Records Act, (California Government Code §6250 et. seq.), and the San Francisco Sunshine Ordinance, (San Francisco Administrative Code Chapter 67). Such records are subject to public inspection and copying unless exempt from disclosure under federal, state or local law.

(b) Confidential Information. Confidential Information includes, but is not limited to, the identity of actual and potential clients of HELUNA HEALTH, client lists, particular needs of each client, the manner in which business is conducted with each client, addresses, telephone numbers, and specific characteristics of clients; Subcontractor/Subawardee shall not disclose in any manner whatsoever any of the aforesaid Confidential Information, directly or indirectly, or use it in any way whatsoever, either during this Agreement or at any time thereafter, except as required in the course of Subcontractor's/Subawardee's work with HELUNA HEALTH or except as otherwise provided in this Agreement or permitted by law. Further, Subcontractor/Subawardee shall develop and maintain procedures and take other reasonable steps in furtherance of HELUNA HEALTH's desire to maintain the confidentiality of its Confidential Information.

(c) Funding Agency Confidentiality. Subcontractor/Subawardee shall also comply with all confidentiality obligations imposed by the Funding Agency in the Funding Award Agreement, if attached as Exhibit C.

14. RECORD RETENTION AND ACCESS TO RECORDS

Subcontractor/Subawardee shall grant to HELUNA HEALTH, the Funding Agency and the U.S. Comptroller General and their respective authorized representatives upon demand, access to any books, documents, papers and records of Subcontractor/Subawardee relating to this Agreement or the Services for audit, examination, excerpt and transcription. Subcontractor/Subawardee shall retain all such records for seven (7) years (or longer if required under HELUNA HEALTH's record retention policy, under the Funding Award Agreement or by law, including under Circular A-110, Subpart C, Post-Award Requirements and FAR Subpart 4.7 Contractor Records Retention - 4.703 Policy) after final payment is made under this Agreement and all pending matters are closed, unless extended by an audit, litigation, or other action involving the records, whichever is later.

15. GENERAL TERMS

(a) Amendments. Amendments to this Agreement shall be in writing, signed by the party to be obligated by such amendment and attached to this Agreement.

(b) Governing Law; Venue. This Agreement shall be interpreted, construed and governed by, in accordance with and consistent with the laws of the State of California with venue in San Francisco.

(c) Equitable Relief. In light of the irreparable harm to HELUNA HEALTH that a breach by Subcontractor/Subawardee of Sections 9, 10, 13 and 14 of this Agreement would cause, in addition to other remedies set forth in this Agreement and other relief for violations of this Agreement, HELUNA HEALTH shall be entitled to enjoin Subcontractor/Subawardee from any breach or threatened breach of such Sections, to the extent permitted by law and without bond.

(d) Binding Agreement. All terms, conditions and covenants to be observed and performed by the parties hereto shall be applicable to and binding upon their respective agents, employees, heirs, executors, administrators, affiliates, subsidiaries, associates, employees, successors and assigns.

(e) Captions. All captions (section headings) set forth herein are inserted only as a matter of convenience and for reference, and shall not affect the interpretation of this Agreement.

(f) Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original but all of which, when taken together, shall constitute one and the same document.

(g) Additional Documents. The parties hereto each agree that they shall execute and, if appropriate, acknowledge any and all additional and other documents, instruments and writings which may be reasonably requested by the other party in order to fully carry out the intent and purpose of this Agreement.

(h) Entire Agreement. This Agreement, and all documents referred to in it, or incorporated in it, is an integrated document containing and expressing all terms, covenants, conditions, warranties and agreements of the parties relating to the subject matter hereof. No other or prior agreements or understandings, written or oral, pertaining to the same shall be valid or of any force or effect.

(i) Facsimile or Email Transmissions. A facsimile transmission or transmission by Email of the executed signature page of this Agreement shall be accepted as, relied upon as, and deemed to be, an original.

(j) Fair Interpretation. The language appearing in all parts of this Agreement shall be construed, in all cases, according to its fair meaning in the English language, and not strictly construed for or against any party hereto. This Agreement has been prepared jointly by the parties hereto after arm's length negotiations and any uncertainty or ambiguity contained in this Agreement, if any, shall not be interpreted or construed against any party, but according to its fair meaning applying the applicable rules of interpretation and construction of contracts.

(k) No Waiver. No failure or delay by any party in exercising a right, power or remedy under the Agreement shall operate as a waiver of any such right or other right, power or remedy. No waiver of, or acquiescence in, any breach or default of any one or more of the terms, provisions or conditions contained in this Agreement shall be deemed to imply or constitute a waiver of any other or succeeding or repeated breach or default hereunder. The consent or approval by any party hereto to or of any act of the other party hereto requiring further consent or approval shall not be deemed to waive or render unnecessary any consent or approval to or of any subsequent similar acts.

(l) Notices. Any notice, demand, consent or other communication required or permitted to be given hereunder shall be made in the English language and shall be so given by personal delivery, by (i) registered or certified (return receipt) or First Class United States Postal Service mail, postage pre-paid, or (ii) recognized overnight national courier service, or (iii) facsimile transmission confirmed by letter sent by First Class United States Postal Service mail, postage pre-paid, or (iv) by email confirmed by letter sent by First Class United States Postal Service mail, postage pre-paid, addressed to the recipient of such notice at the following address or facsimile number, as the case may be, or any other address or facsimile number or email address provided by a party in the manner described hereinabove:

In the case of HELUNA HEALTH, addressed to:

Heluna Health
13300 Crossroads Parkway North, Suite 450
City of Industry, CA 91746
Attention: Veronica Reyes
Facsimile: (562) 692-6950
Email: Contracts@helunahealth.org

In the case of Subcontractor, addressed to:

San Francisco Department of Public Health
1380 Howard Street
San Francisco, CA 94103
Attention: Sajid Shaikh
Facsimile: (415) 503-4710
Email: Sajid.shaikh@sfdph.org

Any such notice shall be deemed to have been received by the addressee, and service thereof shall be deemed effective, five (5) days following deposit thereof with the United States Postal Service, or upon actual receipt, whichever first occurs, unless the address for delivery is not within one of the United States or its territories or possessions, in which case service shall be effective seven (7) days following deposit, or upon actual receipt, whichever first occurs.

(m) Remedies Non-Exclusive. Except where otherwise expressly set forth herein, all remedies provided by this Agreement shall be deemed to be cumulative and additional and not in lieu of or exclusive of each other or of any other remedy available to the respective parties at law or in equity.

(n) Severability. If any term, provision, condition or other portion of this Agreement is determined to be invalid, void or unenforceable by a forum of competent jurisdiction, the same shall not affect any other term, provision, condition or other portion hereof, and the remainder of this Agreement shall remain in full force and effect, as if such invalid, void or unenforceable term, provision, condition or other portion of this Agreement did not appear herein.

(o) Limitation of Liability. EXCEPT FOR A BREACH OF SECTIONS 9 AND 13 ABOVE AND EXCEPT TO THE EXTENT INCLUDED IN A PARTY'S INDEMNIFICATION OBLIGATIONS UNDER SECTION 11 ABOVE, IN NO EVENT SHALL ANY PARTY BE LIABLE TO THE OTHER FOR ANY INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES, WHETHER BASED ON BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE), OR OTHERWISE, AND WHETHER OR NOT THAT PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

(p) Non-Assignability. None of the parties shall assign, transfer, sell, encumber, hypothecate, alienate or otherwise dispose of this Agreement, or any right, title or interest to or in this Agreement, nor shall a party delegate any duty or obligation to be performed hereunder, without the express written consent of the other party having been first obtained, except that any party may assign this Agreement without the consent of the other party in the case of a reorganization, merger, consolidation, or sale of all or substantially all of its assets so long as the assignee expressly assumes all of the obligations of the assignor under this Agreement. Notwithstanding the foregoing, HELUNA HEALTH may assign this Agreement to an affiliate of HELUNA HEALTH without the consent of the other party. Any attempt to assign this Agreement other than as permitted above shall be null and void.

(q) Signing Person. The individuals signing this Agreement on behalf of an entity represents and warrants that he/she has authority to bind such entity to this Agreement.

[Signatures follow on next page]

The undersigned have caused this Subcontract/Subaward Agreement to be executed as of the date first set forth above:

HELUNA HEALTH

DocuSigned by:
Peter Dale 10/25/2021
Peter Dale
Chief Program Officer

CITY AND COUNTY OF SAN FRANCISCO

DocuSigned by:
Heidi Burbage 10/22/2021 | 11:32 AM PDT
Signature: Heidi Burbage
Heidi Burbage, Acting Director of PHD
Print Name, Title [If any entity]

EXHIBIT A
TO SUBCONTRACT/SUBAWARD AGREEMENT

SCOPE OF WORK (SOW)

Phillip Coffin, MD, MIA Director of Substance Use Research at the San Francisco Department of Public Health (SFDPH) is the Principal Investigator (PI) of M3 DDI. Dr. Coffin will dedicate (11.4%) 1.37 person months each year for this study. Dr. Coffin is a board-certified internist, infectious disease specialist, and addiction medicine specialist, with expertise in clinical trials of pharmacologic and behavioral interventions for substance use, HIV, HCV, and overdose, as well as epidemiologic and observational studies of substance use. As PI, Dr. Coffin will be responsible for the overall scientific, operational, and administrative aspects of the study, and he will oversee the day-to-day management of the regulatory and clinical activities for this study. They will directly supervise the Study Coordinator, Study Clinician, and Data Manager. Dr. Coffin will ensure that all staff adheres to good clinical practice (GCP) guidelines, and that all adverse events and serious adverse events are reported in a timely manner. He will be available in the office (his office is in the hall used for seeing participants) as well as on-call for study staff and for participant emergencies or questions and will meet regularly with staff to discuss adverse events and other clinical issues. He will work closely with the Study Coordinator to address requirements of all regulatory parties including University of California San Francisco's (UCSF) Committee on Human Research, which acts as the local IRB for the SFDPH, the DSMB, and NIDA. In addition, Dr. Coffin will initiate and serve as an author on study publications and present results at scientific meetings. Of note, the contract for Dr. Coffin's time includes the cost of rent for PHFE staff at SFDPH offices.

**EXHIBIT B
TO SUBCONTRACT/SUBAWARD AGREEMENT
BUDGET**

Principal Investigator/Program Director (Last, first, middle):					Coffin				
DETAILED BUDGET FOR INITIAL BUDGET PERIOD				DIRECT COSTS ONLY		FROM		THROUGH	
				1-Jun-21				31-May-22	
PERSONNEL (Applicant organization only)					<small>DOLLAR AMOUNT REQUESTED (omit cents)</small>				
		<small>TYPE</small>	<small>%</small>	<small>INST.</small>					
	<small>ROLE ON</small>	<small>APPT.</small>	<small>EFFORT</small>	<small>BASE</small>	<small>SALARY</small>	<small>FRINGE</small>			
<small>NAME</small>	<small>PROJECT</small>	<small>(months)</small>	<small>ON</small>	<small>SALARY</small>	<small>REQUESTED</small>	<small>Rate</small>	<small>BENEFITS</small>	<small>TOTALS</small>	
Phillip Coffin	PI	12	0.114	\$199,300	\$22,720	35.00%	\$7,952	\$30,672	
SUBTOTALS		<small>FTE Total</small> 0.11			\$22,720		\$7,952	\$30,672	
OTHER EXPENSES (Itemize by category)									
Rent		<small>FTE PHFE</small>	<small>FTE CCSF</small>	<small>Months</small>	<small>sq. ft</small>	<small>rate</small>	<small>total</small>		
		2.85	0.11	12	250	\$2	17784		
								\$17,784	
TOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD					\$48,456				
Modified Direct Costs					\$48,456				
Indirect Cost					<small>25%</small> \$7,668				
TOTA COSTS YEAR					YEAR 2 \$56,124				

EXHIBIT C
TO SUBCONTRACT/SUBAWARD AGREEMENT
FLOW DOWN PROVISIONS

Refer to following pages.


Recipient Information
1. Recipient Name

PUBLIC HEALTH FOUNDATION
 ENTERPRISES, INC.
 13300 CROSSROADS PKWY N STE 450

 CITY OF INDUSTRY, CA 91746

2. Congressional District of Recipient

32

3. Payment System Identifier (ID)

1952557063A1

4. Employer Identification Number (EIN)

952557063

5. Data Universal Numbering System (DUNS)

082199324

6. Recipient's Unique Entity Identifier
7. Project Director or Principal Investigator

PHILLIP O COFFIN, MD
 Director Of Substance Use Research
 pcoffin@gmail.com
 415-554-8176

8. Authorized Official

Peter Dale
 pdale@phfe.org

Federal Agency Information
9. Awarding Agency Contact Information

Pamela G. Fleming
 Grants Management Officer
 NATIONAL INSTITUTE ON DRUG ABUSE
 pfleming@mail.nih.gov
 301-480-1159

10. Program Official Contact Information

KATRINA L. FOSTER
 Scientific Review Administrator
 NATIONAL INSTITUTE ON DRUG ABUSE
 katrina.foster@nih.gov
 301-827-5815

Federal Award Information
11. Award Number

5U01DA051080-02

12. Unique Federal Award Identification Number (FAIN)

U01DA051080

13. Statutory Authority

42 USC 241 31 USC 6305 42 CFR 52

14. Federal Award Project Title

Mirtazapine for methamphetamine use disorder: drug-drug interaction study

15. Assistance Listing Number

93.279

16. Assistance Listing Program Title

Drug Abuse and Addiction Research Programs

17. Award Action Type

Non-Competing Continuation

18. Is the Award R&D?

Yes

Summary Federal Award Financial Information
19. Budget Period Start Date 06/01/2021 – End Date 05/31/2022

20. Total Amount of Federal Funds Obligated by this Action	\$2,182,386
20 a. Direct Cost Amount	\$2,121,005
20 b. Indirect Cost Amount	\$61,381
21. Authorized Carryover	\$0
22. Offset	\$0
23. Total Amount of Federal Funds Obligated this budget period	\$2,182,386
24. Total Approved Cost Sharing or Matching, where applicable	\$0
25. Total Federal and Non-Federal Approved this Budget Period	\$2,182,386

26. Project Period Start Date 06/01/2020 – End Date 05/31/2022

27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	\$4,387,973
--------------------------------------------------------------------------------------------------------------	-------------

28. Authorized Treatment of Program Income

Additional Costs

29. Grants Management Officer - Signature

Amy Connolly

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.



RESEARCH PROJECT COOPERATIVE AGREEMENT
Department of Health and Human Services
National Institutes of Health



NATIONAL INSTITUTE ON DRUG ABUSE

SECTION I – AWARD DATA – 5U01DA051080-02

Principal Investigator(s):

PHILLIP O COFFIN, MD

Award e-mailed to: pdale@helunahealth.org

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of \$2,182,386 (see “Award Calculation” in Section I and “Terms and Conditions” in Section III) to PUBLIC HEALTH FOUNDATION ENTERPRISES 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 U01DA051080. 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,

Amy Connolly
Grants Management Officer
NATIONAL INSTITUTE ON DRUG ABUSE

Additional information follows

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

Salaries and Wages	\$239,258
Fringe Benefits	\$88,955
Personnel Costs (Subtotal)	\$328,213
Consultant Services	\$33,813
Materials & Supplies	\$9,192
Travel	\$6,647
Other	\$94,295
Subawards/Consortium/Contractual Costs	\$1,648,845
Federal Direct Costs	\$2,121,005
Federal F&A Costs	\$61,381
Approved Budget	\$2,182,386
Total Amount of Federal Funds Authorized (Federal Share)	\$2,182,386
TOTAL FEDERAL AWARD AMOUNT	\$2,182,386
AMOUNT OF THIS ACTION (FEDERAL SHARE)	\$2,182,386

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	THIS AWARD	CUMULATIVE TOTALS
2	\$2,182,386	\$2,182,386

Fiscal Information:

Payment System Identifier: 1952557063A1
Document Number: UDA051080A
PMS Account Type: P (Subaccount)
Fiscal Year: 2021

IC	CAN	2021
DA	8472630	\$2,182,386

NIH Administrative Data:

PCC: CC/KLF / **OC:** 41029 / **Released:** Connolly, Amy 05/13/2021

Award Processed: 05/14/2021 12:10:50 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5U01DA051080-02

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 – 5U01DA051080-02

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:

- The grant program legislation and program regulation cited in this Notice of Award.
- Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- 45 CFR Part 75.
- 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.
- Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- 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

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).

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) U01DA051080. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see <http://grants.nih.gov/grants/policy/awardconditions.htm> for additional award applicability information.

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 represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: <http://grants.nih.gov/grants/policy/policy.htm#gps>.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the eRA Commons (Commons) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, <http://grants.nih.gov/grants/policy/policy.htm#gps>, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) quarterly cash transaction data. A final quarterly federal cash transaction report is not required for awards in PMS B subaccounts (i.e., awards to foreign entities and to Federal agencies). NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures or quarterly federal cash transaction reporting. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level. If the grantee submits a final expenditure FFR but does not reconcile any discrepancies between expenditures reported on the final expenditure FFR and the last cash report to PMS, NIH will close the award at the lower amount. This could be considered a debt or result in disallowed costs.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: <http://grants.nih.gov/grants/forms.htm>. This paragraph does not

apply to training grants, fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience.*

NIH strongly encourages electronic submission of the final invention statement through the Closeout feature in the Commons, but will accept an email or hard copy submission as indicated below.

Email: The final invention statement may be e-mailed as PDF attachments to: NIHCloseoutCenter@mail.nih.gov.

Hard copy: Paper submissions of the final invention statement may be faxed to the NIH Division of Central Grants Processing, Grants Closeout Center, at 301-480-2304, or mailed to:

National Institutes of Health
Office of Extramural Research
Division of Central Grants Processing
Grants Closeout Center
6705 Rockledge Drive
Suite 5016, MSC 7986
Bethesda, MD 20892-7986 (for regular or U.S. Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express deliveries only)

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and should be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

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 – 5U01DA051080-02

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.

FY2021 FUNDING

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

DATA AND SAFETY MONITORING

This award is subject to the current Data and Safety Monitoring Plan (DSMP) submitted and previously approved by NIDA on 3/24/2021. 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.

COOPERATIVE AGREEMENT

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 as set forth in **PAR18-219, "Grand Opportunity in Medications Development for Substance-Use Disorders,"** release date **11/21/2017**, which are incorporated by reference as special terms and conditions of this award.

This RFA may be accessed at <https://grants.nih.gov/grants/guide/pa-files/PAR-18-219.html>

The NIH Project Scientist for this Cooperative Agreement is: **Dr. Jason Sousa**

Email: jason.sousa@nih.gov

Phone: (301) 827-5919

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>.

SPREADSHEET SUMMARY

AWARD NUMBER: 5U01DA051080-02

INSTITUTION: PUBLIC HEALTH FOUNDATION ENTERPRISES

Budget	Year 2
Salaries and Wages	\$239,258
Fringe Benefits	\$88,955
Personnel Costs (Subtotal)	\$328,213
Consultant Services	\$33,813
Materials & Supplies	\$9,192
Travel	\$6,647
Other	\$94,295
Subawards/Consortium/Contractual Costs	\$1,648,845
TOTAL FEDERAL DC	\$2,121,005
TOTAL FEDERAL F&A	\$61,381
TOTAL COST	\$2,182,386

Facilities and Administrative Costs	Year 2
F&A Cost Rate 1	13%
F&A Cost Base 1	\$472,160
F&A Costs 1	\$61,381

EXHIBIT D
TO SUBCONTRACT/SUBAWARD AGREEMENT

FORM OF INVOICE

Invoice format submitted in previous budget year is acceptable.

Please submit invoice to phfe.invoices@sfdph.org. The designated monitor will review and approve subaward expenditure and forward to Heluna Health to process payment.

Final invoice must be signed, marked "Final," and have the statement: "This final invoice represents that all deliverables have been met."

EXHIBIT E
TO SUBCONTRACT/SUBAWARD AGREEMENT
CERTIFICATE OF SELF-INSURANCE COVERAGE DOCUMENT

Refer to following page.



London N. Breed, Mayor
Carmen Chu, City Administrator

**CITY AND COUNTY OF SAN FRANCISCO
OFFICE OF THE
CITY ADMINISTRATOR
RISK MANAGEMENT DIVISION**



April 12, 2021

Blayne Cutler, PhD., M.D,
President, CEO
Heluna Health
12801 Crossroads Parkway South, Suite 200
City of Industry, CA 91746

RE: Heluna Health – Mirtazapine Use Grant

This letter certifies that the City and County of San Francisco is self-insured and self-funded for the following insurance coverages.

General Liability insurance in the amount of \$1,000,000 per occurrence and \$2,000,000 general aggregate for bodily injury, property damage, and personal injury to third parties for liability arising out of the City's negligence in performance of this agreement.

Automobile Liability insurance with limits not less than \$1,000,000 combined single limit per accident for bodily injury and property damage including owned, and non-owned and hired auto coverage as applicable.

Workers' Compensation in statutory amounts with Employer's Liability of \$1,000,000 per accident, injury or illness.

The City and County of San Francisco's self-insurance program is not commercial insurance and has no legal capacity to name another entity as additional insured.

Do not hesitate to contact this office should you have any questions.

Sincerely,

A handwritten signature in blue ink that reads "Matt Hansen".

Matt Hansen
Director