



## Recipient Information

### 1. Recipient Name

KAISER FOUNDATION HOSPITALS  
1800 HARRISON ST FL 16

OAKLAND, CA 94612

### 2. Congressional District of Recipient

13

### 3. Payment System Identifier (ID)

1941105628A1

### 4. Employer Identification Number (EIN)

941105628

### 5. Data Universal Numbering System (DUNS)

150829349

### 6. Recipient's Unique Entity Identifier

### 7. Project Director or Principal Investigator

GREGORY E. SIMON, MD  
Senior Investigator And Psychiatrist  
gregory.e.simon@kp.org  
206-287-2979

### 8. Authorized Official

Marie Kirkman  
ghrigrants@kp.org  
(206) 287-2012

## Federal Agency Information

### 9. Awarding Agency Contact Information

Julie M. Bergerud  
Grants Management Officer  
NATIONAL INSTITUTE OF MENTAL HEALTH  
julie.bergerud@nih.gov  
301-827-6184

### 10. Program Official Contact Information

Michael Freed  
Health Scientist Administrator  
NATIONAL INSTITUTE OF MENTAL HEALTH  
michael.freed@nih.gov  
301-443-3747

## Federal Award Information

### 11. Award Number

3U19MH121738-02S2

### 12. Unique Federal Award Identification Number (FAIN)

U19MH121738

### 13. Statutory Authority

42 USC 241 31 USC 6305 42 CFR 52

### 14. Federal Award Project Title

Buprenorphine Effect on Suicidal Behavior

### 15. Assistance Listing Number

93.242

### 16. Assistance Listing Program Title

Mental Health Research Grants

### 17. Award Action Type

Supplement (REVISED)

### 18. Is the Award R&D?

Yes

## Summary Federal Award Financial Information

### 19. Budget Period Start Date 09/17/2020 – End Date 08/31/2021

20. Total Amount of Federal Funds Obligated by this Action \$0

20a. Direct Cost Amount \$0

20b. Indirect Cost Amount \$0

21. Authorized Carryover \$0

22. Offset \$0

23. Total Amount of Federal Funds Obligated this budget period \$514,616

24. Total Approved Cost Sharing or Matching, where applicable \$0

25. Total Federal and Non-Federal Approved this Budget Period \$514,616

### 26. Project Period Start Date 09/17/2020 – End Date 08/31/2022

27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period \$5,133,257

### 28. Authorized Treatment of Program Income

Additional Costs

### 29. Grants Management Officer - Signature

Julie M. Bergerud

### 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.



NATIONAL INSTITUTE OF MENTAL HEALTH

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**SECTION I – AWARD DATA – 3U19MH121738-02S2 REVISED**

**Principal Investigator(s):**  
GREGORY E. SIMON, MD

**Award e-mailed to:** KFRI-ResearchAwards@kp.org

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 KAISER FOUNDATION HOSPITALS 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 Of Mental Health of the National Institutes of Health under Award Number U19MH121738. 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,

Julie M. Bergerud  
Grants Management Officer  
NATIONAL INSTITUTE OF MENTAL HEALTH

Additional information follows

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

Salaries and Wages	\$124,786
Fringe Benefits	\$47,674
Personnel Costs (Subtotal)	\$172,460
Materials & Supplies	\$760
Subawards/Consortium/Contractual Costs	\$234,000

Federal Direct Costs	\$407,220
Federal F&A Costs	\$107,396
Approved Budget	\$514,616
Total Amount of Federal Funds Authorized (Federal Share)	\$514,616
<b>TOTAL FEDERAL AWARD AMOUNT</b>	<b>\$514,616</b>

**AMOUNT OF THIS ACTION (FEDERAL SHARE)** \$0

<b>SUMMARY TOTAL FEDERAL AWARD AMOUNT YEAR ( 2 ) (for this Document Number)</b>	
<b>AWARD NUMBER</b>	<b>TOTAL FEDERAL AWARD AMOUNT</b>
3U19MH121738-02S2	\$514,616
5U19MH121738-02	\$2,052,966
3U19MH121738-02S1	\$344,930
<b>TOTAL</b>	<b>\$2,912,512</b>

<b>SUMMARY TOTALS FOR ALL YEARS (for this Document Number)</b>		
<b>YR</b>	<b>THIS AWARD</b>	<b>CUMULATIVE TOTALS</b>
2	\$514,616	\$2,912,512
3	\$274,321	\$2,309,656
4	\$0	\$2,000,066
5	\$0	\$1,967,876

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

**Fiscal Information:**

**Payment System Identifier:** 1941105628A1  
**Document Number:** UMH121738A  
**PMS Account Type:** P (Subaccount)  
**Fiscal Year:** 2020

IC	CAN	2020	2021
NS	8042247	\$514,616	\$274,321

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

**NIH Administrative Data:**

**PCC:** 82-SE / **OC:** 41028 / **Released:** Bergerud, Julie 01/14/2021  
**Award Processed:** 01/15/2021 12:17:29 AM

**SECTION II – PAYMENT/HOTLINE INFORMATION – 3U19MH121738-02S2 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 – 3U19MH121738-02S2 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).

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) U19MH121738. 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/](http://grants.nih.gov/ClinicalTrials_fdaaa/)

This award is funded by the following list of institutes. Any papers published under the auspices of this award must cite the funding support of all institutes.

National Institute Of Neurological Disorders And Stroke (NINDS)
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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

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**SECTION IV – MH SPECIFIC AWARD CONDITIONS – 3U19MH121738-02S2 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**

**REMOVE HUMAN SUBJECTS RESTRICTION:**

This revised award removes the provisional term from the award issued on 09/17/2020 and reflects NIMH receipt and acceptance of the certification of IRB approval dated 09/04/2020.

THIS REVISED AWARD SUPERSEDES THE NOTICE OF AWARD ISSUED ON 09/17/2020. THE FOLLOWING TERMS & CONDITIONS REMAIN IN EFFECT.

**INFORMATION:**

This grant is awarded with the understanding that project delays and challenges may occur due to COVID-19. It is NIMH's intention to ensure the ultimate success of each project: to that end, we will work with recipients on a case-by-case basis to identify flexibilities and find solutions. You are encouraged to refer to the NIH Guide (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-086.html>, and updates referenced therein) and to the regularly updated Frequently Asked Questions (<https://grants.nih.gov/faqs/#/covid-19.htm>) for guidance on delays in research progress, delays in financial and RPPR reporting, costs, and other relevant issues, and contact your grants specialist and/or program officer with questions.

**RESTRICTION: ADMINISTRATIVE SUPPLEMENT:**

This award provides an administrative supplement in the amount of **\$514,616 total costs** (\$407,220 direct costs + \$107,396 facilities and administrative costs) to evaluate the effects of initiating buprenorphine treatment on subsequent suicidal behavior among people with opioid use disorder, including those with and without co-occurring mental health conditions or other known risk factors for suicidal behavior per recipient's request dated 04/01/2020. These funds may not be used for any other purpose without the prior written approval of NIMH staff. Funds carried over will remain restricted for the stated purpose only. Any ultimate balance of the restricted funds must be specifically identified on the Federal Financial Report (if applicable).

Future year support for this supplement is reflected below:

<b><u>YEAR</u></b>	<b><u>AMOUNT</u></b>	<b><u>BUDGET PERIOD</u></b>
-03	\$274,321 TC	07/01/2021 -06/30/2022

**HEAL Central Data Sharing Platform Requirements**

The award recipient and its collaborators must comply with all *NIH HEAL Initiative* Data Sharing policies established during the project period. This includes compliance with the *NIH HEAL Initiative* central data platform requirements and timelines developed through the HEAL consortium. It is expected that all data collected by award recipients and their collaborators, as part of the *NIH HEAL Initiative*, will be shared with the *NIH HEAL Initiative* central data platform. All data collected as part of the *NIH HEAL Initiative* are so collected under a Certificate of Confidentiality and entitled to the protections thereof. Institutions 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 institution's NIH funding, including NOT-OD-17-109 and 42 U.S.C. 241(d). Failure to adhere to this criterion may result in enforcement actions.

#### **Declaration of Exceptional Circumstances (DECs)**

This award is funded through the *NIH HEAL Initiative* (<https://www.nih.gov/research-training/medical-research-initiatives/heal-initiative>). The requirements here include, but are not limited to, reporting requirements and data sharing are incorporated due to the need to respond to the national opioid public health crisis. As part of the response to this crisis, the NIH intends to maximize the availability of publications and the sharing of underlying data for *NIH HEAL Initiative* supported research projects. Award recipients are expected to cooperate and comply with all NIH data sharing including the aforementioned central data sharing platform requirements developed for this public health emergency during the project period

#### **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* awardees 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.

#### **AWARD NOTICE - COOPERATIVE AGREEMENT TERMS & CONDITIONS:**

This award has been made in response to the application submitted under the Funding Opportunity Announcement RFA-MH18-935 and 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 Section VI. Copy of these Terms and Conditions may be accessed at the following internet address:  
<https://grants.nih.gov/grants/guide/pa-files/PA-18-935.html>

#### **HUMAN SUBJECTS RESEARCH**

This award includes human subject research studies and must conform to the DHHS policies for the [Protection of Human Subjects](#) research, which are a term and condition of award. Human subjects research is covered by the 2018 Common Rule, and may not be initiated until the associated protocols have received IRB approval as specified in [45 CFR g46](#). Failure to comply with the terms and conditions of award may result in the disallowance of costs and collected data and/or additional enforcement actions as outlined in Section 8.5 of the NIH Grants Policy Statement.

#### **DATA AND SAFETY MONITORING:**

The level and frequency of human subject data and safety monitoring should always be commensurate with the risk and nature of the research. Human subject data and safety monitoring for this grant is the responsibility of the Principal Investigator(s) and the IRB of record for this grant. The recipient is reminded of required reporting pursuant to NIHGPS 4.1.15.3 and the [NIMH Reportable Events Policy](#) cited in NOT-MH-19-027, as appropriate.

#### **SINGLE INSTITUTIONAL REVIEW BOARD (sIRB):**

This grant includes a plan for single IRB as outlined in the application dated 04/01/2020. As such, an Authorization (Reliance) Agreement must be established with each site prior to conducting non-exempt human subjects research at that site. This agreement should describe the responsibilities of all parties and how communication between parties will occur--e.g.,



notification of the outcome of regulatory review, how protocol changes will be handled and who will responsible for reporting of unanticipated problems and non-compliance. Please refer to <https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm> for additional information and guidance.

#### **CONSORTIUM / CONTRACTUAL COSTS:**

This award includes funds for consortium activity with:

**Kaiser Foundation Research Institute, Northern California**  
**Kaiser Foundation Research Institute, Southern California**  
**Henry Ford Health System**

Each consortium is to be established and administered in accordance with the NIH Grants Policy Statement, <http://grants.nih.gov/grants/policy/nihgps/index.htm>. No foreign performance site may be added to this project without the written prior approval of the National Institute of Mental Health.

#### **SPREADSHEET SUMMARY**

**AWARD NUMBER:** 3U19MH121738-02S2 REVISED

**INSTITUTION:** KAISER FOUNDATION HOSPITALS

Budget	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	\$124,786	\$83,498		
Fringe Benefits	\$47,674	\$31,784		
Personnel Costs (Subtotal)	\$172,460	\$115,282		
Materials & Supplies	\$760	\$463		
Subawards/Consortium/ Contractual Costs	\$234,000	\$86,814		
TOTAL FEDERAL DC	\$407,220	\$202,559		
TOTAL FEDERAL F&A	\$107,396	\$71,762		
TOTAL COST	\$514,616	\$274,321	\$0	\$0

Facilities and Administrative Costs	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	62%	62%		
F&A Cost Base 1	\$173,220	\$115,745		
F&A Costs 1	\$107,396	\$71,762		