



NATIONAL INSTITUTE OF MENTAL HEALTH

Grant Number: 5U19MH121738-02
FAIN: U19MH121738

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

Project Title: Mental Health Research Network III

Carol Sather
Director; Grants, Business Systems & Services
KAISER FOUNDATION RESEARCH INSTITUTE
1730 Minor Avenue, Suite 1600
Seattle, WA 981011448

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

Period Of Performance:
Budget Period: 07/01/2020 – 06/30/2021
Project Period: 09/23/2019 – 06/30/2024

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$2,052,966 (see “Award Calculation” in Section I and “Terms and Conditions” in Section III) to KAISER FOUNDATION RESEARCH INSTITUTE in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 31 USC 6305 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the “Terms and Conditions” is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as “Research reported in this publication was supported by the National Institute 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 contact the individual(s) referenced in Section IV.

Sincerely yours,

Tamara A. Kees
Grants Management Officer
NATIONAL INSTITUTE OF MENTAL HEALTH

Additional information follows

SECTION I – AWARD DATA – 5U19MH121738-02**Award Calculation (U.S. Dollars)**

Salaries and Wages	\$213,107
Fringe Benefits	\$85,947
Personnel Costs (Subtotal)	\$299,054
Materials & Supplies	\$1,413
Travel	\$9,150
Other	\$45,206
Subawards/Consortium/Contractual Costs	\$1,471,137

Federal Direct Costs	\$1,825,960
Federal F&A Costs	\$227,006
Approved Budget	\$2,052,966
Total Amount of Federal Funds Obligated (Federal Share)	\$2,052,966
TOTAL FEDERAL AWARD AMOUNT	\$2,052,966

AMOUNT OF THIS ACTION (FEDERAL SHARE) \$2,052,966

SUMMARY TOTALS FOR ALL YEARS		
YR	THIS AWARD	CUMULATIVE TOTALS
2	\$2,052,966	\$2,052,966
3	\$2,035,335	\$2,035,335
4	\$2,000,066	\$2,000,066
5	\$1,967,876	\$1,967,876

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

Fiscal Information:

CFDA Name: Mental Health Research Grants
CFDA Number: 93.242
EIN: 1941105628A1
Document Number: UMH121738A
PMS Account Type: P (Subaccount)
Fiscal Year: 2020

IC	CAN	2020	2021	2022	2023
MH	8472591	\$2,052,966	\$2,035,335	\$2,000,066	\$1,967,876

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:** 41029 / **Released:** GM_SA 06/17/2020
Award Processed: 06/18/2020 12:02:08 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5U19MH121738-02

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 – TERMS AND CONDITIONS – 5U19MH121738-02

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.

- 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/>.

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

Clinical Trial Indicator: No

This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

FUNDING RESTRICTION

Due to the scientific and programmatic concerns of **Signature Project 1** titled Digital Mindfulness Based Cognitive Therapy for Perinatal Depression, **\$575,606 TC** representing **91.67%** of the funds awarded for **the Project 1** is restricted and may not be expended for this grant until all NIH administrative requirements have been met.

The recipient must respond to the issues as outlined in the email **dated 6/10/2020** to the institution and PI from **Dr. Michael Freed, NIMH Program Officer**. The requested response must be signed by both the Principal Investigator and the Authorized Signing Official and submitted in PDF format via email to both NIMH Program Official and Grants Management Specialist.

Failure to comply may result in suspension and/or termination of this project. Please note that this restriction remains in effect until the Notice of Grant Award has been revised to remove this restriction. The NIMH will notify the recipient via a revised Notice of Award (NoA) when these NIH administrative requirements have been met.

REMINDER: Delayed Onset on Project 001 (Signature Project 1): Phase 2 (the implementation trial) & Project 002 (Signature Project 2)

In the absence of certification of IRB approval for Project 001 (Signature Project 1): Phase 2 (the implementation trial) & Project 002 (Signature Project 2), this award is issued with the following restriction: only activities that are clearly severable and independent from activities that involve human subjects may be conducted under this award until the project has received IRB approval consistent with 45 CFR Part 46, and certification of IRB approval has been submitted to and accepted by the National Institute of Mental Health (NIMH). Failure to comply with this term may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action.

Funds included in this award for research involving human subjects in Project 001 (Signature Project 1): Phase 2 (the implementation trial) & Project 002 (Signature Project 2), are restricted pending acceptance of certification of IRB approval by the NIMH.

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.

The NIH is concerned about the safety and welfare of human subject participants and research staff and has issued [Guidance for NIH-funded Clinical Trials and Human Subjects Studies Affected by COVID-19](#). For the purposes of RMR reporting, the NIMH requests that study teams continue to enter their anticipated recruitment milestones and actual recruitment numbers and succinctly indicate in the comments box if and how COVID-19 has impacted study recruitment efforts. NIMH staff will continue to monitor and work with you as [additional guidance and information becomes available](#).

AWARD NOTICE - COOPERATIVE AGREEMENT TERMS & CONDITIONS:

This award has been made in response to the application submitted under the Funding Opportunity Announcement **RFA/PA: MH19-225** 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. Award Administration Information**. Copy of these Terms and Conditions may be accessed at the following internet address: <https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-19-225.html>

PARTICIPANT RECRUITMENT - MILESTONES:

Future NIMH support for this study is contingent upon adequate participant recruitment based on projected milestones as approved in the Recruitment Milestone Reporting system (RMR) on 9/18/2019. It is expected that

- 24 of the 96 total projected participants for HSS Study ID 278304 will be recruited by 4/1/2020;

- 150 of the 460 total projected participants for HSS Study ID 278300 will be recruited by 8/1/2020;

- 100 of the 400 total projected participants for HSS Study ID 278307 will be recruited by 4/1/2023.

This tri-yearly recruitment report should be submitted electronically to NIMH after each milestone period of April 1, August 1 and December 1

at: <http://wwwapps.nimh.nih.gov/rmr/displayHome.action>. In the event that actual recruitment falls significantly below projected milestones, NIMH may consider withholding future support and/or negotiating an orderly phase-out of this study. Information regarding the NIMH Policy for the Recruitment of Participants in Clinical Research is available at: <http://grants.nih.gov/grants/guide/notice-files/NOT-MH-19-027.html>.

NIH PROJECT SCIENTIST:

The Project Scientist for this award is **Dr. Susan Azrin** (301-443-3267; azrinst@mail.nih.gov) from NIMH.

CONSORTIUM / CONTRACTUAL COSTS:

This award includes funds for consortium activity with organizations listed below. 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.

- Baylor Scott & White Memorial Hospital, Texas
- Essentia Institute of Rural Health, Minnesota
- Weill Medical College of Cornell University, New York
- Georgia State University, Georgia
- Harvard Pilgrim Health Care, Massachusetts
- HealthPartners Institute, Minnesota
- Henry Ford Health System, Michigan
- Kaiser Permanente, Colorado
- Kaiser Permanente, Georgia
- Kaiser Permanente, Hawaii
- Kaiser Permanente, Northern California
- Kaiser Permanente, Northwest, Oregon
- Kaiser Permanente, Southern California
- Palo Alto Medical Foundation Research Institute, California
- University of Colorado, Boulder, Colorado
- University of Washington, Washington

SINGLE INSTITUTIONAL REVIEW BOARD (sIRB):

This grant includes a plan for single IRB as outlined in the application dated 02/26/2019. 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.

DATA SHARING PLAN:

This award is subject to the data sharing guidance outlined in Clinical Trials (NOT-MH-14-015), RDoC (NOT-MH-15-012), NDAR (NOT-MH-09-005). Please note that NOT-MH-19-041 clarifies the timeline related to NIMH data sharing and can be found at <https://grants.nih.gov/grants/guide/notice-files/NOT-MH-19-041.html>. The recipient agrees to adhere to the resource and data sharing plan negotiated with NIMH Program staff. Dissemination of study data will be in accord with the Recipient's accepted data sharing plan as stated in the application. Please note that a statement of progress on the Sharing Plan must be included in the Research Performance Progress Report (RPPR) under section C.5 "Other Products and Resource Sharing". Failure to adhere to the sharing plan as mutually agreed upon by the Recipient and the NIH/IC may result in Enforcement Actions as described in the NIH Grants Policy Statement.

Complete NIMH data sharing terms and conditions can be found at <https://nda.nih.gov/contribute/sharing-regimen.html>. Instructions are available at <http://grants.nih.gov/grants/rppr/index.htm>. Complete guidelines on data sharing are available at http://grants.nih.gov/grants/policy/data_sharing/index.htm.

DATA AND SAFETY MONITORING:

This grant is expected to involve a Data and Safety Monitoring Board (DSMB). The recipient and Principal Investigator(s) should review the [NIMH Policy Governing Independent Safety Monitors and Independent Data and Safety Monitoring Boards](#) cited in NOT-MH-19-027. Each RPPR submitted should include copies of all DSMB reports in RPPR Section G.1 since the last annual award. The recipient is also 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.

CLINICAL TRIAL REQUIREMENTS:

This award is subject to additional certification requirements with each submission of the Annual, Interim, and Final Research Performance Progress Report (RPPR). The recipient must agree to the following annual certification when submitting each RPPR. By submitting the RPPR, the AOR signifies compliance, as follows:

In submitting this RPPR, the SO (or PD/PI with delegated authority), certifies to the best of his/her knowledge that, for all clinical trials funded under this NIH award, the recipient and all investigators conducting NIH-funded clinical trials are in compliance with the recipient's plan addressing compliance with the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information. Any clinical trial funded in whole or in part under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the completion date, even if the completion date occurs after the period of performance.

GCP TRAINING:

NIH expects that all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonisation (ICH) as stated in NOT-OD-16-148

STAFF CONTACTS

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

Grants Management Specialist: Jackie Chia
Email: Jackie.Chia@nih.gov **Phone:** 301-443-1341

Program Official: Michael Freed

SPREADSHEET SUMMARY

GRANT NUMBER: 5U19MH121738-02

INSTITUTION: KAISER FOUNDATION RESEARCH INSTITUTE

Budget	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	\$213,107	\$283,326	\$289,861	\$307,230
Fringe Benefits	\$85,947	\$116,726	\$119,630	\$127,220
Personnel Costs (Subtotal)	\$299,054	\$400,052	\$409,491	\$434,450
Materials & Supplies	\$1,413	\$2,172	\$2,109	\$2,088
Travel	\$9,150	\$9,150	\$9,150	\$9,150
Other	\$45,206	\$91,258	\$106,046	\$103,304
Subawards/Consortium/Contractual Costs	\$1,471,137	\$1,218,985	\$1,149,255	\$1,081,254
TOTAL FEDERAL DC	\$1,825,960	\$1,721,617	\$1,676,051	\$1,630,246
TOTAL FEDERAL F&A	\$227,006	\$313,718	\$324,015	\$337,630
TOTAL COST	\$2,052,966	\$2,035,335	\$2,000,066	\$1,967,876

Facilities and Administrative Costs	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	61.5%	61.5%	61.5%	61.5%
F&A Cost Base 1	\$369,115	\$510,111	\$526,853	\$548,992
F&A Costs 1	\$227,006	\$313,718	\$324,015	\$337,630