



NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Grant Number: 1R01HL144406-01
FAIN: R01HL144406

Principal Investigator(s):

Adithya Cattamanchi (contact), MD
David Wesley Dowdy, MD

Project Title: Options for Delivery of Short-Course Tuberculosis Preventive Therapy: The 3HP Options Trial

Hutchinson, Sharon
UCSF Contracts and Grants Officer
UCSF Office of Sponsored Research
155 North Fresno Street
Fresno, CA 937012302

Award e-mailed to: cgrasteam@ucsf.edu

Period Of Performance:

Budget Period: 08/01/2018 – 06/30/2019

Project Period: 08/01/2018 – 06/30/2023

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$725,916 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to The Regents of the UCSF in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 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 Heart, Lung, And Blood Institute of the National Institutes of Health under Award Number R01HL144406. 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,

Ronald Caulder
Grants Management Officer
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Additional information follows

SECTION I – AWARD DATA – 1R01HL144406-01**Award Calculation (U.S. Dollars)**

Salaries and Wages	\$107,080
Fringe Benefits	\$39,983
Personnel Costs (Subtotal)	\$147,063
Consultant Services	\$7,500
Materials & Supplies	\$63,020
Travel	\$23,700
Other	\$3,118
Subawards/Consortium/Contractual Costs	\$301,674
Publication Costs	\$2,000

Federal Direct Costs	\$548,075
Federal F&A Costs	\$177,841
Approved Budget	\$725,916
Total Amount of Federal Funds Obligated (Federal Share)	\$725,916
TOTAL FEDERAL AWARD AMOUNT	\$725,916

AMOUNT OF THIS ACTION (FEDERAL SHARE) \$725,916

SUMMARY TOTALS FOR ALL YEARS			
YR	THIS AWARD		CUMULATIVE TOTALS
1		\$725,916	\$725,916
2		\$685,495	\$685,495
3		\$679,879	\$679,879
4		\$666,706	\$666,706
5		\$664,659	\$664,659

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

Fiscal Information:

CFDA Name: Lung Diseases Research
CFDA Number: 93.838
EIN: 1946036493A6
Document Number: RHL144406A
PMS Account Type: P (Subaccount)
Fiscal Year: 2018

IC	CAN	2018	2019	2020	2021	2022
HL	8475164	\$725,916	\$685,495	\$679,879	\$666,706	\$664,659

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

NIH Administrative Data:

PCC: LLLA A / **OC:** 414A / **Released:** CAULDERR 07/30/2018
Award Processed: 07/31/2018 12:19:10 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01HL144406-01

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 – 1R01HL144406-01

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- a. The grant program legislation and program regulation cited in this Notice of Award.

- b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- c. 45 CFR Part 75.
- d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm> for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of “Research and Development” at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VI Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

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) R01HL144406. 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/

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 – HL Special Terms and Conditions – 1R01HL144406-01

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.

NHLBI FUNDING GUIDELINES

This award is being issued in accordance with the NHLBI FY 2018 Operating Guidelines which can be found at: <https://www.nhlbi.nih.gov/research/funding/general/current-operating-guidelines>

ADJUSTED INITIAL BUDGET PERIOD

This award is issued for an 11-month budget period. Any subsequent noncompeting performance period(s) will begin on July 1 and will be 12 months in duration. The project period end date has been adjusted accordingly.

MULTIPLE PI - Prior Approvals

In keeping with NOT-OD-06-054 (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-054.html>), as this award has multiple Principal Investigators (PIs), although the signatures of all the PIs are not required on prior approval requests submitted to the agency, the recipient institution must secure and retain the signatures of all of the PIs for their own internal processes.

CONSORTIUM/CONTRACTUAL

This award includes funds awarded for consortium activity with Johns Hopkins University and Infectious Disease Research Collaboration. The recipient, as the direct and primary recipient of NIH grant funds, is accountable to NIH for the performance project, the appropriate expenditures of grant funds by all parties, and all other obligations of the recipient, as specified in the NIH Grants Policy Statement. In general, the requirements that apply to the recipient, including the intellectual property requirements also apply to consortium participant(s)

MILESTONE ACCRUAL PLAN (MAP):

NHLBI support of this study is contingent upon adequate participant recruitment based on the recipient's Milestone Accrual Plan dated 07/26/18. The recipient is expected to demonstrate best effort compliance in accordance with the NHLBI Milestone Accrual Policy (<https://www.nhlbi.nih.gov/grants-and-training/policies-and-guidelines/accrual-of-human-subjects-milestones-policy>.) Failure to achieve minimally acceptable milestone recruitment levels may result in the withholding of future support and or negotiating an orderly close-out of this study.

FOREIGN TRAVEL

Recipients must comply with the requirements of the Fly America Act (49 U.S.C. 40118) which generally provides that foreign air travel funded by Federal funds may only be conducted on U.S. flag air carriers and under applicable Open Skies Agreements.

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: Erin A Davis
Email: davisea@mail.nih.gov **Phone:** 301-827-8026

Program Official: Elisabet V Caler
Email: lis.caler@nih.gov **Phone:** 301-435-0222

SPREADSHEET SUMMARY

GRANT NUMBER: 1R01HL144406-01

INSTITUTION: The Regents of the UCSF

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	\$107,080	\$107,080	\$120,432	\$120,432	\$124,433
Fringe Benefits	\$39,983	\$39,983	\$44,889	\$44,889	\$46,584
Personnel Costs (Subtotal)	\$147,063	\$147,063	\$165,321	\$165,321	\$171,017
Consultant Services	\$7,500	\$6,750	\$6,000		
Materials & Supplies	\$63,020	\$26,855	\$12,176	\$6,500	\$4,000
Travel	\$23,700	\$21,200	\$15,100	\$17,600	\$17,600
Other	\$3,118	\$3,152	\$3,329	\$1,829	\$1,918
Subawards/Consortium/Contractual Costs	\$301,674	\$353,228	\$350,539	\$351,377	\$344,025
Publication Costs	\$2,000	\$2,000	\$2,000	\$4,000	\$4,000
TOTAL FEDERAL DC	\$548,075	\$560,248	\$554,465	\$546,627	\$542,560
TOTAL FEDERAL F&A	\$177,841	\$125,247	\$125,414	\$120,079	\$122,099
TOTAL COST	\$725,916	\$685,495	\$679,879	\$666,706	\$664,659

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	60%	60.5%	61.5%	61.5%	61.5%
F&A Cost Base 1	\$296,401	\$207,020	\$203,926	\$195,250	\$198,535
F&A Costs 1	\$177,841	\$125,247	\$125,414	\$120,079	\$122,099