



EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

**Grant Number:** 5UG1HD076457-07  
**FAIN:** UG1HD076457

**Principal Investigator(s):**  
RICHARD J DERMAN, MD

**Project Title:** TJU-JNMC Global Network for Women's & Children's Health Research Unit

Margaret Burwell  
Assistant to the Director  
125 S. 9th Street  
Philadelphia, PA 191075125

**Award e-mailed to:** resadmin@jefferson.edu

**Period Of Performance:**

**Budget Period:** 06/01/2019 – 05/31/2020

**Project Period:** 07/01/2013 – 05/31/2023

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$607,360 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to THOMAS JEFFERSON UNIVERSITY 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 Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number UG1HD076457. 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,

Kimberly Durkin  
Grants Management Officer  
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN  
DEVELOPMENT

Additional information follows

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**SECTION I – AWARD DATA – 5UG1HD076457-07****Award Calculation (U.S. Dollars)**

Salaries and Wages	\$36,764
Fringe Benefits	\$8,750
Personnel Costs (Subtotal)	\$45,514
Consultant Services	\$27,524
Travel	\$9,830
Other	\$403,030
Subawards/Consortium/Contractual Costs	\$75,056

Federal Direct Costs	\$560,954
Federal F&A Costs	\$46,406
Approved Budget	\$607,360
Total Amount of Federal Funds Obligated (Federal Share)	\$607,360
<b>TOTAL FEDERAL AWARD AMOUNT</b>	<b>\$607,360</b>

**AMOUNT OF THIS ACTION (FEDERAL SHARE)** \$607,360

SUMMARY TOTALS FOR ALL YEARS			
YR	THIS AWARD		CUMULATIVE TOTALS
7		\$607,360	\$607,360
8		\$607,360	\$607,360
9		\$607,360	\$607,360
10		\$607,360	\$607,360

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

**Fiscal Information:**

**CFDA Name:** Child Health and Human Development Extramural Research  
**CFDA Number:** 93.865  
**EIN:** 1231352651A1  
**Document Number:** UHD076457C  
**PMS Account Type:** P (Subaccount)  
**Fiscal Year:** 2019

IC	CAN	2019	2020	2021	2022
HD	8014707	\$607,360	\$607,360	\$607,360	\$607,360

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

**NIH Administrative Data:**

**PCC:** PPB -PS / **OC:** 414P / **Released:** SHAWK00 06/12/2019  
**Award Processed:** 06/13/2019 12:12:13 AM

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**SECTION II – PAYMENT/HOTLINE INFORMATION – 5UG1HD076457-07**

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm>

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**SECTION III – TERMS AND CONDITIONS – 5UG1HD076457-07**

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) UG1HD076457. 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 provides support for one or more NIH defined Phase III Clinical Trials. The NIH Policy for research supported as an NIH Phase III Clinical Trial has been amended in Section II.B. of the NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research – Amended October 2001 (see [http://grants.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm)).

A description of plans to conduct analyses, as appropriate, by sex/gender and racial/ethnic groups must be included in clinical trial protocols. Cumulative subject accrual and progress in conducting subset analyses must be reported to NIH in the annual Progress Reports. Final analyses of sex/gender and racial/ethnic differences must be reported in the required Final

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 – HD Special Terms and Conditions – 5UG1HD076457-07**

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.

NIH staff has determined that the submitted Continuation Progress Report is within the approved scope of work.

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**TOTAL COSTS**

This award is funded at a total cost ceiling of \$607,360. Funds may be rebudgeted as necessary between direct and facilities and administrative costs consistent with policy and institutional requirements for prior approval; however, no additional funds will be provided.

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**CLINICAL TRIALS**

The clinical trial(s) supported by this award are subject to the plan dated 11/24/2017 submitted to NICHD and the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. The policy states that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant and that primary summary results will be reported in ClinicalTrials.gov not later than one year after the completion date. The reporting of summary results is required even if the primary completion date occurs after the period of performance.

This award is subject to additional certification requirements with submission of the Annual, Interim and Final Research Performance Progress Reports (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.

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**CONSORTIA**

This award includes funds awarded for consortium activity with KLE Society's Jawaharlal Nehru Medical College in Karnataka, India .

Consortia are to be established and administered as described in the NIH Grants Policy Statement (rev. 10/17) (<http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>).

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**FOREIGN COMPONENT**

This award includes funding for the following sites: KLE Society's Jawaharlal Nehru Medical College in Karnataka, India .

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**COOPERATIVE AGREEMENTS**

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 terms and conditions of award as set forth in the SPECIAL REQUIREMENTS section of RFA-HD-HD18-009, "Re-Competition of Global Network for Women's and Children's Health Research (UG1)," posted date July 18, 2017, which are hereby incorporated by reference as special terms and conditions of award.

Copies of this RFA are available at <http://www.nih.gov/grants/guide/index.html>

These special terms and conditions of award are in addition to, and not in lieu of, otherwise applicable OMB administrative guidelines; Federal Regulations, including HHS Grant Administration Regulations at 45 CFR Part 75; other HHS regulations; and the NIH Grants Policy Statement (rev. 10/17).

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**Project Scientist Contact Information:**

**Project Scientist:** Marion Koso-Thomas, MD  
**Email:** [kosomari@mail.nih.gov](mailto:kosomari@mail.nih.gov) **Phone:** 301.435.6873

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**FUNDING OPPORTUNITY**

This award is subject to the requirements indicated in RFA-HD18-009, which are hereby incorporated by reference. Copies of this Funding Opportunity Announcement are available at <http://grants.nih.gov/grants/guide/index.html>.

**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:** Kimberly Durkin  
**Email:** [kimberly.durkin@nih.gov](mailto:kimberly.durkin@nih.gov) **Phone:** 301-451-0820

**Program Official:** Caroline Signore  
**Email:** [signorec@mail.nih.gov](mailto:signorec@mail.nih.gov) **Phone:** (301) 496-5577 **Fax:** (301) 496-3790

**SPREADSHEET SUMMARY****GRANT NUMBER:** 5UG1HD076457-07**INSTITUTION:** THOMAS JEFFERSON UNIVERSITY

Budget	Year 7	Year 8	Year 9	Year 10
Salaries and Wages	\$36,764	\$36,764	\$36,764	\$36,764
Fringe Benefits	\$8,750	\$8,750	\$8,750	\$8,750
Personnel Costs (Subtotal)	\$45,514	\$45,514	\$45,514	\$45,514
Consultant Services	\$27,524	\$27,524	\$27,524	\$27,524
Travel	\$9,830	\$9,830	\$9,830	\$9,830
Other	\$403,030	\$403,030	\$403,030	\$403,030
Subawards/Consortium/Contractual Costs	\$75,056	\$75,056	\$75,056	\$75,056
TOTAL FEDERAL DC	\$560,954	\$560,954	\$560,954	\$560,954
TOTAL FEDERAL F&A	\$46,406	\$46,406	\$46,406	\$46,406
TOTAL COST	\$607,360	\$607,360	\$607,360	\$607,360

Facilities and Administrative Costs	Year 7	Year 8	Year 9	Year 10
F&A Cost Rate 1	56%	56%	56%	56%
F&A Cost Base 1	\$82,868	\$82,868	\$82,868	\$82,868
F&A Costs 1	\$46,406	\$46,406	\$46,406	\$46,406