

# Morehouse School of Medicine/Tuskegee University/ and O'Neal Comprehensive Cancer Center at The University of Alabama at Birmingham

# Comprehensive Partnerships to Advance Cancer Health Equity (CPACHE) PAR-23-308

# Solicitation for Full and Pilot-Level Project Applications to Include in the Competitive Renewal Application of CPACHE-U54

#### **KEY DATES:**

#### FINAL APPLICATION NEW DEADLINE DUE \*

March 14, 2025

(\*No application will be accepted after the **new** deadline of March 14<sup>th</sup> at 5 pm Central Standard Time).

Notification to applicant to revise if selected

June 6, 2025

Final revised application to include in the competitive renewal

July 1, 2025

Award Effective Date (if successful in our competitive renewal)

September 1, 2026

<u>Purpose of this solicitation</u>: To continue to address cancer disparities in our region, the Morehouse School of Medicine (MSM) /Tuskegee University (TU) / O'Neal Comprehensive Cancer Center (OCCC) at the University of Alabama at Birmingham (UAB) partnership, will submit its competitive renewal application in response to the Funding Opportunity Announcement (PAR-23-308).

For programmatic details, please refer to the webpage from the following hyperlink:

#### https://grants.nih.gov/grants/guide/pa-files/PAR-23-308.html

The goals of this MSM/TU/UAB Partnership are: 1) advance the scientific knowledge in basic, clinical, translational, prevention, control, behavioral, and/or population cancer research, particularly cancers that disproportionately affect racial/ethnic minorities and underserved populations 2) cancer research education, and

3) outreach focused on cancer health disparities and reducing the cancer burden in our region as well as in the country. Based on its exceptional productivity and positive impact on all aspects of its cancer health disparity research and education efforts, this Partnership has been competitively renewed twice and currently in its third funding cycle.

The primary purpose of this solicitation for **three-year full** (well-developed research projects)/**pilot** (exploratory projects) grant applications is to build on our successes and to enhance the integrated collaborative infrastructure at the partner institutions that enable us to conduct research leading to the elimination of cancer disparities.

- Research projects, in general, should be in any area of basic, clinical, translational, prevention, control, behavioral, and/or population research. These projects are encouraged to include (as appropriate) translational research, and emerging technologies (such as nanotechnology, proteomics, genomics, artificial intelligence, and imaging), precision medicine, and/or therapeutic clinical trials accrual of underserved populations.
- Research may be focused on pediatric, adolescent, and young adult cancers. Hypothesis-driven outreach research
  projects are also appropriate, including those aimed at increased high quality, clinically annotated biospecimens from
  underserved populations.
- Joint research projects conducted primarily at ISUPS may be in any area of cancer research. These projects may focus, for example, on general areas of environmental carcinogenesis, cancer biology, molecular epidemiology, and/or behavioral issues related to cancer prevention, treatment, and control.
- Joint research projects conducted primarily at the Cancer Center must specifically address areas of cancer disparity in underserved and/or socio-economically disadvantaged populations.

All submissions must be *joint projects* between all three institutions (MSM and O'CCC-UAB or TU and O'CCC-UAB).

The funds directed to these research projects are to be distributed appropriately according to work conducted between the institutions. Research projects primarily originating at the MSM or TU may be in <u>any area of cancer research</u>. However, research projects primarily originating at the O'CCC-UAB must address <u>cancer disparities</u> among racial/ethnic minorities and/or underserved populations.

We are particularly interested in *hypothesis-driven* projects that address cancer disparities in the entire spectrum of cancer research, including basic laboratory research, clinical/preclinical and translational research, prevention and control research, behavioral, population, and/or outreach. Areas of research conducted within the Partnership include cancer disparities at the molecular level, biology, therapeutic target identification, molecular characterization, tumor suppression, integrative cancer genomics, cancer prevention (e.g., cancer screening, chemoprevention), collaborative clinical trial research (e.g., clinical trial participation), or healthy lifestyle initiatives.

The Partnership expects that successful *pilot* research projects may become full research projects within the Partnership, during the next funding cycle, or to evolve, within 3-years, into a full project or into an independent, competitive project that is fundable by NIH or another agency. Likewise, full projects are expected to evolve into an independent, competitive project that is fundable by NIH or another agency within NIH.

#### **Project Requirements and Award Budgets**

- For *Pilot* Projects, combined/joint budgets of two co-leaders (one from UAB-O'CCC and the other either from TU or MSM), cannot exceed \$120,000 in direct costs per year for up to three years. The pilot projects are exploratory studies in any area of cancer research and follow the requirements stated above.
- For Full Projects, combined/joint budgets of two co-leaders (one from UAB-O'CCC and the other either from TU or MSM) cannot exceed \$240,000 in direct costs per year for up to three years or continue for longer than three years. For projects involving clinical trials, funds may be budgeted for data and safety monitoring, if justified. Note that Full Research Projects are expected to be well developed and supported by sufficient preliminary data.

#### **Eligibility**

All faculty members with expertise in the areas of basic, clinical/translational, or cancer control/population science, and health outcomes, including those investigators already in the Partnership (with/without currently funded projects), and irrespective of faculty rank or current NIH, ACS, or other funding, are eligible to apply. However, Early-Stage Investigators are encouraged to partner with established investigators of MSM, TU, or UAB-O'CCC. Current partnership investigators of pilot projects may submit proposals with **new specific aims** that are not merely an extension of currently funded projects.

A detailed Career Development and Mentorship Plan are required if the Co-Leader is an Early-Stage Investigator (ESI) defined as scientist or faculty member of any rank with no prior major independent research funding from NIH or equivalent agencies (e.g., the investigator has never had a funded R01, P01, or another comparable award). Having had funded small (e.g., R03 or R21) and/or training, (e.g., K) awards **do not count** against an applicant's eligibility (See Career Development and Mentorship Plan section below).

Investigators with questions or those needing help identifying potential co-leaders from partnering institutions are encouraged to contact the PIs or grant administrators listed below.

#### **APPLICATION PREPARATION GUIDELINES**

The proposal format for Projects should follow <u>NIH application instructions</u> and format specifications as follows:

PHS 398 forms https://grants.nih.gov/grants/funding/phs398/phs398.pdf updated 03/2020).

# **Format Specifications**

Follow font and format specifications. Otherwise, application processing may be delayed, or the application may not be reviewed.

#### **Font**

- Use an *Arial, black font color, and font size of 11 points or larger*. A symbol font may be used to insert Greek letters or special characters; the font size requirement still applies.
- Type density, including characters and spaces, must be no more than 15 characters per inch.
- Type may be no more than six lines per inch.
- Use black ink that can be clearly copied.
   The print must be clear and legible.

#### **Paper Size and Page Margins**

- Use a standard paper size (8 ½" x 11")
- Use at least one-half inch margins (top, bottom, left, and right) for all pages, including continuation pages. No information should appear in the margins, except the PD/PI's name and page numbers.

### Page Formatting

- Because most reviewers will be reviewing applications as electronic documents and not paper versions, applicants are strongly encouraged to use only a standard, single-column format for the text. Avoid using a two-column format since it can cause difficulties when reviewing the document electronically.
- The application must be single-sided and single-spaced.
- Consecutively number pages throughout the application. Do not use suffixes (e.g., 5a, 5b).
- Do not include additional pages between the face page and page 2.
- Do not include unnumbered pages.

#### Figures, Graphs, Diagrams, Charts, Tables, Figure Legends, and Footnotes

For these, you may use smaller type size, but it must be in black font color, readily legible, and follow the
font typeface requirement. Color can be used in figures; however, all text must be in black font color, clear
and legible.

#### Grantsmanship

- Use English and avoid jargon.
- If terms are not universally known, spell out the term the first time it is used and note the appropriate abbreviation in parentheses. The abbreviation may be used thereafter.

#### **Photographs and Images**

- Do not include photographs or other materials that are not printed directly on an application page in the body
  of the application. Pictures or other materials that are glued or taped onto application pages are incompatible
  with the current duplication/scanning process.
- You may include black-and-white or color images in the six (6) submitted copies provided such images are printed directly on the application page and are necessary to the content of the application.

#### Application/Forms:

<u>Face Page</u> for each Co-Leader [(Page 14 - NIH PHS 398, Section 4.1) to be signed by division head or department chair)]

#### Title Page including:

- The title of the project
- Names of co-leaders\* from the MSM/TU and the O'CCC-UAB
- A one-paragraph abstract (max 30 lines) stating the objectives of the project
  - \* NOTE: Identify areas to be addressed in the career development plan for less experienced Project co-leaders (respective Career Development Plans are to be included in Section C, see below)

**Form Page 2** (Page 20 - NIH PHS 398 Sections 4.2.1—4.2.5): Project Summary and Relevance, Project/Performance Sites/Key personnel, Other Significant Contributors, Human Embryonic Stem Cells

Table of Contents: Research Grant Table of Contents (Page 21 - NIH Section 4.3)

A budget of initial budget period \*\* (Page 22 - NIH PHS 398 Section 4.4 first year)

**Budget** for the entire three-year project period \*\* (Page 25 - NIH PHS 398 Section 4.5)

- \*\* Please Note: The following types of expenditures are allowable:
  - a. Research supplies and animal maintenance
  - b. Technical assistance
  - c. Domestic travel when necessary to carry out the proposed research
  - d. Publication costs, including reprints
  - e. Cost of computer time
  - f. Special fees (pathology, photography, etc.)
  - g. Stipends for graduate students and postdoctoral assistants if their role is to promote and sustain the project presented by the junior faculty member
  - h. Equipment costing less than \$2,000
  - i. Registration fees for scientific meetings
  - j. Investigator salary
  - \*\* The following types of expenditures are **NOT** allowed:
    - a. Secretarial/administrative personnel
    - b. Tuition
    - c. Foreign travel
    - d. Honoraria and travel expenses for visiting lecturers
    - e. Per diem charges for hospital beds
    - f. Non-medical services to patients
    - g. Construction or building maintenance
    - h. Major alterations
    - i. Purchasing and binding of periodicals and books
    - j. Office and laboratory furniture
    - k. Office equipment and supplies
    - I. Rental of office or laboratory space
    - m. Recruiting and relocation expenses
    - n. Dues and membership fees in scientific societies

Biographical Sketch (Page 25 - NIH PHS 398 Section 4.6)

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02-28-2023)

https://grants.nih.gov/grants/forms/biosketch.htm

Resources (Page 29 - NIH PHS 398 Section 4.7)

Research Strategy [(Page 33 - NIH PHS 398 Section 5.5.3)

Full Projects should be no more than **twelve (12)** pages, and Pilot Projects should be no more than **six (6)** pages and include the following:

- Significance
- Innovation
- Preliminary Studies (if available)
- Approach

Describe how this full/pilot level project relates to the overall priorities of the Partnership and the targeted research area(s). Include any preliminary data (if available). Describe, as appropriate for the nature of the project, experimental methods/study design, or the training, outreach, and/or education plans and objectives. For example, include identification of the target pool (students or minority population), and/or the method of program evaluation and tracking. Describe the role played by each of the co-investigators/mentors. Identify aspects of the project that will be conducted primarily at the MSI and at the Cancer Center. Research projects conducted primarily at either MSM or TU may be in any area of cancer research, but research projects conducted primarily at the O'Neal Cancer Center must specifically address cancer health disparities research.

Other Sections of PHS 398 Research Plan (Page 32 - Sections 5.5 Items # 4-15) must also be completed (but are excluded from page limitations). In particular, Research Plan sections pertaining to human subjects and vertebrate animals must be strictly followed. See the note below. Respective information must also be included (in cumulative fashion) in Sections 4-15 for the entire application.

Career Development and Mentorship Plan (if needed, up to 12 pages within "The Candidate" section of each plan plus other required administrative items).

As indicated, career development and mentorship plans must be provided for the less experienced co-leaders and directors of individual projects. The plan description must follow the format similar to applications for Career Development Awards (e.g., K Awards), by providing the following information:

#### The Candidate (limit of 12 pages for items A-D);

- a) Candidate's Background
- b) Career Goals and Objectives: Scientific Biography
- c) Career Development/Training Activities During Award Period
- d) Training in the Responsible Conduct of Research

#### Formal/administrative Items Required for Each Career Development Plan (no page limitation):

• Statements by Sponsor, Co-Sponsor(s), Consultant(s), Contributor(s); and Environment and Institutional Commitment to Candidate

**NOTE:** (1) All NIH-supported biomedical or behavioral research projects involving human subjects must address the respective requirements under the Research Plan, Section E, Human Subjects, following the PHS 398 instructions; (2) Research dealing with Human Subjects and Vertebrate Animals must be accompanied by appropriate documentation as described under the Research Plan, Section F, Vertebrate Animals of the Form PHS 398 instructions; and (3) Research components involving clinical trials must include a data and safety monitoring plan as described in the PHS 398 instructions. *Funds should be budgeted for these activities and should be justified.* The proposed provisions should not duplicate review and monitoring systems already in place at the institution. For any cancer treatment protocol supported directly or indirectly

by the U54, early stopping rules and procedures to detect and monitor adverse drug reactions (ADR) must be provided in the application, or, in the case of protocols subsequent to the funding of a U54, to the NCI Program Director.

**PHS 398 Instructions** to Research Plan, sections pertaining to human subjects and/or vertebrate animals (listed below), must be strictly followed, and appropriate documentation (described in PHS 398 instructions) attached as required.

Section 6. Protection of Human Subjects

Section 7. Inclusion of Women and Minorities

Section 8. Targeted/Planned Enrollment Table

Section 9. Protection of Children

Section 10. Vertebrate Animals

Research components involving clinical trials must include a data and safety monitoring plan, as described in the PHS instructions. Funds should be budgeted for these activities and should be justified. The proposed provisions should not duplicate review and monitoring systems already in place at the institution. For any cancer treatment protocol supported directly or indirectly by Partnership funding, guidelines detailing early stopping rules and procedures to detect and monitor adverse drug reactions must be provided in the application or in the case of protocols to the NCI Program Director subsequent to the funding of the U54 proposal.

#### **Evaluation Criteria**

The full/pilot-level project evaluation criteria include:

- 1. The qualifications of the co-leaders (the contact PI and the other partnering investigator) from the institutions to develop the proposed projects.
- 2. The merits and importance of the proposed full/pilot-level project/program and the degree to which it contributes to the priorities and objectives of the Partnership.
- 3. The project's potential to develop into a full project (during the next Partnership funding cycle) or to achieve independent, peer-reviewed funding.

The comprehensive evaluation will involve the following questions:

- 1. <u>Significance</u>: Does this study address an important problem consistent with the objectives of the Partnership? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field of cancer research and/or research on cancer disparities?
- 2. <u>Co-Leaders</u>: Is the PI, or are the Co-Leaders (the contact PI and the other partnering investigator) appropriately trained and suited to carry out this work? Is the work proposed appropriate to the expertise of the Co-Leaders and other researchers (if any)?
- 3. <u>Innovation</u>: Does the project employ novel concepts, approaches, or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?
- 4. <u>Approach</u>: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?
- 5. <u>Environment</u>: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

The reviewers will be asked to summarize the most important points, addressing the strengths and weaknesses of the application in **one concise** paragraph. The application does not have to be strong in all categories to deserve high merit, but it should have excellent potential to become competitive for peer-reviewed funding. In addition, it must have relevance to the objectives of the Partnership in addressing health disparities, especially applications submitted by UAB OCCC investigators (contact PI/co-leader). If an applicant is a junior faculty member, it must have the potential to advance his/her career. Protection of human subjects; gender-based, minority, and children subjects; animal welfare; biohazards; and budgets are evaluated as well, following NIH Reviewers' Guidelines.

#### Formal Review and Priority Scoring

The NIH scoring system will be used for the evaluation of the applications. Prior to inclusion in the competitive renewal application, selected applicants must respond to reviewer comments as requested following the receipt of proposal reviews and scores.

Please submit the application as a single PDF document.

For scientific inquiries, applicants may contact the U54 Partnership Principal Investigators:

#### **MOREHOUSE SCHOOL OF MEDICINE**

Brian Rivers, PhD, MPH

Director, Cancer Health Equity Institute Professor, Community Health and Preventive Medicine Morehouse School of Medicine

Email: brivers@msm.edu

Tel: 404.752.1127

#### James W. Lillard Jr., PhD, MBA

Associate Dean, Research Affairs Professor, Department of Microbiology, Biochemistry, and Immunology

Morehouse School of Medicine Email: <a href="mailto:jlillard@msm.edu">jlillard@msm.edu</a>

Tel:404.752.1863

#### **TUSKEGEE UNIVERSITY**

# **Timothy Turner, PhD**

Associate Vice President for Research

Tuskegee University

Email: tturner2@tuskegee.edu

Tel: 334.727.8787

#### Vivian Carter, PhD

Department Head, Psychology and Sociology

**Tuskegee University** 

Email: vcarter@tuskegee.edu

Tel: 334.727.8737

#### Windy Dean-Colomb, MD

Adjunct Faculty
Tuskegee University

Email: wdeancol@gmail.com

Tel: 770.400.4720

## O'NEAL COMPREHENSIVE CANCER CENTER at UAB

### Upender Manne, MS., PhD

Professor, Department of Pathology The University of Alabama at Birmingham Email: upendermanne@uabmc.edu

Tel:205.934.4276

#### Isabel Scarinci, PhD, MPH

Professor and Vice-Chair for Global and Rural Health Department of Obstetrics and Gynecology Senior Advisor for Globalization and Cancer O'Neal Comprehensive Cancer Center The University of Alabama at Birmingham

Email: iscarinci@uabmc.edu

Tel:205.975.7177

# For administrative/general inquiries, please contact the Program Managers of the U54 Partnership Jennifer Creighton

Morehouse School of Medicine Email: <a href="mailto:jcreighton@msm.edu">jcreighton@msm.edu</a>

Tel:404.752.1177

### Chiquita Lee, MBA, MPA

Tuskegee University Email: <a href="mailto:clee@tuskegee.edu">clee@tuskegee.edu</a>

Tel:334.421.7525

# Dennis Otali, PhD

The University of Alabama at Birmingham

Email: <u>dennisotali@uabmc.edu</u> Tel: 205.975.9558/ 205.996.2160