Morehouse School of Medicine, Tuskegee University and O'Neal Comprehensive Cancer Center at UAB

REQUEST FOR APPLICATIONS (RFA)
Comprehensive Partnerships to Advance Cancer Health Equity
(CPACHE) **PAR-23-308**

Due Date: March 15, 2024

The Morehouse School of Medicine/Tuskegee University/O'Neal Comprehensive Cancer Center at the University of Alabama at Birmingham (UAB) Partnership is funded by the National Institutes of Health, National Cancer Institute's Center to Reduce Cancer Health Disparities Partnership to Advance Cancer Health Equity (PACHE) program with the overarching goal of addressing cancer disparities through research, education, and outreach. This Request for Applications (RFA) is for pilot projects addressing cancer health disparity research in the Deep South region (Alabama and Georgia). Proposed projects must demonstrate relevance to cancer in the areas of cancer prevention and control, cancer epidemiology, social and behavioral sciences, basic science, or clinical and translational science.

The purpose of this two-year pilot grant, in brief, is to enhance the integrated infrastructure at the partner institutions that enable us to conduct research leading to the elimination of cancer disparities. All submissions must be *joint projects* led by faculty members at the O'Neal Comprehensive Cancer Center at UAB and at one of the minority-serving institutions (MSI). **This means that all projects will require Co-Project Leaders from either Morehouse School of Medicine and O'Neal Comprehensive Cancer Center *or* Tuskegee University and O'Neal Comprehensive Cancer Center.**

For programmatic details, please refer to the webpage at the following hyperlink:
PAR-23-308: Comprehensive Partnerships to Advance Cancer Health Equity (CPACHE) (U54 Clinical Trial Optional) (nih.gov)

Letter of Intent Due **January 15, 2024**

FINAL APPLICATION DUE ** **March 15, 2024
 (*No application will be accepted after the deadline of March 15th at 5 pm Central Standard Time).

Notification of Award to Grant Recipients **July 31, 2024**

Award Effective Date **September 1, 2024**

Please note: Award funds for projects with research on human subjects and/or animal models will not be released until receipt of IRB and/or IACUC approval documents. The funds directed to these research projects are to be distributed appropriately according to work conducted between the two

institutions. Research projects originating primarily at the MSI (defined as greater than 50% of budget at the MSI) may be in any area of cancer research, but research projects originating primarily at UAB (defined as greater than 50% of budget) must address cancer disparities among racial/ethnic minorities and/or underserved populations.

We are particularly interested in hypothesis-driven projects addressing cancer disparities across the spectrum of cancer research, from basic/preclinical to population-based/implementation science. The Partnership expects that successful pilot research projects may become full research projects within the Partnership during the next competitive renewal of the program (However, a separate RFA will be released for full and pilot projects to be included in the renewal application) or lead to independent funding through NIH or other national organizations (e.g., American Cancer Society, Department of Defense).

Pilot projects are not to exceed a total of $120,000 in direct costs per project per year for a period of **two years,** without an opportunity for extension. No indirect costs are allowed.

Eligibility

All faculty members with expertise in the areas of cancer prevention and control, cancer epidemiology, social and behavioral sciences, basic science, or clinical and translational science., including those investigators already in the Partnership (with/without currently funded projects), are encouraged to apply, irrespective of faculty rank or current NIH, ACS, or other funding. **Current Partnership project funded investigators may submit applications with new specific aims that are not merely an extension of currently funded projects.**

Detailed Career Development and Mentorship Plans are required if the PI or Co-Project Leader is an Early-Stage Investigator (ESI) based on the NIH definition. "An ESI is a Program Director/Principal Investigator who has completed their terminal research degree or end of post-graduate clinical training; whichever is later, within the past 10 years and who has not previously competed successfully as a PD/PI for a substantial NIH independent research award." (**See Career Development and Mentorship Plan section).**

Investigators with questions or those needing help identifying potential Co-Project Leaders from partnering institutions are encouraged to contact the PIs or Program Managers listed at the end.

APPLICATION FORMAT:

The format and specification for Projects should follow NIH application instructions and as follows: PHS 398 forms https://grants.nih.gov/grants/funding/phs398/phs398.html *updated 03/2020).*

Format Specifications

Font and format specifications must be followed. Otherwise, application processing may be delayed, or the application may not be reviewed.

Font
- Use an *Arial, typeface, a black font color, and a font size of 11 points or larger*. A symbol font may be used to insert Greek letters or special characters; however, the font size requirement still applies.
- The type may be no more than six lines per inch.
- Use black ink that can be copied.
- Print must be clear and legible.

Paper Size and Page Margins
- Use standard paper size *(8 ½″ x 11″)*.

- Use at least one-half (0.5") inch margins (top, bottom, left, and right) for all documents, including continuation pages (narrow setting in Word layout). No information should appear in the margins, including the PD/PI's name or page numbers.

Page Formatting
- Because most reviewers will be evaluating applications as electronic documents and not paper versions, applicants are 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
- You may use a smaller type size (not below 9 pt.), but it must be in black color font, readily legible, and follow the font typeface requirement. Color can be used in figures; however, all text must be in black color font, 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.

Application/Forms:

Title Page including:

- **The title of the project**
- **Names of Co-Project Leaders* from the MSI (MSM or TU) and the UAB-O' Neal CCC**
- **One paragraph abstract (max 30 lines) stating the objectives of the project**
  - ∗ **NOTE:** Identify areas to be addressed in the career development plan for the less experienced Project Co-Project Leaders (respective Career Development Plans are to be included in Section C, see below)

Face Page (hyperlinked)
For each Co-Leader (NIH Section 4.1) to be signed by the division or department chair. No need to walkthrough the institutional OSP.

Form Page 2 (hyperlinked)
(NIH 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: (hyperlinked)
(NIH Section 4.3) Research Grant Table of Contents

Budget (hyperlinked)
(NIH Section 4.4 *first year*) Details of the initial budget period

Budget (hyperlinked)
(NIH Section 4.5) For the entire two-year project period

** Please Note: The following types of expenditures are allowable:

1. Research supplies and animal maintenance
2. Technical assistance
3. Domestic travel when necessary to carry out the proposed research
4. Publication costs, including reprints
5. Cost of computer time
6. Special fees (pathology, photography, etc.)
7. Stipends for graduate students and postdoctoral assistants if their role is to promote and sustain the project presented by the junior faculty member
8. Equipment costing less than $2,000
9. Registration fees for scientific meetings

** The following types of expenditures are <u>NOT</u> allowed:
1. Investigator salary
2. Secretarial/administrative personnel
3. Tuition
4. Foreign travel
5. Honoraria and travel expenses for visiting lecturers
6. Per diem charges for hospital beds
7. Non-medical services to patients
8. Construction or building maintenance
9. Major alterations
10. Purchasing and binding of periodicals and books
11. Office and laboratory furniture
12. Office equipment and supplies
13. Rental of office or laboratory space
14. Recruiting and relocation expenses
15. Dues and membership fees in scientific societies

Biographical Sketch (OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 01/31/2026)

Resources
(NIH Section 4.7)

Specific Aims
One-page limit

Research Strategy
(NIH Section 5.5.3) up to **six (6)** pages for pilot project applications to include the following items:

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

Describe how this 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 the 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 which aspects of the pilot project will be conducted primarily at the MSI and which will be at the O'Neal 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 (Sections 5.5 Items # 4-15) must also be completed (but are excluded from page limitations). In particular, the sections of the Research Plan about human subjects and vertebrate animals must be strictly followed. Respective information must also be included (in cumulative fashion) in Sections 4-15 for the entire application.

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. 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 the case of protocols after funding of a U54, to the NCI Program Director.

PHS 398 Instructions for the Research Plan, sections about 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.   [The 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 the case of protocols to the NCI Program Director subsequent to funding of the U54 proposal.

REVIEW PROCESS

Applications will be evaluated by expert external (to all three partnering institutions) reviewers that will be assigned by the Partnership Scientific Review Committee (SRC).

<u>Evaluation Criteria</u>
The 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 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 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-Project Leaders</u>: Is the PI or are the Co-Project 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-Project 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, applications must have relevance to the objectives of the Partnership in addressing cancer disparities, especially applications submitted by the UAB investigators (contact PI/Co-Project Leader). If an applicant is an Early-Stage Investigator, then the project must have a significant 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.

<u>Formal Review and Priority Scoring</u>

Within three weeks of the application deadline, the SRC will meet for formal assessment of all applications received. Applications will be assigned to external reviewers for scoring using the NIH criteria for project significance, innovation, investigator(s), approach, and environment. Additionally, each project will be evaluated for relevance to the objectives of the Partnership. The SRC will provide a detailed, written critiques to the Co-Project Leaders (the contact PI and the other partnering co-Project Leader) to optimize funded projects and to strengthen subsequent submissions of unfunded projects. **Selected applicants must respond to reviewer comments as requested following receipt of proposal reviews and scores.**

All projects that are recommended for funding by the SRC will be submitted to the Program Steering Committee (PSC), an external advisory board, for final approval. This final approval process includes an evaluation of the critiques from the reviewers; assessment of the priority scores; and if requested by the PSC, a full review of the proposed project.

Please submit the application (or questions) via email attachment as a single PDF document to the Partnership Program Managers: Jennifer Creighton (jcreighton@msm.edu), Morehouse School of Medicine; Chiquita Lee (clee@tuskegee.edu), Tuskegee University ; or Suzanne Byan-Parker, PhD (sbyanparker@uabmc.edu), The University of Alabama at Birmingham.

U54 PARTNERSHIP PRINCIPAL INVESTIGATORS:

<u>MOREHOUSE SCHOOL OF MEDICINE</u>

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: jlillard@msm.edu
Tel:404.752.1863

<u>TUSKEGEE UNIVERSITY</u>

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

<u>O'NEAL COMPREHENSIVE CANCER CENTER at UAB</u>

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

U54 ADMINISTRATIVE / GENERAL INQUIRY CONTACT

Jennifer Creighton
Program Manager
Morehouse School of Medicine
Email: jcreighton@msm.edu
Tel:404.752.1177

Chiquita Lee, MBA, MPA
Program Manager
Tuskegee University
Email: clee@tuskegee.edu
Tel:334.421.7525

Suzanne Byan-Parker
Program Manager
University of Alabama at Birmingham
Email: sbyanparker@uabmc.edu
Tel: 205-934-6071