# M E M O R A N D U M

**DATE:** February 25, 2014

**TO:** Faculty atthe Morehouse School of Medicine/Tuskegee University/ University of Alabama at Birmingham

**FROM:** James Lillard, PhD; Timothy Turner, PhD; Roberta Troy, PhD; Upender Manne, PhD; Edward E. Partridge, MD; and Mona Fouad, MD, MPH

PI’s of the Morehouse School of Medicine/Tuskegee University/UAB Comprehensive Cancer Center Partnership

**RE:**  Pilot-Level Project Funding Application

**KEY DATES**:

Letter of Intent (LOI) to include Project Title and list of Co-Leaders (investigators) is due **March 28, 2014**.

Final Application due date: **June 13, 2014**.

As part of the collaboration among the Morehouse School of Medicine/Tuskegee University/ University of Alabama at Birmingham Comprehensive Cancer Center (MSM-TU-UAB CCC) Partnership, funding will be provided to support developmental research pilot projects for YR 09 and YR 10 of this funding cycle. This funding opportunity is to ensure a flow of pilot studies, with the potential of being developed into larger studies that have the capability to guide research and transform clinical practice.

The Morehouse School of Medicine/Tuskegee University/UAB Comprehensive Cancer Center Partnership will be submitting a competitive renewal application for the U54 level Partnership in 2016. In preparation for our submission, we are soliciting scientifically sound pilot-level projects that have the potential to become independently funded projects at completion of this funding cycle and thus strengthen renewal efforts.

These pilot-level projects must demonstrate relevance to cancer and can be in the areas of prevention and control, clinical pilot projects, cancer disparities, basic science, outreach, and/or cancer education and training. We are particularly interested in projects that will enhance our understanding of the molecular biology and pathogenesis of cancer or pre-clinical studies, while providing opportunities for translation into the clinical setting.

We anticipate funding 3-4 pilot projects; however, the number of projects selected for funding will be determined by the number of meritorious applications submitted, as well as the availability of funds. The funds directed to these research projects are to be divided appropriately between the institutions. Research projects conducted primarily at the Minority Serving Institution (MSI) (defined as greater than 50% of budget at MSI) may be in any area of cancer research, but research projects conducted primarily at the UAB Comprehensive Cancer Center (defined as greater than 50% of budget at the CCC) must specifically address areas of cancer disparity in minority and underserved populations. The Partnership expectation is that successful pilot research projects *may* become full research projects within the Partnership during the next funding cycle or independently funded R03 or R21 projects. However, all projects selected for inclusion in the next competitive renewal application will undergo a separate round of the peer review process.

**Eligibility**

All investigators at the Research/Clinical level and beyond with expertise in the areas of basic, clinical or cancer control/population science and outcomes*, 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. All submissions must be ***joint projects*** between the UAB Cancer Center and one of the minority serving institutions (MSI). **This means all projects from Morehouse School of Medicine and/or Tuskegee University will require co-leaders/mentors form UAB CCC.** **Currently funded Partnership investigators may submit proposals with new specific aims in related research areas; however, extension of current aims (e.g. analyzing more cell lines or large(r) series of samples) will not be permitted.**

For the purpose of this RFA, a junior investigator is any scientist or faculty member with no prior independent research funding from NIH or equivalent agencies (i.e., no R01, P01, etc., awards, but small awards [e.g., R03, R21] and training [K awards] do not count). (**See Career Development and Mentorship Plan section).**

Applicants may respond to announcements or may be sought out by the co-leaders or other members of the Partnership Internal Advisory Committee (IAC). The amount of the award is $120,000/year (indirect costs will not be permitted) and the project should be completed within two years.

**The application process is as follows:**

The project must demonstrate relevance to any cancer field and can be in the areas of prevention and control, disparities, pre-clinical/clinical pilot projects, epidemiology, social and behavioral sciences, or basic science. **The project will require co-investigators from UAB CCC and Morehouse School of Medicine and/or Tuskegee University (see the Eligibility section).** If the main applicant (contact PI/Co-Leader) is from UAB CCC, the research topic should focus on cancer health disparities; however, for applications originating from either MSM or TU, the research topic can be on any aspect of cancer. A joint cancer research project might focus, for example, on general areas of environmental carcinogenesis, molecular epidemiology, or behavioral issues related to cancer prevention, treatment, and control. Minority junior faculty members are encouraged to respond to this funding opportunity.

The pilot-level cancer research project (not to exceed $120,000 in direct costs per year per project/program for no more than 2 years) is to be divided appropriately between the two participating institutions as described above.

Investigators with questions are encouraged to contact Dr. James Lillard [(404) 752-1863] at Morehouse School of Medicine; or Dr. Timothy Turner [(334) 727-8787] at Tuskegee University; or Dr. Upender Manne [(205) 934-4276], at UAB for assistance. All investigators are encouraged to apply irrespective of faculty rank or current NIH, ACS, **current Partnership,** or other funding.

**The proposal format for Pilot-level Projects should follow** [**NIH application instructions**](http://grants.nih.gov/grants/funding/phs398/phs398.docx) **and format specifications as is as follows:**

**Please use** [**PHS 398 forms**](http://grants.nih.gov/grants/funding/phs398/phs398.html) **(Revised 8/20/2012)**

## Format Specifications

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

####  Font

* Use an Arial, Helvetica, Palatino Linotype, or Georgia 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; 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.
* Print must be clear and legible.

####  Paper Size and Page Margins

* Use 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, including the PD/PI's name and page numbers.

####  Page Formatting

* Because a number of 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

* You may use a smaller type size (not less than 9) but it must be in a black font color, readily legible, and follow the font typeface requirement. Color can be used in figures; however, all text must be in a 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. [Note: Please try to avoid excessive use of non-universal abbreviations; their usage often makes the reviewers’ job more difficult by requiring them to search the text for meaning].

####  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 critical to the content of the application.

**Application/Forms: (Similar to NIH-R21 grant with additional requirements based on the applicant status)**

 **Title Page** including:

* **The title of project**
* **Names of co-leaders\* from the MSI and the UAB-CCC**
* **One paragraph abstract stating the objectives of the project**
	+ **NOTE:** Identify areas to be addressed in the career development plan for the less experienced Project co-leaders (respective Career Development Plans are to be included in Section C, see below)

 [**Face Page**](http://grants.nih.gov/grants/funding/phs398/fp1.docx) **for each Co-Leader** [(NIH Section 4.1)to be signed by division or department chair)]

[**Form Page 2**](http://grants.nih.gov/grants/funding/phs398/fp2.docx) **(NIH Sections 4.2.1––4.2.5):** ProjectSummary and Relevance, Project/Performance Sites/Key personnel, Other Significant Contributors, Human Embryonic Stem Cells

 [**Table of Contents**](http://grants.nih.gov/grants/funding/phs398/fp3.docx):Research Grant Table of Contents (NIH Section 4.3)

 **Detailed** [**Budget**](http://grants.nih.gov/grants/funding/phs398/fp4.docx) **of initial budget period \*\* (**NIH Section 4.4 *first year*)

 [**Budget**](http://grants.nih.gov/grants/funding/phs398/fp5.docx) **for the entire Two-year project period \*\*** (NIH Section 4.5)

 **\*\* 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
10. Investigator salary

 **\*\*** The following types of expenditures are **NOT** allowed:

1. Secretarial/administrative personnel
2. Tuition
3. Foreign travel
4. Honoraria and travel expenses for visiting lecturers
5. Per diem charges for hospital beds
6. Non-medical services to patients
7. Construction or building maintenance
8. Major alterations
9. Purchasing and binding of periodicals and books
10. Office and laboratory furniture
11. Office equipment and supplies
12. Rental of office or laboratory space
13. Recruiting and relocation expenses
14. Dues and membership fees in scientific societies

 [**Biographical Sketch**](http://grants.nih.gov/grants/funding/phs398/biosketchsample.docx)(Four page-NIH Section 4.6)

[**Resources**](http://grants.nih.gov/grants/funding/phs398/resources.docx) (NIH Section 4.7)

 **Specific Aims (One page limit)**

[**Research Strategy**](http://grants.nih.gov/grants/funding/phs398/checklist.docx) [(NIH Section 5.5.3) up to **Six** pages] to include the following items:

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

 Describe how this 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 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 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 UAB Comprehensive 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, Research Plan sections pertaining to human subjects and vertebrate animals must be strictly followed. See 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 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 funding of the U54 proposal.

Review Process

The Partnership Scientific Review Committee (SRC) will assign each application to a primary and secondary reviewer external to the Partnership institutions. The reviewers will include members of the SRC and other *ad hoc* reviewers, based upon expertise in relevant areas.

Evaluation Criteria

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 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. Significance: 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. Approach: 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?
3. Innovation: 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. Co-Leaders: 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)?
5. Environment: 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 the UAB CCC investigators (contact PI/co-leader) and if an applicant is a junior faculty member, it 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.

### Formal Review and Priority Scoring

Within three weeks, the Partnership Scientific Review Committee (SRC) will meet for formal review and priority scoring of all applications received. By NIH criteria, each project will be scored for scientific merit and relevance to the objectives of the Partnership. The SRC will provide a detailed, written critique to the Co-Leaders (the contact PI and the other partnering investigator) in order to optimize funded projects and to strengthen subsequent submissions of unfunded projects. The options are to recommend funding or not recommend funding because of (1) low merit, (2) low relevance to the objectives of the Partnership, or (3) low potential to develop into a full research project or to achieve independent funding.

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

**Conclusion**

Partnership leaders and appropriate Partnership committees will make the final selection of grant recipients by **July 25, 2014**. We anticipate funding 3-4 awards with funding effective **September 1, 2014**. Please note: Award funds for projects with human subjects-based research will not be released until receipt of IRB approval. In addition, award funds for projects using animal models will not be released until receipt of appropriate approval documentation.

Please submit the application via email attachment as a single WORD or PDF document to all of the Partnership Program Managers: [UAB-Suzanne Byan-Parker (szparker@uab.edu), TU-Chiquita Lee (leec@mytu.tuskegee.edu), or MSM-Rene Jackson (rjackson@msm.edu)]. **No applications will be accepted after the deadline**.

If you have any questions concerning the submission of the proposal, please contact any of the Partnership Program Managers.

**Partnership Leadership**

**Upender Manne, MS., PhD**

Professor

Department of Pathology

University of Alabama at Birmingham

**Edward E. Partridge, MD, Director**

UAB Comprehensive Cancer Center

Professor, Gynecologic Oncology

University of Alabama at Birmingham

**Mona Fouad, MD, MPH**

Professor and Director, Division of Preventive Medicine

Director, UAB Minority Health & Research Center

University of Alabama at Birmingham

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

Associate Dean, Research Affairs

Director, MSM Cancer Research Program

Professor, Department of Microbiology, Biochemistry, and Immunology

Morehouse School of Medicine, Morehouse University

**Timothy Turner, PhD**

Professor, Department of Biology

Tuskegee University

**Roberta M. Troy, PhD**Associate Professor, Department of Biology

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