



Morehouse School of Medicine

REQUEST FOR APPLICATIONS (RFA) Diversity in Cancer Research Institutional Development Grant (DCRIDG) Pilot Research Grant Program

Due Date: March 1, 2022

Morehouse School of Medicine (MSM) and three historically black medical schools, including Charles Drew Medical School, Howard University, and Meharry Medical College, were awarded the American Cancer Society Inaugural Diversity in Cancer Research Institutional Development Grant (DICRIDG). This program award aims to improve diversity, equity, and inclusion in the cancer research field. It is expected this program award will create a more inclusive research environment, foster novel, and innovative cancer research, and increase the competitiveness and representation of R-funded investigators at MSM.

We are particularly interested in hypothesis-driven projects that address the entire spectrum of cancer research, from basic/preclinical to population-based science. Current research areas within the Cancer Health Equity Institute include cancer health disparities, cancer health equity, clinical trial participation, cancer biology, therapeutic target identification, molecular characterization, and implementation science. However, projects may be in the areas of basic, clinical, translational, prevention and control, behavioral, and/or population research. When appropriate, projects should include translational research, emerging fields, and technologies (such as nanotechnology, proteomics, genomics, imaging, artificial intelligence, and machine learning), precision medicine, and/or therapeutic clinical trials accrual of underserved areas populations. Research may be focused on pediatric cancer or those adolescent or young adults and rural populations. Preliminary data are not required for pilot research projects. However, they are expected to be developed based on a strong rationale.

Key Dates:

Letter of Intent January 31, 2022

FINAL APPLICATION DUE*

March 1, 2022

Notification of Award to Grant Recipients

April 1, 2022

Award Effective Date**

April 1, 2022

^{*}No application will be accepted after the deadline of March 1st at 5 pm EST

^{**}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.

Eligibility

The ACS DICRIDG is intended to fund full-time faculty within the first 6 years of their faculty appointment at MSM who have not obtained R-level funding. Awardees will participate in structured mentorship activities and lead a cancer research study. Awardees will be mentored by research faculty with complementary expertise in the Principal Investigators (PI) area of research.

The proposal format below should follow <u>NIH application instructions</u>, <u>ACS All Grant Instructions</u>, and format specifications as follows:

PHS 398 forms https://grants.nih.gov/grants/funding/phs398/phs398.pdf 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. No information should appear in the margins, including the PD/PI's name and 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:

Face Page (hyperlinked)

(NIH Section 4.1) to be signed by the pilot project PI (#13).

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 (applicable sections)

Budget (hyperlinked)

(NIH Section 4.4) Details of the budget period

Pilot projects are not to exceed \$30,000 in direct costs.

Budget Justification (hyperlinked)

(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 (special justification is necessary for items exceeding this amount).
- 9. Registration fees for scientific meetings
 - ** The following types of expenditures are **NOT** 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 09/30/2024)

Checklist

(NIH Section 5.6)

Research Strategy

Please use the format specifications above.

The research strategy includes up to **six (6)** pages for pilot project applications to include the following items:

Section A below (Specific Aims) should not exceed 1 page. Sections B- F below must not exceed 5 pages, and these page limits do not apply to Sections (G) through (J).

- **A. Specific Aims** (not to exceed 1 page). List the hypothesis, objectives, and goals of your proposed research and briefly describe the scientific aims.
- **B. Background and Significance.** Concisely summarize and critically evaluate the literature. Provide a model (i.e., animal model or conceptual model) or theoretical framework guiding your research. Specifically, state how the successful completion of the work proposed will advance scientific knowledge and/or aspects of clinical practice that are important for better understanding cancer or management of cancer patients or reducing burdens from cancer.
- **C.** Cancer Relevance: How is this research relevant, or how will it impact persons at risk for, or living with, cancer and their family members and/or caregivers? The relevance to cancer may be indirect, but the connection must be clearly articulated by the applicant.
- **D. Innovation:** What is the potential that the proposed study will challenge and seek to shift current research understanding or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Does the research propose meaningful improvements or address critical gaps?
- **E. Preliminary Studies.** Provide results of your prior research that are relevant to this proposal. Preliminary data aren't expected or required. Reprints or preprints may be included in the Appendix. Note that the entire application is considered confidential.
- **F.** Research Design. Describe your overall hypothesis, proposed methods, procedures, and data analysis in enough detail to permit evaluation by other scientists; include your rationale for approaches and analysis. Explain your project's feasibility and how the experiments proposed will address the Specific Aims. Discuss potential difficulties and limitations of your proposed methods and provide alternative approaches. The inclusion of an experimental timeline can be helpful.
- **G. Experimental Details** (optional not to exceed 3 pages). This section is available if more in-depth description of the experimental design, technologies, or assays are needed to convey the specific approaches and procedures proposed. This section is also appropriate for articulating specifics regarding how you plan to use findings from this research to inform a larger study.

H. Environment for Research and Training

Briefly describe the existence of an appropriate academic and research environment for the proposed research study and/or training program, including:

- departmental and other institutional personnel;
- ongoing research and other relevant activities;

- · facilities and resources;
- access to any populations or individuals to be studied;
- · relevant collaborative relationships; and
- any relevant accreditation from professional societies or organizations.

Describe how the presence of these resources will directly benefit you and your research.

- I. Statement of Science Outreach and Advocacy (not to exceed 1 page). ACS considers it important that scientists communicate the results of their research to a wide range of communities. Explain the potential impact of your proposed project on your community and to the ACS's mission to save lives, celebrate lives, and lead the fight for a world without cancer. Share any previous experiences in science outreach and advocacy. Describe your plans for disseminating your work in the cancer arena through advocacy, awareness, education, or service. Please include your plans for sharing your research and research findings with your (non-academic) community members and for engaging with community partners in the dissemination process.
- **J. References.** Each literature citation should include title, authors, book or journal, volume number, page numbers, and year of publication. There is no page limitation; this section is not included in the research plan page limit of Sections (B) through (F).

Other Sections of PHS 398 Research Plan (Sections 5.5 Items # 5-15) must also be completed, if applicable (but are excluded from page limitations).

Career Development Plan

Please use the format specifications above.

Describe the candidate and their career development goals. How will the candidate participate in the career development activities being supported by the Career Development Enhancement Fund?

Mentoring and Training Plan

Please use the format specifications above.

The following sections must be prepared by the proposed *primary mentor(s)*.

Faculty or Scientific Appointment (of Candidate)

A letter from the Department Chair (or equivalent) must be included in the application. This letter should clearly indicate the commitment of the institution to the support of the applicant and their research program. Details should include but are not limited to, faculty rank, salary support, available space for the research proposal, the amount of protected time for clinical researchers, administrative support, core facilities, institutional faculty development, research training, resources to support coursework or travel or other resources to foster the successful career development of the applicant. The letter should also describe the Department's long-term goals for the applicant's career.

• Program Goals and Proposed Training

Describe the overall goals of the proposed program and indicate how the grant, if awarded, will advance the candidate's career as an independent researcher. Provide a description of the specific plans for research training, including core curriculum studies, courses, and lectures. For each mentor, describe their role, area of expertise, and the frequency and mode of contact with the Candidate should be provided. Explain in detail the activities

planned for the period of the award, including clinical, research, teaching, coursework, administrative duties, etc., and skills the candidate will gain from the mentoring experience. Estimate the percentage of time allocated to each area. The primary mentor is expected to compose the mentoring and training plan. If an additional mentor is involved in the candidate's training, describe this person's participation as well. Include a table indicating the timeline of implementation and completion of the Training Plan.

Training Experience of Mentor(s)

Document your background and experience in training clinical and applied cancer researchers. Describe *in detail* (table format preferred) your mentoring experience (e.g., list the researchers you have trained, the extent of their training, and their current involvement in clinical or applied cancer research). Fully describe your current professional responsibilities and activities.

Biographical Sketch of Mentor(s)

Provide biographical information requested for *all mentors*. Complete the NIH Biosketch template. Follow the format and instructions provided by the NIH. Use a separate "Biographical Sketch" template for each mentor. *Note:* The Biographical Sketch may not exceed 5 pages.

Mentor(s) Commitment Letter(s)

A letter of commitment must be provided from each mentor. The letter should include an assessment of the Candidate's research ability and potential, motivation, ability to plan and conduct research, knowledge of the field of study, and ability to work as a member of a research team. Letters may also include other attributes of the Candidate, such as character or motivation. The letters will need to be provided as an appendix to your application.

Provide a description of the specific plans for research training, including core curriculum studies, courses, and lectures. For each mentor, describe their role, area of expertise, and the frequency and mode of contact with the Candidate should be provided. Explain in detail the activities planned for the period of the award, including clinical, research, teaching, coursework, administrative duties, etc., and skills the candidate will gain from the mentoring experience. Estimate the percentage of time allocated to each area. The primary mentor is expected to compose the mentoring and training plan. If an additional mentor is involved in the candidate's training, describe this person's participation as well. Include a table indicating the timeline of implementation and completion of the Training Plan.

COMPLIANCE

Human Subjects

Selection of study population. When conducting research on humans, provide the rationale for the selection of your target population, including the involvement of children, minorities, special vulnerable populations, such as neonates, pregnant women, prisoners, institutionalized individuals, or others who may be considered vulnerable populations*. This should include research subject gender and the rationale for why certain populations may be excluded based on your research question and specific aims.

Complete the <u>planned enrollment form</u> (hyperlinked) based on your proposed study sample size to estimate the total number of subjects by primary ethnicity and race, race/ethnicity subgroup (if applicable), and gender. Also include estimates of the sample distribution by gender, race, and ethnicity (if available). For example, if your sample size is 200, to complete the total number for the subjects' column by race (based on what you know about the population demographics or the existing dataset you plan to analyze) multiply by the estimated percentage.

Estimated percentage of the	Estimated total number of
population by race	subjects
50% White	100 (200 x 0.50)
49% AA	98 (200 x 0.49)
1% Asian	2 (200 x 0.01)

For applicants performing non-human subjects research, please check the box that most appropriately describes your research.

Potential benefits and risks and knowledge gained. Succinctly describe the potential benefits and risks to subjects (physical, psychological, financial, legal, or other). Additionally, provide justification for why potential risks to subjects are reasonable in relation to the anticipated benefits to research participants and others. Where appropriate, describe alternative treatments and procedures, including the risks and potential benefits of the alternative treatments and procedures, to participants in the proposed research.

Research Specimens and Data. If the proposed research involves biospecimens, provide a description of how the research material will be obtained from living subjects and what materials will be collected. Additionally, describe the specific non-biological data from human subjects and how it will be collected, managed, and protected (e.g., demographic data elements), including who will have access to research data and what measures will be implemented to keep personally identifiable private information confidential.

Collaborating sites

List any collaborating sites where research on human subjects will be performed and describe the role of those sites and collaborating investigators in performing the proposed research. Explain how data from the site(s) will be obtained, managed, and protected.

Note: See the Department of Health and Human Services Office of Research Protection Subparts B-D for additional protections for vulnerable populations. http://www.hhs.gov/ohrp/policy/populations/index.html

Vertebrate Animals

Provide the rationale for the inclusion of live vertebrate animals according to the 1) necessity for the use of the animals and species proposed; 2) appropriateness of the strains, ages, and gender of the animals to be used for the experimental plan proposed; and 3) justifications for, and appropriateness of, the numbers used for the experimental plan proposed. When completing the Targeted Enrollment Table, select non-human subjects' research and check the box that most appropriately describes your research.

Biohazards

Briefly describe whether materials or procedures proposed are potentially hazardous to research personnel, equipment, and/or the environment, and describe what protections will be used to mitigate any risk. The assessment related to biohazards should include potential biological or chemical hazards.

<u>Authentication of Key Biological and/or Chemical Resources</u>

Briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies.

Key biological and/or chemical resources may or may not be generated with ACS funds and:

- 1. may differ from laboratory to laboratory or over time;
- 2. may have qualities and/or qualifications that could influence the research data; and
- 3. Are integral to the proposed research.

These include, but are not limited to, cell lines, specialty chemicals, antibodies, and other biologics. Researchers should transparently report on what they have done to authenticate key resources so that consensus can emerge. Standard laboratory reagents that are not expected to vary do not need to be included in the plan. Examples are buffers and other common biologicals or chemicals. Information in this section must focus only on authentication and/or validation of key resources to be used in the study; all other methods and preliminary data must be included within the page limits of the research strategy. Applications identified as non-compliant with this limitation may be withdrawn from the review process.

NOTE: 1) All biomedical or behavioral research projects involving human subjects must address the respective requirements under the Research Plan, Human Subjects, following the above instructions and <u>ACS All Grant Instructions</u>. 2) Research dealing with Human Subjects and Vertebrate Animals must be accompanied by appropriate documentation. 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 DCRIDG, 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 DCRIDG, to the MSM PI.

Appendices

In addition to the application templates, other key documents may be uploaded and submitted as part of the application. However, applicants are urged to keep this section as brief as possible.

Appended materials may include:

- Biosketches
- Letters of support or commitments
- Recent reprints or preprints (optional)
- Logic Model

Review Process

PART I

A junior investigator's research is not expected to reflect the breadth and depth of a senior scientist. Nevertheless, the research plan must be fundamentally sound. In critiquing the research study, please be as specific and as detailed as possible about the following elements:

- **a. Significance:** Does the project address an important problem or a critical barrier to progress in the field? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or interventions that drive this field?
- **b. Cancer Relevance:** How is this research relevant to persons at risk for, or living with, cancer and their family members and/or caregivers and friends?
- **c. Innovation/Improvement:** What is the potential that the proposed study will challenge and seek to shift current research understanding or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Does the research propose meaningful improvements or address critical gaps?
- d. Candidate/Research Team: Does the PI and research team (including mentor(s)) have the training and experience needed to carry out the proposed research? Do team members have complementary skills and qualifications needed for successful implementation and analysis of the proposed research? Has the research team previously collaborated on research or publications? If not, are members of the proposed study team appropriate to carry-out the research?
- **e. Approach:** Are the hypothesis and aims appropriate for answering the research question? Are the overall strategy, methodology, analyses, and timeline well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility, and will particularly risky aspects be managed?
- **f. Environment:** Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment, and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

PART II COMPLIANCE STATEMENTS

- **a. Human Subjects.** If the project involves research on humans, are the plans for the protection of human subjects from research risks justified in terms of the scientific goals and research strategy proposed? For example, are the potential benefits and risks to subjects articulated reasonable and appropriate given the study design, are there plans to conduct sub-analysis by group, are there plans for data security and confidentiality, biohazards, and data and safety monitoring (if applicable) adequate?
- b. Inclusion of Women, Minorities, and Children. When the proposed project involves human subjects, evaluate the adequacy of the proposed plans for inclusion or exclusion of minorities, male and female genders, as well as children.
- c. Vertebrate Animals. The peer review committee will evaluate the involvement of live, vertebrate animals as part of the scientific assessment according to the following points: 1) necessity for the use of the animals and species proposed; 2) appropriateness of the strains, ages, and gender of the animals to be used for the experimental plan proposed; 3) justifications for, and appropriateness of, the numbers used for the experimental plan proposed.
- **d. Biohazards.** Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

PART III OVERALL RECOMMENDATIONS

Briefly summarize your critique and state your level of enthusiasm using one of these descriptive terms: outstanding, excellent, good, fair, or not competitive. See ACS SCORING GUIDELINES for the relationship between numeric scores and the descriptive terms used in this section. For outstanding proposals, concisely describing why there is excitement is as important as listing minor deficits. Briefly include recommendations for improvement to aid in resubmitting an application.

Applications will be evaluated by expert external reviewers that will be assigned by the Scientific Review Committee (SRC).

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 goals of the ACS DCRIDG in addressing cancer health disparities. If an applicant is a junior 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 ACS Reviewing and Scoring Guidelines.

Formal Review and Priority Scoring

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 ACS DCRIDG. The SRC will provide a detailed, written critique to the PIs to optimize funded projects and to strengthen subsequent submissions of unfunded projects. **Selected applicants must respond to reviewer comments as requested after receiving proposal reviews and scores.**

ACS SCORING GUIDELINES

Please use the *entire* range of scores (1.0 - 5.0). A suggested table of terms is provided. Match your score as closely as possible to your written recommendations.

Outstanding (1.0 - 1.4): The proposal is deemed outstanding considering all criteria for that grant mechanism. This rating indicates that the application is worthy of funding (budget permitting). If weaknesses exist, they are few and very minor; the strengths far outweigh these minor concerns. Applications receiving at least one Outstanding rating during the preliminary review will be discussed at the meeting.

Excellent (1.5 - 1.9): The proposal merits strong support but has minor flaws that can be corrected relatively easily upon resubmission.

Good (2.0 - 2.4): The proposal is somewhat lacking in approach, excitement and/or significance or may have multiple flaws. It represents a worthwhile research project but is not competitive for funding in the present form.

Fair (2.5 - 2.9): The proposal has serious flaws. The concept and approach should be fully reconsidered.

Not Competitive (3.0 - 5.0): The proposal has serious deficiencies and should not be supported as submitted.

Abstain: For various reasons (e.g., Conflict of Interest) a score is not given.

Administrative Disapproval: The proposal cannot be funded because of an administrative problem, such as ineligibility for the award mechanism.

Scientific Disapproval: This includes applications that raise serious concern, including unethical or unacceptable research (used very sparingly).

Please submit the application via email attachment as a single PDF document to Josylen Huston (<u>jhuston@msm.edu</u>) and Jennifer Creighton (<u>jcreighton@msm.edu</u>),

Email questions to cancerhealthequity@msm.edu

SCIENTIFIC CONTACTS:

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ADMINISTRATIVE / GENERAL INQUIRY CONTACT:

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