

This competition is closed. Document provided for reference only (as of 9/25/2009).

**DORIS DUKE CHARITABLE FOUNDATION
INNOVATION IN CLINICAL RESEARCH 2009
Catalyzing Breakthroughs in Sickle Cell Disease
REQUEST FOR APPLICATIONS**

Key Dates

Letters of Intent due:	June 24, 2009 (New Deadline)
Proposals due:	July 8, 2009
Notice of Award:	September 25, 2009
Award Start Date:	November 1, 2009

About the Doris Duke Charitable Foundation

The Doris Duke Charitable Foundation (DDCF) is a nonprofit philanthropic organization that was created in 1996 in accordance with the will of Doris Duke, a life-long philanthropist. The Foundation's mission is to improve the quality of people's lives through grants supporting the performing arts, environmental conservation, medical research and the prevention of child maltreatment, and through preservation of the cultural and environmental legacy of Doris Duke's properties. In addition, in 2007 the foundation launched two special initiatives in Climate Change and African Health. The Innovation in Clinical Research Award (ICRA) Program described in this RFA is part of the Foundation's Medical Research Program.

Purpose and Research Objectives

The DDCF Innovation in Clinical Research Award Program provides seed funding for early-stage, multi-disciplinary research projects in clinical investigation. Approximately 10% of the DDCF Medical Research Program grant funds have supported innovative, high risk research as part of the core grant-making strategy to push the 'frontiers' of clinical research in targeted disease areas.

The 2009 Innovation in Clinical Research Award competition invites proposals for cutting edge, unconventional clinical research that has the potential to catalyze innovative breakthroughs in Sickle Cell Disease (SCD). It is the hope that these awards will attract new investigators into clinical SCD research.

SCD is an inherited blood disorder with severe clinical morbidities that affects over 70,000 Americans of predominantly African descent. With 1 out of 400 African-Americans affected, SCD has a substantial public health impact complicated by racial and economic disparities in health care quality and access. In the mid 1980's, major treatment innovations such as hydroxyurea and antibiotic prophylaxis substantially improved the life expectancy of sickle cell disease patients. Now, almost thirty years later, exciting new discoveries and advances in areas such as stem cell research, genetics/genomics, and pharmacogenetics offer considerable promise for breakthroughs in development of new and improved therapies.

DDCF encourages investigators proposing the following types of sickle cell disease research to apply:

- Early translational phase testing of novel therapeutic approaches
- Development of new treatments or cures drawing from innovations in other fields such as cancer research, and
- Genetic and genomic approaches to study variability in the severity of SCD
- Innovative research projects that take advantage of existing tissue repositories and clinical trials already being supported by other sources such as grants from the National Institutes of Health/National Heart, Lung and Blood Institute

This competition is closed. Document provided for reference only (as of 9/25/2009).

Award Description

The 2009 Innovations in Clinical Research Awards will provide \$150,000 per year for three years to support direct research expenses including salary support, plus 8% (\$12,000) for indirect costs. It is anticipated that up to four awards will be made in 2009.

The Medical Research Program recognizes the importance of cross-disciplinary collaboration in advancing clinical research. Therefore, teams of two Co-Principal Investigators, particularly where one or both investigators have not previously worked in SCD research but who bring expertise, innovative approaches and/or novel findings that shed new light onto the clinical problems of SCD are strongly encouraged to apply. Co-PIs may be from the same or different institutions.

It is expected that the research projects submitted for this award may be less developed in terms of preliminary data and feasibility testing than those submitted for funding by research project grants such as an NIH R01. However, it is also expected that, if successful at the conclusion of this award, the projects will attract additional funding from federal and private sources.

NOTE: For applicants who apply for and are awarded an NIH Challenge Grant in Health and Science Research (**RFA-OD-09-00; NIH deadline: April 27, 2009**) for clinical research in sickle cell disease, the foundation will consider allowing the ICRA grant to provide support for years 3 and 4 of the project. A list of the NHLBI Challenge Topics for 2-year NIH funding made possible through the American Recovery and Reinvestment Act of 2009 can be found at www.nhlbi.nih.gov/recovery/challenge-grants.html. Indicate in the Letter of Intent (**DDCF deadline: 5 pm EDT on June 24, 2009**) whether the project has been submitted for an NIH Challenge Grant.

Eligibility

- Applicants must hold an advanced degree (MD, PhD, MD/PhD, or the equivalent) and a faculty level appointment (Instructor, Assistant Professor, Associate Professor, or Professor). Junior investigators must identify a mentor.
- Projects must fit within DDCF's definition of clinical research (see definition below).
- Applicants do not have to be U.S. citizens.
- Up to two **Co-Principal Investigators** are allowed. Co-PIs will be considered equivalent members of the scientific team and will share responsibility for the scientific and technical conduct and reporting of a project. However, one person must be designated as the administrative Principal Investigator on the online web submission and application transmittal forms. The administrative Principal Investigator must be from the institution accepting and administering the award (see below) and will be responsible for meeting the terms and conditions of the award.
- Women and under-represented minorities in medicine, including Blacks or African Americans, Hispanics or Latinos, American Indians, Alaskan Natives, and Native Hawaiians, are encouraged to apply.
- Institutions accepting and administering any DDCF award must be exempt from federal income taxation as an organization described in Section 501(c)(3) of the Internal Revenue Code of 1986, as amended (the "Code") and must not be a private foundation or a Type III supporting organization as defined in Section 509(a) of the Code.

Definition of Clinical Research

For the purposes of this award program, clinical research is defined as research conducted with human subjects and/or materials from identified human subjects with direct application to the prevention, diagnosis, or treatment of any human disease.

The Foundation's definition of clinical research includes:

- Studies on the etiology and pathogenesis of human disease
- Therapeutic interventions
- Clinical trials
- Epidemiological studies
- Disease control research
- Operations and implementation research

This competition is closed. Document provided for reference only (as of 9/25/2009).

It is expected that the proposed research will require Institutional Review Board (IRB) approval. Occasionally, the Foundation has funded research that does not require IRB approval, such as research using de-identified patient populations. If a research project that does not require IRB approval is being proposed, applicants are strongly encouraged to contact DDCF program staff to discuss whether the proposed research falls within the Foundation's definition of clinical research.

Note: DDCF does not support experiments that utilize animals or primary tissues derived from animals.

Review Process

Dr. Edward Benz (Dana-Farber Cancer Institute) and Dr. David Ginsburg (University of Michigan) will co-chair a review panel composed of experts with broad expertise drawn from fields relevant to SCD. Because this grant program aims to provide seed funds for early-stage projects, preliminary data are not required. However, a brief discussion of the feasibility and appropriateness of the methodology as well as the relevance of the project must be provided.

The relevance and level of innovation of the proposed research and the overall scientific track-record (i.e., not restricted to SCD research) of the investigator(s) will each be evaluated and scored by the reviewers. A budget for the proposal and description of institutional resources, including laboratory space, financial and other resources available to the Principal Investigator(s) will be included as part of an administrative review.

Selection Criteria

- Originality and inventiveness of the concept and approach
- Relevance of the question posed to the field sickle cell disease
- Potential for clinical application
- Evidence of the investigator(s)' potential to drive innovation in SCD clinical research

Application Process

1. Letters of Intent are due at 5 pm EDT on June 24, 2009 (see detailed instructions below). Letters of intent are non-binding and will be used by DDCF to assess the number of expected applications and the breadth of topics for planning purposes only.
2. Online applications are due on July 8, 2009 (see detailed instructions below).
3. Awards will be announced by September 25, 2009.
4. Start of the grant term is November 1, 2009.

Letters of Intent

A Letter of Intent (LOI) must be submitted electronically at <http://ddcf-icra-lois.aibs.org> by June 24, 2009. Submitting an LOI does not obligate a potential applicant to submitting a proposal. Nonetheless, proposals will not be accepted unless an LOI has been submitted. The LOI must be completed at the web site. LOIs submitted by other methods will not be accepted. The LOI will contain (1) the name and contact information of the Principal Investigator(s); (2) a tentative title of the project; (3) up to six keywords; (4) a one paragraph description of the question to be addressed, and, (5) *indication of whether the project has been submitted as a Challenge Grant to the NIH for funding as part of the American Recovery and Reinvestment Act of 2009.*

Online Submission of Applications

Applicants must submit a complete research proposal using the foundation's online system (<http://ddcf-icra.aibs.org>) on or before 5 pm EDT on July 8, 2009. Applications submitted by other methods will not be accepted. It is the responsibility of the applicant to ensure that s/he meets all of the eligibility requirements.

Institutional Review Board Approval

Institutional Review Board approval, if necessary, is not required at the time of proposal submission. However, if a grant is awarded, DDCF strongly prefers that Institutional Review Board approval be in place by the grant start date, November 1, 2009. Institutional Review Board approval must be in place no later than June 1, 2010. The grantee may not conduct activities supported by the ICRA that involve human subjects until a copy of the Institutional Review Board approval is

This competition is closed. Document provided for reference only (as of 9/25/2009).

received and reviewed by DDCF staff. We recommend that you coordinate with your Institutional Review Board to ensure timely approval.

Proposal Forms and Instructions

Applicants must use the templates provided for the proposal materials and follow all of the instructions listed on page 2 of the template. **Application templates will be emailed to all investigators who have submitted a Letter of Intent.** Applications that do not meet the page limits (including letters) and formatting instructions will not be accepted.

Proposals must contain the following items:

1. **Cover Page** (use template provided; must fill in online)
Provide all of the information requested including signatures and initials. (Please note: the original must be signed in blue ink and initials must be handwritten and *not* typed.)
2. **Section I: Project Description** (Maximum 4 pages; 12-point font)
All elements below must be included in 4 pages. ***Information that might identify the individual applicant and/or institution must be excluded from this section.***
 - A. Research Question and Impact
 - Describe the research question to be addressed
 - State why your proposal is important. How will the proposed research impact or improve sickle cell disease patient care; why is it innovative?
 - B. Research Plan and Methodology
 - Describe the approach that will be used to address the research question. Address the feasibility and appropriateness of the methodology.

Please note: References to scientific literature are not required, and, if included, must fall within the maximum 4-page limit for this section. Use clear language without jargon or abbreviations that may not be recognized by reviewers with broad expertise that may not be specific to your field. Because this program aims to provide seed funds for early stage projects, preliminary data are not required.
3. **Section II: Applicant Information**
 - a. **Biographical Sketch** (Maximum 4 pages per Principal Investigator; do not attach reprints)
A complete NIH-style biographical sketch including the applicant's name and position title, education and training information (earliest training and degree), research and professional experience (concluding with the current position), and other sources of research support. Provide complete references to original peer-reviewed scientific reports only; highlight first author (or equivalent) publications. No reviews, chapters, books or abstracts should be listed.
 - b. **Personal Statement** (Maximum 1 page per Principal Investigator)
Describe your most innovative and/or significant research endeavors.
 - c. **Description of Resources** (Maximum 1 page per Principal Investigator)
Specify the general laboratory/office facilities at your disposal. Indicate the specialized equipment and facilities required for your research and their availability. Describe facilities for patient studies if needed, such as hospital units or clinical research centers.
4. **Budget and Budget Justification** (use Excel template provided)

Questions

If you have any questions concerning this RFP or completing the application submission, please send an email to ddcf@aibs.org with "2009 ICRA" as the subject line.