



**Doris Duke Charitable Foundation  
2019 Request for Applications  
Sickle Cell Disease/Advancing Cures**

**GRANT OPPORTUNITY**

*The Doris Duke Charitable Foundation (DDCF) is excited to announce a new funding opportunity for “Sickle Cell Disease/Advancing Cures.” This program will support research to advance curative approaches for sickle cell disease including gene modification and drug therapies to restore hemoglobin function.*

**KEY DATES**

Full proposals due	May 31, 2019, 3 pm ET
Notice of Award	End of July 2019
Award Start Date	September 1, 2019

**PROGRAM DESCRIPTION**

Research in the past five decades has resulted in decreased childhood mortality and improved disease management options for patients with sickle cell disease. However, further efforts are needed to advance curative approaches that aim to attack the disease at its core by safely and sustainably increasing red blood cells that do not sickle. The Sickle Cell Disease/Advancing Cures program was created to support research into cures for sickle cell disease. The first round of grants in the Sickle Cell Disease/Advancing Cures program were awarded in September 2017. We are now announcing an opportunity to apply for funding for new research projects.

This program seeks to support sickle cell disease research that will:

- Advance gene therapies into the clinic, including gene addition and genome editing.
- Build on globin regulatory mechanisms to restore red blood cell function.
- Advance bone marrow transplant approaches to minimize toxicities and improve outcomes.

**AWARD INFORMATION**

DDCF has committed approximately \$5 million over three years to support five to ten research projects for Sickle Cell Disease/Advancing Cures. The number of funded projects will depend on the number of meritorious applications received and their budgets. Flexible annual direct cost amounts of \$150,000 - \$300,000 will be considered, plus an annual 10% indirect cost allowance. If the research project would require more than \$300,000 of annual direct costs, please [contact us](#) ahead of the application submission deadline. The 3-year award term will be September 1, 2019 to August 30, 2022.

DDCF seeks to fund research needed to advance curative therapies (e.g., gene modification, bone marrow transplant) or new drug candidates that would decrease sickling of red blood cells (e.g., molecules that would increase fetal hemoglobin). We encourage crossover of researchers from other disciplines and specialties to work on sickle cell disease.

Applicants must propose a *clinical* research project that meets DDCF's definition (see page 4). Please note that DDCF does not support research with non-human animals, in keeping with the wishes expressed in Doris Duke's will.

## ELIGIBILITY CRITERIA

DDCF values diversity in the biomedical research workforce and considers it to be necessary to produce significant advances in research. All are invited, particularly those historically underrepresented in biomedical research, to take on the challenge of advancing cures for sickle cell disease.

**Eligible investigators** must:

- Hold an advanced doctoral degree (PhD, MD, MD/PhD, DO, or equivalent degree). Although several of the DDCF Medical Research Programs are open to medical doctors only, please note that Sickle Cell Disease/Advancing Cures applicants are not required to have an MD.
- Have a full-time faculty rank appointment (Instructor, Assistant Professor, Associate Professor, or Professor) at an academic institution or the equivalent position in a nonprofit research organization. The institution must be located in the U.S.
- Be affiliated with a U.S.-based institution that is 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. *Applicants do not have to be U.S. citizens.*
- Propose a research project that meets DDCF's definition of clinical research (see definition on page 4) and is responsive to the goals of the program.
- Propose a research project that does not utilize non-human animals or primary tissues derived from them. This funding does not preclude researchers from pursuing research with non-human animals or their primary tissue with other non-DDCF sources of funding.
- Submit only one application as Principal Investigator. An investigator may, however, be considered part of the key personnel of another application.

Applications may be submitted by an individual principal investigator or by teams of up to two principal investigators who will be co-equals sharing the responsibility for leading and directing the research project. In the case of a team application, one of the principal investigators must submit the application and be designated as DDCF's point of contact for the application and grant, if awarded. The submitting investigator, referred to as Principal Investigator 1 in the online application, should be affiliated with the institution that would administer the grant if awarded and must meet all the eligibility criteria listed above.

## **501(C)(3) STATUS OF THE APPLICANT'S INSTITUTION**

DDCF can award grants only to institutions that have determination letters from the US Internal Revenue Service documenting exemption 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 that they are not a private foundation or a Type III supporting organization as defined in Section 509(a) of the Code. Please note that this requirement does not exclude participation of applicants at state universities, which may not have 501(c)(3) status. State university applicants are encouraged to apply through their grant-receiving arms (e.g. applicants from the University of Texas may apply through the University of Texas Foundation). DDCF encourages applicants to seek guidance from their institutions to identify the appropriate institutional entity through which they can apply. DDCF is unable to provide information on the tax ID that applicants must use to gain access to the application site.

## **APPLICATION PROCESS**

To be considered for this award, applicants must submit full applications by the deadline, May 31, 2019, 3pm Eastern Time (ET) through DDCF's online system. Note that a letter of intent is not required. A full application consists of an online form, proposal attachment, and project budget. Applications from eligible individuals that comply with the application preparation instructions will be evaluated by a scientific review panel. Applicants will be notified of the outcome of the competition at the end of July 2019. All communications will be made through email. We recommend applicants add "[ddcf@aibs.org](mailto:ddcf@aibs.org)" to their email safe senders list.

## **REVIEW AND SELECTION CRITERIA**

Full proposals will be reviewed by a panel of scientific experts. The selection criteria will evaluate the following characteristics of the application:

- Potential of the proposed research to transform curative therapies or to advance new pharmacologic approaches with high potential to restore hemoglobin function.
- Scientific rigor of the methodology to address the proposed research question.
- Originality and inventiveness of the concept and approach.
- Appropriateness of the investigators' background, expertise, and track record of research accomplishment.
- Adequate resources and infrastructure to conduct the proposed research.

## **DEFINITION OF CLINICAL RESEARCH**

For this program, clinical research is defined as the scientific investigation of the etiology, prevention, diagnosis, or treatment of human disease using human subjects, human populations or materials of human origin. Included in the definition are studies that utilize tissues or pathogens only if they can be linked to a patient.

It is expected that the research protocols of grant applicants will require Institutional Review Board (IRB) approval. Occasionally, DDCF has funded research that does not require IRB approval, such as research using de-identified data from patient populations. If a research project is being proposed that does not

require IRB approval, applicants are strongly encouraged to [contact program staff](#) to discuss whether the proposed research falls within DDCF's definition of clinical research.

In keeping with the wishes expressed in Doris Duke's will, experiments that utilize non-human animals or primary tissues derived from them will not be supported by this program. Animal-based research is allowed to be presented as preliminary evidence supporting the proposal or to be pursued through other funding concurrent with the project. However, the aims themselves may not include research with non-human animals.

### **USE OF HUMAN SUBJECTS**

Institutional Review Board approval, if necessary, is not required at the time of application. If a grant is awarded, DDCF strongly prefers Institutional Review Board approval to be in place by the grant start date, September 1, 2019. Institutional Review Board approval **must** be in place by December 1, 2019. The grantee may not conduct activities supported by this award that involve human subjects until Institutional Review Board approval is in place. We recommend that you coordinate with your Institutional Review Board to ensure timely approval.

Applications for research projects subject to Investigational New Drug (IND) approvals must have an approved IND at the time of full proposal submission, May 31, 2019, 3 pm ET. Exceptions will be considered on a case-by-case basis, please [contact us](#) ahead of the deadline.

### **GERMLINE GENE EDITING**

The research community is recommending further research and deliberations before altering genes that are passed down to future generations,<sup>1</sup> and DDCF program staff agree with this stance. Although heritable genome editing may offer the only opportunity for prospective parents who are homozygous for the sickle cell mutation to have offspring who are free of the disease, it must be approached with thoughtfulness and care.<sup>2</sup> Research on the considerable technical difficulties that must be overcome before applying genome editing to germline cells or early embryos could be eligible for this grant program. Please [contact us](#) to discuss suitability if you are planning such experiments.

### **GUIDELINES AND POLICIES**

#### **General policies for grantees**

DDCF has a public access policy for grantee publications. In addition, DDCF, as a member of the Health Research Alliance ([www.healthra.org](http://www.healthra.org)), has agreed to deposit basic grant information into a database of privately funded awards. Find more information on public access, grant information sharing, and other policies [here](#).

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<sup>1</sup> Daley GQ, Lovell-Badge R, Steffann S: After the Storm – A Responsible Path for Genome Editing. NEJM. January 16, 2019.

<sup>2</sup> National Academies of Sciences, Engineering, and Medicine. 2017. Human Genome Editing: Science, Ethics, and Governance. Washington, DC: The National Academies Press.

### **Intellectual property policy for this program**

DDCF intellectual property policy varies by grant program. The intellectual property policy for the Sickle Cell Disease/Advancing Cures program can be found [here](#). DDCF recognizes that most patients with sickle cell disease are outside the United States in economically disadvantaged settings that pose barriers to access to disease care and treatment. DDCF's charitable objective is to promote access to knowledge and disease treatments generated through grants in this program for patients in economically disadvantaged countries. It is expected that grantee institutions will act in support of DDCF's charitable goals. For questions please [contact us](#).

### **ABOUT THE DORIS DUKE CHARITABLE FOUNDATION**

The Doris Duke Charitable Foundation is a philanthropic organization with the mission to improve the quality of people's lives through grants supporting the performing arts, environmental conservation, medical research and child well-being, and through preservation of the cultural and environmental legacy of Doris Duke's properties.

### **QUESTIONS**

Please consult our online [Frequently Asked Questions](#) or email us at [ddcf@aibs.org](mailto:ddcf@aibs.org) with "2019 SCD/AC – [Last name]" as the subject line. Questions will be answered within two business days. Please do not call as we cannot guarantee that phone inquiries will be directed to the appropriate program staff. Kindly use e-mail only to ensure your questions are addressed in a timely fashion.

## APPLICATION INSTRUCTIONS

Investigators must submit a complete application electronically using DDCF’s online application portal by **3 pm ET on May 31, 2019**. Deadline extensions are not granted. Competition outcomes will be announced in late July 2019. To start a new application, you will need to obtain the tax identification number (also known as the Employer Identification Number or EIN) of the grant-receiving organization, the organization that would accept and administer the award. The applicant will be unable to access the pre-proposal application submission form without this information.

**START a new application here:**  
[https://www.GrantRequest.com/SID\\_1149?SA=SNA&FID=35025](https://www.GrantRequest.com/SID_1149?SA=SNA&FID=35025)

**RETURN to an existing application here:**  
[https://www.grantrequest.com/SID\\_1149?SA=AM](https://www.grantrequest.com/SID_1149?SA=AM)  
**Once you have initiated an application, please bookmark this page**

A complete application consists of fields submitted through the online application form plus attachments. We suggest that you log into the online application portal prior to the application submission deadline to ensure that all information requested in the form will be available at the time of submission.

Use the following checklist to ensure that you gather all the information required to submit an application. The proposal attachment must include ALL items listed in 1-10. Applicants are strongly encouraged to review their application and attachments prior to submission. Incomplete applications will be disqualified from the competition without prior notice.

**A complete application contains:**

	<b>Online form</b>
<input type="checkbox"/>	I. Principal investigator information (ORCID number is a required field for the PI submitting the application, you may register for one at <a href="https://orcid.org/register">https://orcid.org/register</a> )
<input type="checkbox"/>	II. Institutional contact information (pre-award, post-award, and communications contacts)
<input type="checkbox"/>	III. Project information
	<b>Attachments</b>
	IV. Proposal attachment ( <b>assembled into one PDF document</b> )
<input type="checkbox"/>	1. Research Plan (9 page limit)
<input type="checkbox"/>	2. Potential pitfalls and alternative approaches (1 page limit)
<input type="checkbox"/>	3. Data sharing (1 page limit)
<input type="checkbox"/>	4. Literature Cited in Research Plan (No page limit)
<input type="checkbox"/>	5. Description of Resources (1 page limit)
<input type="checkbox"/>	6. Budget Justification (1 page limit)
<input type="checkbox"/>	7. Letters of collaboration (Consultant/Collaborative/Contractual Arrangements/Industry Interest if applicable, 1 page per letter)
<input type="checkbox"/>	8. List of Key Personnel (1 page limit)
<input type="checkbox"/>	9. NIH format biographical sketch of the principal investigator(s) and other key personnel (maximum 5 pages each)
<input type="checkbox"/>	10. Signed Assurance Form (found at the end of these instructions)
	V. Budget in excel format ( <a href="#">template provided</a> )

## ONLINE FORM

Enter all of the information requested into the electronic application system. Fields marked with an asterisk are required. You will not be able to submit the form without entering information into the required fields. DDCF uses fields in the form to generate a cover page for your proposal. Complete the electronic form by entering the following information:

### I. Principal Investigator Information

- ORCID number, required for the principal investigator submitting the application: If applicants do not have one, they can register for one at <https://orcid.org/register>. We recommend that you register in advance of the proposal submission deadline to prevent delays in the final submission of the proposal. Learn more about ORCID [here](#).
- First name, middle initial and last name.
- Post-baccalaureate academic degree(s) and year(s) received
- Current appointment title
- Additional current job titles
- Department name
- Office address
- Telephone number
- Institutional email address. Note that commercial email addresses such as Gmail, Yahoo, etc. are not acceptable. All communications regarding the application will be sent to the institutional address.
- Field(s) of research training (select from the list)
- Clinical specialty and subspecialty (select from the list, select not applicable if not a medical doctor)

### II. Institutional contact information

Enter name, title and contact information for each of the individuals at your institution responsible for managing pre-award research proposals, post-award grants and contracts, and public relations/communications.

### III. Project information

- Project title (up to 255 characters, including spaces)
- Grant amount being requested: Flexible annual direct cost amounts of \$150,000 - \$300,000 will be considered, plus an annual 10% indirect cost allowance. Budgets requiring annual direct costs higher than \$300,000 may be considered if well justified; please [contact us](#) ahead of the application submission deadline to discuss the rationale.
- Research classification (select from the pull down list in the online application form)
- Research approach (select from the pull down list in the online application form)
- Abstract (up to 250 words) without Greek characters or special symbols
- **Institutional Review Board (IRB) Approval:** Indicate whether the project is subject to IRB approval, whether approval has been obtained and the date of approval (if applicable). There is no requirement for the IRB approval to be in place at the time of application. If a grant is awarded, DDCF strongly prefers Institutional Review Board approval to be in place by the grant

start date, September 1, 2019. Institutional Review Board approval **must** be in place by December 1, 2019.

*Please note: If the proposed research project does not require IRB approval, applicants or their institutions are strongly encouraged to [contact program staff](#) to discuss whether the proposed research falls within DDCF's definition of clinical research.*

- **Investigational New Drug (IND) Approval:** If necessary, Investigational New Drug Approval must be in place by the application submission deadline, May 31, 2019, 3 pm ET

## ATTACHMENTS

### IV. Proposal attachment, consisting of parts 1 through 10 below and assembled into a single PDF

#### ***Formatting Instructions***

- **Font:** Use 12-point font size throughout unless noted otherwise. Smaller font sizes are acceptable for use in tables, figure legends, the biographical sketch, and the list of cited literature.
- **Please number the pages**
- **Page Margins:** Page margins must not be smaller than 0.5 inch on all sides.
- **Page Limits:** Do not exceed the page limits stated for each section.
- **Section Headers:** Each numbered section (1-10 below) must begin on a new page and include the section name (e.g., Research Plan, etc.).
- **Appendices:** Do not attach any additional materials, doing so may disqualify you from the competition.
- **Color Figures:** Applicants may include color figures as reviewers will be provided with electronic color copies of the application.
- **Encryption:** Please do not encrypt the proposal document. We will encrypt the documents prior to their distribution to the peer-review panel.

The following sections must be compiled into a **single PDF proposal document** in the order listed below for submission with your application.

#### 1. **Research Plan (Maximum 9 pages)**

Single spaced including figures, excluding literature cited.

**NOTE: The review committee is comprised of experienced scientists and will broadly reflect areas supported by this award, however, your proposal might not necessarily be reviewed by experts in your specific field of research. Therefore, it is in your best interest to define all acronyms, to keep your research plan free of jargon, and to make it understandable to a non-specialist.**

*The research plan must include all required sub-sections bulleted below in the order specified. We recommend that applicants copy/paste the sub-sections into their working document to ensure that all are included and clearly labeled. Proposals with a research plan missing sub-sections or with sub-sections out of order might be disqualified from the competition without prior notice.*

- **Clinical Significance:** Address the following questions (*no more than two sentences each*)
  - What is the clinical research question to be addressed?
  - How would the proposed research transform curative therapies or to advance new drug candidates that would restore hemoglobin function?
  - How will the proposed research impact or improve patient care?
- **Hypotheses and Specific Aims:** Clearly state each hypothesis being tested and the corresponding proposed specific aim.
- **Background and Significance:** Discuss the scientific knowledge that led to the stated hypotheses and specific aims and cite critical references.
- **Preliminary Results:** Present data pertinent to the proposed research, especially if they substantiate the validity of a new technique or hypothesis or demonstrate expertise in a new area of research. If applicable, present evidence of therapeutic target validation in animals and/or human models and prior efforts to gather pharmacokinetic and pharmacodynamic information.
- **Research Design and Methods:** Describe the procedures and methodology that will be used to accomplish the specific aims of the project. For each specific aim, describe as applicable:
  - The study design to address the stated hypothesis (e.g. cohort, cross sectional, case-control, etc.)
  - Whether this will be a pilot study to assess the standard deviation of the outcome of interest and enable calculation of “n” and effect size for a future study.
  - The subjects or samples (age, age group, gender, etc.) and their source.
  - Selection criteria, inclusion and exclusion criteria for participants.
  - Recruitment plan, including use of incentives. Provide evidence of the feasibility to recruit the proposed number of participants for the study.
  - Predictor, outcome, and confounding variables.
  - Sample size including related power analyses
  - Randomization of and blinding to treatment.
  - Methods to measure or assess predictor and outcome variables. Indicate if the predictor and outcome variables will not be obtained through direct measure but through calculation and how the calculation will be made.
  - How the data will be analyzed.
  - Plans for data management. For example: format in which the data will be generated, procedures for ensuring data quality, considerations of ethical consent for data use and reuse, any metadata that will be generated, its description and data standards to be used.
  - Any potential difficulties and alternate approaches that might be taken to accomplish the aims.
- **Timeline:** Provide estimated milestones and timeframe for accomplishing key goals.

## 2. Potential pitfalls and alternative approaches (1 page limit)

Discuss any potential difficulties and alternate approaches that might be taken to accomplish the goals. If applicable:

- Provide evidence of safety for all key clinical reagents (such as drugs, imaging reagents, etc.) that will be used as part of the clinical protocol. If safety data are unavailable, indicate how

the research design would be modified should unexpected significant adverse events preclude use of those key drugs.

- Key clinical reagent availability: Indicate alternative clinical reagents that could be used should these, including the test intervention if applicable, become unavailable. If the study involves testing of a new indication, elaborate on the role of the drug manufacturer in the study.
- Discuss alternative approaches to address unexpected low patient recruitment.
- Indicate alternative approaches should the patient samples or target patient population become unavailable.

### **3. Data sharing (1 page limit)**

Sharing clinical research data has great potential to unlock new discoveries for the advancement of human health. It can accelerate the development of new knowledge by using datasets to test novel ideas or expand previous studies, and it encourages collaboration among scientists. Recognizing the benefits of shared datasets, DDCF requires applicants to describe a plan for how they would share their data. DDCF does not mandate data sharing at this time. Having a data sharing plan does not oblige applicants to share their data should an award be made.

In this section, please address the four questions below. If you do not plan to share your data, please justify in your answers to these questions. If an award is made, DDCF will consider a separate data sharing grant to facilitate sharing by grantees wishing to make their data available for future research.

- What data will be shared? For example, individual participant data collected during a trial after deidentification, metadata, genetic sequencing, etc.
- Who will have access to the data? Indicate if the data will be accessible to anyone who wishes to access the data, researchers with a reasonable proposal for reuse, etc.
- Where will the data to be shared be located? Describe, for example, if the data would be located in an existing database or repository, whether it is public, or if a new one has to be developed.
- When will the data be shared? Describe any embargo period and when the embargo would start.

### **4. Literature Cited in Research Plan (No page limit, Use 10-point font)**

Provide complete references to the literature cited in the body of the Research Plan.

### **5. Description of Resources (Maximum 1 page)**

Identify unique resources such as subjects, materials, registries, biobanks, equipment, or facilities that you will need to complete the proposed research plan. Do not list general laboratory and office facilities at your disposal such as office square footage and general use computer equipment. Verify that you have access to the specialized equipment and facilities required for your research including facilities for patient studies if needed, such as hospital units or clinical research centers.

For any study requiring participation of human subjects or their samples:

- Quantitatively substantiate feasibility of subject recruitment by indicating patient volume at the recruitment sites, estimated eligible pool, existence of studies at the site that compete for the same patient population, institutional safeguards to enable study completion in light of competing studies, resources dedicated to patient recruitment.
- Access to samples: Provide evidence that access to necessary samples has been secured.

**6. Budget Justification (Maximum 1 page)**

Provide a budget justification for investigators' time spent on the grant, large or unusual budget allocations, and other expenses that may not be self-evident. If applicable, indicate if other financial contributions (matching or in-kind) exist or will be made to complement the DDCF project budget.

**7. Letters of collaboration on institutional letterhead (Each letter maximum 1 page)**

If applicable, include letters verifying any consulting, collaborative, or contractual arrangements necessary to conduct the proposed research. If committed industry partners exist that are interested in the outcome of the proposed research aims for subsequent therapeutic development, applicants may include letters of industry interest. **These should not be letters of recommendation.**

**8. List of key personnel and roles on the project (1 page limit)**

Provide a list of personnel who will make substantive and scholarly contributions to the development and execution of the research project, whether or not they request salaries or compensation. The key personnel section includes the principal investigator(s), co-investigators, and collaborators. The list should include name, title, institution, and role on the project. Trainees and consultants should not be listed as key personnel.

**9. NIH-format biographical sketches with funding information (maximum 5 pages each)**

Include the biographical sketches of the principal investigator(s) and other key personnel. The biographical sketch should include research support information and must be in the current NIH format. Do not include biographical sketches for consultants or trainees.

**10. Assurance form**

The Assurance Form, provided in the last page of this document, **must be signed by the applicant and an Institutional Official.** A scanned PDF of this document must be included as part of the proposal document. Applications missing this form will be disqualified from the competition.

**V. Budget**

The Excel document [Budget Template](#) must be used. The template can also be downloaded from the online application form and must be uploaded as a single Excel file.

**The Budget Template contains THREE worksheets.** The first contains the detailed Year 1 budget. The second contains the summary budget for the entire grant. Use the third worksheet only if applicable to indicate the first year of a subcontract budget. No rows or columns may be deleted, moved, or manipulated in size. It is acceptable to add rows to the Year 1 budget template, as necessary. Please include the budget justification as section #6 of the proposal (see above).

### **Guidelines for Preparing the Year 1 Budget:**

- **Personnel:** There is no required percent effort for the Principal Investigator(s). If salary support is requested, the percent effort committed to the project must be equal to or greater than the percentage of salary charged. Be sure to list the Principal Investigator(s) in the budget table under Personnel even if no salary is requested. Salaries for research staff should be based on current actual salaries for existing employees. If a position is “to be named,” use the salary of an equivalent employee. Fringe benefits should be budgeted for salaried positions based on the appropriate rates at your institution. Fringe benefits typically cover charges such as FICA, retirement, and health insurance. Nurse, research coordinator, and trainee efforts are allowable costs as long as these positions would directly support the proposed research plan. If trainees are post-doctoral fellows, salary must be greater than or equal to the NIH National Research Service Award (NRSA) Fellowship stipend, determined by the number of full years of relevant postdoctoral experience when the award is issued. Relevant experience may include research experience (including industrial), teaching assistantship, internship, residency, clinical duties, or other time spent in a health-related field beyond that of the qualifying doctoral degree.
- **Consultants:** Consultants are individuals who provide expert knowledge for your project and are not employed at your institution. Consultant costs should be reasonable and necessary to your project.
- **Equipment:** Equipment is non-expendable, tangible property that has a useful life of more than one year. If the total for equipment exceeds \$10,000, break down the costs.
- **Supplies:** Supplies are expendable items and must be necessary for the conduct of the research project. If the total for supplies exceeds \$10,000, break down the costs into categories such as reagents, disposables, etc.
- **Travel:** Travel costs should be reasonable and based on current rates. Typically a budget contains one trip per year to a scientific meeting. We also require that you budget for attendance to a potential annual grantee meeting. An approximate cost of \$1,000 is expected to cover travel and ground transportation expenses for our meeting.
- **Subject costs:** Expenses related to human subject participation (such as recruitment, participation incentives, subject remuneration, travel reimbursement, phlebotomy charges, etc.) and clinical laboratory analyses of human subjects or their samples (such as clinical laboratory assays, imaging charges, study medications, etc.) should be listed in this section of the budget.
- **Other expenses:** Publication costs may be included as other expenses.
- **Total Direct Costs:** Total direct costs are the total costs from all items budgeted in the proposal, including equipment. Direct costs are costs that will be used to directly support the program activities.
- **Indirect Costs:** Indirect costs are the costs that cannot be directly associated with the grant but are incurred as a result of the organization taking on the proposed activity. Indirect costs may not exceed 10% of annual total direct costs, including equipment.
- **Subcontracts:** If subcontracts will be established, please indicate the subcontract budget for the first year of the grant in the corresponding spreadsheet (third tab in the Excel template). Indirect costs, if any, are capped at 10% of the subcontract direct costs. Please note that indirect costs on the subcontract count toward the main budget indirect cost allowance.

## QUESTIONS?

Please consult our online [Frequently Asked Questions](#) or email [ddcf@aibs.org](mailto:ddcf@aibs.org) with “2019 SCD-AC-Applicant last name” as the subject line. Questions will be answered within two business days. Please do not call; we will promptly reply to any inquiries submitted over email. We cannot assure that phone calls will reach the appropriate contact at DDCF. For this reason, we strongly encourage applicants to contact us via email.

### PLEASE NOTE:

- The submission of an application is final, and modifications are not allowed.
- Only proposals submitted through the DDCF online application portal will be accepted.
- Applicants will receive an automatically generated email from the online application portal upon submitting their application. Applicants are advised to check their spam if this email is not received.
- DDCF cannot confirm the completeness of an application once submitted.
- Proposals that include materials additional to those required by the instructions or do not meet the page limits and formatting instructions will be disqualified from the competition without prior notice.
- Applications missing any of the required sections will be disqualified from the competition without prior notice.
- Applicants not adhering to the instructions will not be notified or given a chance to revise their submission.
- The maximum size for all attachments *combined* is 1000 MB. Please note that files with certain extensions (such as “exe,” “com,” “vbs” or “bat”) cannot be uploaded.
- DDCF grantees are subject to public access and application information sharing policies described [here](#). Please read these policies and guidelines and confirm to yourself that you will be able to comply with them if an award is made.

**DORIS DUKE SICKLE CELL DISEASE/ADVANCING CURES  
Assurance Form for Online Application Submission**

Principal Investigator:		Title:	
Department:		Institution:	
Project Title:			

**SIGN IN BLUE INK**

**PART A: PRINCIPAL INVESTIGATOR ASSURANCE:** I certify that the statements contained in the application materials submitted online are true, complete, and accurate to the best of my knowledge. I certify that the following statements are true.

- I hold an advanced doctoral degree (PhD, MD, MD/PhD, DO, or equivalent).
- I have a full-time faculty rank appointment at an academic institution or the equivalent position in a nonprofit research organization.
- The proposed research aims do **not** include experiments that utilize non-human animals or tissues derived from them.
- I understand that if my proposal is recommended for funding, DDCF expects that I will have IRB approval by the start date of September 1, 2019 or no later than December 1, 2019.
- I understand that if my research plan is subject to IND approval, this approval has been obtained on or before the deadline for submission of this full proposal, May 31, 2019, 3 pm ET unless authorized by DDCF to make a submission pending IND approval.

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**Principal Investigator Signature**

Date

**PART B. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE:** I certify that the application materials to be submitted by the above Principal Investigator have been reviewed on \_\_\_\_\_, 2019 and are true, complete, and accurate to the best of my knowledge, and that this individual meets the requirements outlined above. I also certify that the organization that would receive and administer the grant has determination letters from the Internal Revenue Service documenting that it is a 501(c)(3) organization according to the Internal Revenue Code of 1986, as amended (the "Code") and is not a private foundation or a Type III supporting organization as defined in Section 509(a) of the Code). I certify that no part of the grant (if awarded) would be used for a purpose that is not specified in Section 170(c)(2)(B) of the Internal Revenue Code.

APPLICANT ORGANIZATION:		EIN:	
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**Authorized Institutional Official Signature**

Date

Name:	
Title:	
Department:	
Address:	
Telephone:	
E-mail:	

<b>This signed form must be uploaded as a PDF as part of the complete online application package no later than 3 pm ET on May 31, 2019</b>
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