DORIS DUKE CHARITABLE FOUNDATION (DDCF)
2020 REQUEST FOR APPLICATIONS
CLINICAL SCIENTIST DEVELOPMENT AWARD

GRANT OPPORTUNITY

Approximately 17 grants of up to $495,000 each over 3 years ($150,000 direct cost and $15,000 indirect costs per year) will be awarded to early-career physician scientists (MD, MD/PhD, DO or foreign equivalent degree) at the Assistant Professor rank working at US degree-granting institutions to support clinical research that will enable their transition to independent research funding.

KEY DATES

Pre-proposal applications due November 19, 2019, 3 pm ET
Invitation to submit a full proposal By 5 pm ET on January 17, 2020
Full proposal due March 13, 2020, 3 pm ET
Notice of Award End of May, 2020
Award Start Date July 1, 2020

PROGRAM DESCRIPTION

Physician scientists pursuing research careers face challenges that are particular to their dual roles as researchers and health care providers. The purpose of the Doris Duke Clinical Scientist Development Award (CSDA) is to provide support to physician scientists at the Assistant Professor rank to: 1) conduct an outstanding clinical research project, 2) enable research time protection to ease the tension between research and clinical responsibilities, and 3) facilitate development of strong mentorship relations. Ultimately, the CSDA program aims to enable physician scientists’ achievement of independent and successful research careers.

AWARD INFORMATION

The 2020 Clinical Scientist Development Award consists of $150,000 annual direct costs plus $15,000 (10%) annual indirect costs for three years. The award project period is July 1, 2020 - June 30, 2023. DDCF expects to fund approximately 17 applications in 2020. The priority of the CSDA program is to fund outstanding individuals with promise for outstanding clinical research careers, whose projects will address highly significant research questions and lead to career advancement. DDCF does not have funding priorities based on disease area or research type.
ELIGIBILITY CRITERIA
For the 2020 cycle only, criteria will be revised from year to year

The CSDA is a highly competitive award. Typically, only 10% of all reviewed applications are funded. Competitive applicants are expected to have research experience and productivity consistent with the rank of Assistant Professor. To be eligible for this award, applicants must:

- Have received an MD, DO, or foreign equivalent degree from an accredited institution.
- Have a valid, active US medical license at the time of application, but do not have to be US citizens.
- Work at a US academic institution that grants doctoral degrees and is able to receive an award as an organization with 501(c)(3) Internal Revenue Service status. Please see the information on page 4 and consult with your institutional grants office.
- Have a full-time, post-training faculty appointment as Assistant Professor at a US academic institution that grants doctoral degrees. Adjunct, affiliated, temporary, part-time or acting faculty positions are not eligible for this competition. Applicants that become Associate Professor on or before the award start date of July 1, 2020 will not be eligible for the award. Applicants from Harvard Medical School should check our FAQs to determine eligibility of their faculty appointment.
- Have been appointed to their first post-training full-time assistant professor faculty position between December 1, 2015 and December 1, 2018 (i.e., have been at the appointment no more than 4 years but at least 1 year). Exceptions to the four-year requirement will be considered on a case-by-case basis for individuals who do not meet this criterion because of situations such as family or medical leave. Check our FAQs for examples of situations for which DDCF may make an exception. DDCF approval of exemptions must be obtained prior to submitting a pre-proposal. Exemption requests must be made by October 18, 2019. Exemptions are not granted for applicants with less than one year at their academic position.
- Not have served as the principal investigator of a single or multi-principal investigator, multi-year research grant with annual direct funding in the amount of $225,000 or higher with a start date prior to and inclusive of July 1, 2020, except for National Institutes of Health (NIH) career development awards. Startup packages are excluded from this requirement. The CSDA is not for researchers who have already attained this level of funding, even if the researcher substituted for the original principal investigator of the grant.
- Not have applied for a single or multiple-principal investigator NIH R01 research grant or equivalent as principal investigator that has a start date prior to and inclusive of July 1, 2020. This includes but is not limited to: research projects that are part of a P01 program project, P50 center grant or a U01 cooperative agreement, DP1, DP2, R37, and VA Merit grants.
- Not be in a graduate degree program at the time of the award. All education and training toward advanced degrees must be completed by the award start date, July 1, 2020.
- Be guaranteed a minimum overall research time protection of 75% of full-time professional effort by the institution where the applicant has an appointment, in the event an award is
made. There is no explicit minimum percent effort that must be dedicated to the CSDA project. Applicants in specialties that require considerable effort to maintain clinical competency skills, such as those in surgery, are eligible to apply if a minimum effort commitment to research of 50% during the award term could be guaranteed by the institution. Reviewers will evaluate whether an effort commitment of less than 75% would be conducive to committed and long-lasting clinical research careers.

If you have any questions about these eligibility criteria check our FAQs or email ddcf@aibs.org. Please note that requests for exceptions to eligibility criteria must be made as indicated on page 5 and will not be considered after October 18, 2019.

Other requirements
- A clinical research project must be proposed, as defined by the Doris Duke Charitable Foundation, in any disease area. A definition of clinical research can be found on page 5. The clinical research question should have strong potential to impact the field.
- A mentor must be designated, or mentorship team assembled, and the role of the mentor(s) must be described. Mentors are expected to play an active role during the course of the Clinical Scientist Development Award in fostering the applicant’s career development as a physician scientist and capacity for independence. Mentors are expected to act as advocates for the applicant at the departmental, institutional and professional levels and provide scientific guidance for the proposed project.
- Experiments that utilize non-human animals or any tissues derived from them, including established cell lines, must not be included in the proposed research. Animal-based research may be presented as preliminary evidence supporting the research plan but the aims themselves must not include research with non-human animals.
- If applicable, Investigational New Drug Approvals must be in place by the deadline for submission of a full proposal. See page 5.
- Institutional Review Board (IRB) approvals are not necessary at the time of application. However, DDCF strongly prefers IRB approvals to be in place by the grant start date, July 1, 2020. IRB approval must be in place by October 1, 2020. See page 5.

Other funding
- Applicants are allowed to hold an NIH K series award or other career development award at the same time as the CSDA grant. Principal investigators of the NIH Director's Early Independence Award (DP5) and in the R00 phase of Pathway to Independence Award (K99/R00) grants are eligible to apply provided that they meet all other eligibility criteria.
- Applicants must not propose research aims or budget expenses that directly overlap with another funded project. Application for support of CSDA research aims that simply extend those of other grants is discouraged.

We strongly encourage applications from women and those from groups that are underrepresented in medicine, including Blacks or African Americans, Hispanics or Latinos, American Indians, Alaskan Natives, and Native Hawaiians.
501(c)(3) STATUS OF THE APPLICANT’S INSTITUTION

DDCF can award grants only to institutions that have 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

Applying for this award is a two-stage process:

1. **Stage 1, pre-proposal application.** Interested candidates who meet the eligibility criteria will need to submit one pre-proposal application by **November 19, 2019 at 3 pm ET**. In brief, the pre-proposal includes investigator information, electronic confidential forms from the mentor and department chair, biographical sketches and a 2-page research plan description. Detailed instructions begin on page Error! Bookmark not defined.

2. **Stage 2, full proposal application.** Submission of full proposals will be by invitation only after review of pre-proposal applications. By January 17, 2020, about 50 applicants will be invited to submit a full application. Instructions on how to prepare the full application will be provided by email with the invitation to participate. Full applications will be **due on March 13, 2020 at 3 pm ET**. Applicants will be notified of the outcome of the competition at the end of May 2020.

All communications, including the invitation to submit a full application and declinations, will be made through email. We recommend applicants add “ddcf@aibs.org” to their email safe senders list.

REVIEW AND SELECTION CRITERIA FOR PRE-PROPOSAL APPLICATIONS

The goal of the stage 1 review is to identify early-career physician scientists with great promise (committed, productive, well-trained, and with a history of original research) who are addressing a major clinical issue. Strong mentorship environment should be evident. Scientific premise and overall scope of the project should be feasible and appropriate. Investigators should not yet be independent researchers. Detailed review criteria for pre-proposal applications can be found in the Attachment.

Please note: The foundation recognizes the importance of critical feedback but has limited ability to supply written comments for all submitted applications. No written comments will be provided for pre-proposal applications. Written comments will be provided for full proposal applications when possible but may not always be available because of limited resources and unforeseen circumstances. Please evaluate if receipt of written feedback is a requirement for you as you decide whether to submit an
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 patient populations. If a research project is being proposed that does not require IRB approval, applicants are strongly encouraged to contact DDCF program staff to discuss whether the proposed research falls within the DDCF’s definition of clinical research. Please email ddcf@aibs.org with questions regarding the eligibility of your research project.

Please note that the Medical Research Program does not support research that uses non-human animals or any tissues derived from them, including established cell lines. The extension of the restriction to established cell lines from non-human animals was added this year.

APPLICATION REQUIREMENTS FOR USE OF HUMAN RESEARCH SUBJECTS

Institutional Review Board approval, if necessary, is not required at the time of application. However, if necessary, Investigational New Drug approval must be in place by the deadline for submission of a full proposal, March 13, 2020, 3 pm ET. If a grant is awarded, DDCF strongly prefers Institutional Review Board approval to be in place by the grant start date, July 1, 2020. Institutional Review Board approval must be in place by October 1, 2020. The grantee may not conduct activities supported by the CSDA 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.

GUIDELINES AND POLICIES

DDCF grants are subject to policies described here. Our policies may differ from those of the National Institutes of Health. For example, DDCF does not have restrictions on the use of human fetal tissue and embryonic stem cells, or the support for clinical trials in career development awards.

ELIGIBILITY EXEMPTION REQUESTS

DEADLINE OCTOBER 18, 2019, 5 PM ET

All eligibility criteria exemption requests must be submitted by October 18, 2019, 5 pm ET. Interested applicants must submit the form at https://www.surveymonkey.com/r/CSDA2020. Requests will only be accepted through this form. Please do not provide additional materials, we will get in touch if any other information is needed. In addition to contact information, you will need to:

1. Indicate the specific eligibility criterion from which you seek to be exempted and why it renders you ineligible for the competition.
2. Present a clear and brief justification for the request (1000 character limit). If you are beyond the fourth year of your first faculty appointment and would be applying to the CSDA for the first
time, indicate why an application was not submitted to earlier competitions. Reasons for such a request might include situations such as parental leave, child care, elder care, or medical conditions.

3. Attach a biographical sketch that lists the full official start date for your academic appointments.

4. Attach a letter from the corresponding Human Resources department confirming start and end dates of a leave, if one was taken.

All requests will be evaluated as a group. As a result, even if submitted early, responses to all exemption requests will be communicated by the end of business day on October 22, 2019.

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

If you have any questions concerning this Request for Applications please consult our online Frequently Asked Questions or email Joanne Sullivan at ddcf@aibs.org with “2020 CSDA – your last name” as the subject line. Questions will be answered within 2 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 the foundation. For this reason, we strongly encourage applicants to contact us via email.
ATTACHMENT

Clinical Scientist Development Award Stage 1, Pre-proposal Application, Review Criteria

Pre-proposal applications are reviewed by active researchers with deep understanding of the challenges of the physician-scientist career path. Reviewers consider the following criteria when evaluating each pre-proposal application.

**Investigator**

The review searches for applicants who are still transitioning to independence and developing their research program. This award is not intended for those who are likely to receive an NIH R01 or another major research grant near the time of the CSDA application or start of the award. Evaluation of the investigator considers:

- The applicant’s promise to make significant contributions to the field.
- Demonstration of the applicant’s inventiveness and talent.
- Appropriateness of the applicant’s formal research training, laboratory experience, and productivity.
- Strength of the applicant’s original research in the relevant area.
- Evidence that the proposed research will be driven by the applicant with guidance from a mentor only as needed.
- Evidence that the CSDA will move the candidate forward and provide a pathway to future research grant funding. The applicant should still be transitioning to independence, and this transition should not be imminent.
- Percent time dedicated to research. Successful applicants’ current level of effort commitment to research may be lower than 75%, however, it must be evident that 75% research time protection during the award will be achieved and propel future independent and committed research careers. The foundation will make exceptions for specialties in which the applicant has to spend significant time in clinical duties to maintain clinical competency (such as surgery and invasive cardiology), but the percent research can be no lower than 50%. If applicants have assessed that their clinical competency skills require decreased research effort commitment, reviewers are asked to evaluate if such decreased research effort is justified and conducive to a lasting career in research.

**Mentoring Environment**

- Evidence that the mentor(s) will actively foster the applicant’s career advancement as a physician scientist and capacity for independence during the course of the project.
- Potential of the mentor(s) to act as advocate(s) for the applicant at the departmental, institutional and professional levels.
- Evidence that the mentor(s) will be able to provide scientific guidance for the proposed project.
- Evidence of the mentor’s successful research career, including grant support.

**Significance**
• Impact on human health. Does the disease or health issue being studied pose a major clinical burden (with considerable morbidity and mortality, whether it is a rare or common condition)?
• Likelihood of the research to influence the field and the career advancement of the applicant.
• Potential of the research, if carried out successfully, to fill critical gaps in evidence or knowledge.

Originality

• Does the applicant propose new work, not previously done by others, to address a clinically meaningful research question?

Study design

• Appropriateness of the methodology and scope of the project. Because a detailed methodology description is not required for the pre-proposal application, reviewers are asked to assess only if the study design overview is sound to address the proposed aims.