



**DORIS DUKE CHARITABLE FOUNDATION (DDCF)
2021 REQUEST FOR APPLICATIONS
CLINICAL SCIENTIST DEVELOPMENT AWARD**

GRANT OPPORTUNITY

Approximately 12-18 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 Instructor or 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 13, 2020, 3 pm ET
Invitation to submit a full proposal	By 5 pm ET on January 15, 2021
Full proposal due	March 12, 2021, 3 pm ET
Notice of Award	End of May 2021
Award Start Date	July 1, 2021

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 Instructor or Assistant Professor rank to: 1) conduct an outstanding clinical research project with high significance to improve human health, 2) enable research time protection to ease the tension between research and clinical responsibilities, and 3) facilitate development of strong mentorship relations in a supportive institutional environment. Ultimately, the CSDA program aims to enable physician scientists' achievement of independent and successful research careers.

AWARD INFORMATION

The 2021 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, 2021 - June 30, 2024. DDCF expects to fund approximately 12-18 applications in 2021. The priority of the CSDA program is to fund outstanding individuals with promise for meaningful 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

New this year: Based on input from our Scientific Advisory Council, Instructors at any qualifying institution are eligible to apply, in addition to physician scientists at the Assistant Professor level. To be

eligible for a CSDA, “Instructors” must have a **full-time, post-training faculty appointment**. Please note that fellows in subspecialty fellowship programs who received the title of “Instructor” but who are still in training are not eligible. CSDA applicants must be junior faculty who have completely finished all training (residency, fellowship, and any research years post-fellowship but prior to faculty) and have been in a full-time faculty position for at least one year but no more than four years.

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 Instructor or Assistant Professor. We understand that COVID-19 has negatively affected research productivity and will be mindful of this general impact when evaluating applications for this competition. 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.
- Be junior, full-time faculty who have completely finished all training (residency and fellowship, or post-doctoral research if applicable). 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, 2021, will not be eligible for the award.
- Have been appointed to their first post-training, full-time Instructor or Assistant Professor faculty position between December 1, 2016, and December 1, 2019 (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 delays in career advancement due to COVID-19, family or medical leave, or for applicants whose eligibility is affected by the change in eligibility criterion for instructors (i.e., those who had post-training Instructor titles prior to Dec 1, 2016 and who planned to apply this year but no longer fit the new eligibility criteria). For COVID-19-related delays, exceptions of up to 6 months will be considered. 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 16, 2020. Exemptions are not granted for applicants with less than one year at their academic position.
- *Not* have served as the principal investigator of an extramural single or multi-principal investigator, multi-year (term >12 months) research grant, cooperative agreement, or contract with annual direct funding in the amount of \$225,000 or higher with a start date prior to and inclusive of July 1, 2021. 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. *National Institutes of Health (NIH) K-series career development awards and startup packages are excluded from this requirement.*

- *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, 2021. 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, 2021.
- 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 6 and will not be considered after October 16, 2020.

Other requirements and considerations

- A *clinical research* project—as defined by the Doris Duke Charitable Foundation—in any disease area must be proposed. DDCF’s definition of clinical research can be found on page 5. This program does not set funding priorities based on research type or disease area. The clinical research question should have strong potential to impact the corresponding field and be achievable within the scope of the award amount and 3-year term. To learn more about the breadth of fields and research types funded in past competitions, please see grantees of the program at <https://www.ddcf.org/grants/Grant-Recipients/>.
- 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 6.
- 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, 2021. IRB approval **must** be in place by October 1, 2021. See page 6.

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.

APPLICANTS FROM GROUPS UNDERREPRESENTED IN BIOMEDICAL RESEARCH

The Doris Duke Charitable Foundation recognizes that a diverse workforce that represents the demographics of the population of the United States is better poised to address health issues affecting all communities. DDCF strongly encourages individuals from groups underrepresented in biomedical research to apply because DDCF is committed to the retention and advancement of early-career physician scientists who are conducting seminal clinical research and who belong to populations whose exclusion from research based on their race, ethnicity, gender, disability, sexual orientation, or lack of resources has resulted in underrepresentation in the workforce. DDCF defines individuals underrepresented in biomedical research as those who identify as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians and other Pacific Islanders, women, individuals with disabilities, LGBTQ+, or having overcome limitations in access to science afforded by privilege (e.g., coming from an environment with limited access to the knowledge, skill and ability required to enroll in and graduate from a health professions school; or coming from a family with an annual income below a level based on low-income thresholds according to family size published by the U.S. Bureau of the Census).

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 13, 2020, 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 8.

2. **Stage 2, full proposal application.** Submission of full proposals will be by invitation only after review of pre-proposal applications. By January 15, 2021, 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 12, 2021, at 3 pm ET. Applicants will be notified of the outcome of the competition at the end of May 2021.

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 health issue, whether related to a rare or common disease. Supportive mentoring and institutional environment should be evident as they are critical to building successful careers in research. 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 Attachment 1 on page 20.

Submitted pre-proposal applications are also evaluated for adherence to instructions. Compliance with formatting, application length, and information content is sought to ensure a fair review process. Non-compliant applications are not reviewed by the review panel. To avoid disqualification, we strongly encourage you to check your application against the list in Attachment 2 on page 22, which includes administrative compliance criteria.

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 in Stage 1. Written comments will be provided for full proposal applications in Stage 2 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 application.

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 (including health services and epidemiology), 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. Experiments that utilize non-human animals or any tissues derived from them, including established cell lines, must not be included in the proposed research.

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.

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 12, 2021, 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, 2021. Institutional Review Board approval **must** be in place by October 1, 2021. 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 16, 2020, 5 PM ET

All eligibility criteria exemption requests must be submitted by **October 16, 2020, 5 pm ET**. Interested applicants must submit the form at <https://www.surveymonkey.com/r/CSDA2021>. 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, childcare, elder care, or medical conditions. Typically, the amount of time beyond fourth year that can be exempted equals the sum of leaves. For COVID-19-related delays, exceptions of up to 6 months will be considered.
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.

A copy of the [Eligibility Exemption Request Form](#) is provided here *only for reference* so you can gather the necessary materials. 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 21**,

2020.

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 "2021 CSDA – your 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 the foundation. For this reason, we strongly encourage applicants to contact us via email.

STEP-BY-STEP INSTRUCTIONS ON HOW TO PREPARE AND SUBMIT A COMPLETE PRE-PROPOSAL APPLICATION

OVERVIEW OF HOW TO SUBMIT AN ONLINE PRE-PROPOSAL APPLICATION

A complete pre-proposal application consists of (1) electronic confidential support forms submitted by the mentor and the department chair at the applicant's request; and (2) a pre-proposal attachment and project information submitted via the online pre-proposal application form. The detailed components of the complete pre-proposal are described in the checklist on the next page. Please note that partially completed applications will be disqualified from the competition. To begin a pre-proposal application submission, do the following:

1- Visit

https://ddcf.smapply.io/prog/csda_mentorship_and_institutional_commitment_form_request to send a request to the mentor and department chair to fill out electronic confidential support forms. Read more about the support forms on page 10. We suggest that you visit this site to make requests well in advance of the deadline so that the mentor and department chair receive timely instructions on how to submit the confidential forms. Mentor information provided here must match that provided in the online pre-proposal submission form. **Note** that the site to request support forms from the department chair and mentor is different from the pre-proposal form submission site.

2- Obtain the *nine-digit 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 number.* Applicants at public universities may need to check with their university foundations for the correct tax ID. Only tax IDs from organizations with 501(c)(3) status are recognized by the online application system. If the tax ID is not recognized by the online application system, please see our [FAQs](#) and verify with your institution that you are using the appropriate tax ID number.

3- Start an online pre-proposal form at

https://www.GrantRequest.com/SID_1149?SA=SNA&FID=35114 and complete the eligibility questionnaire. Upon completion of the questionnaire, eligible applicants will gain access to the pre-proposal application form. Once you gain access, we strongly suggest that you bookmark [this website](#), download the applicant biographical sketch template and ensure that all required information has been gathered in advance of the deadline. *Please use the bookmark to return to a pre-proposal form in progress. Using the first link to start an application will create multiple new forms.*

Note that the pre-proposal application site is different from the site listed in #1 above, and **both sites must be visited** to complete an application.

Use the table on the next page to see a summary of the information required to submit a pre-proposal application.

Summary of Pre-proposal Application Components

A complete pre-proposal application consists of:

		<i>Instructions on page</i>
	Online confidential support forms (applicant must visit https://ddcf.smapply.io/prog/csda mentorship and institutional commitment form request)	10
<input type="checkbox"/>	I. Mentorship form	
<input type="checkbox"/>	II. Institutional commitment form from the department chair	
	Online pre-proposal application form (See the corresponding page for the web address; the site is different from the one above. Make sure you visit both and submit the corresponding forms)	13
<input type="checkbox"/>	III. Principal Investigator information and affiliations	
<input type="checkbox"/>	IV. Project information	
<input type="checkbox"/>	V. Mentor information	
<input type="checkbox"/>	VI. Contact information for the department chair who will provide confirmation of institutional support	
	VII. Principal investigator demographic information	
	Pre-proposal application attachment (assembled into one PDF document) Submitted through the online pre-proposal application form	15
<input type="checkbox"/>	VIII. Biographical sketch of the applicant, with funding information (use this template), 3-page limit not counting funding information)	15
<input type="checkbox"/>	IX. NIH format biographical sketch of the mentor(s) using the NIH template, 5-page limit	17
<input type="checkbox"/>	X. Research plan description (2-page maximum)	17
<input type="checkbox"/>	1. Career accomplishments and research experience	
<input type="checkbox"/>	2. Significance of the proposed research	
<input type="checkbox"/>	3. Goal of the proposed project and research specific aims	
<input type="checkbox"/>	4. Study design overview	
<input type="checkbox"/>	5. Role of the CSDA in the transition to independence	
<input type="checkbox"/>	XI. Cited literature (required, no page limit, does not count toward the research plan page limit)	18
	XII. Sponsored research office letter to confirm eligibility, review, and approval of the submission	18

ONLINE CONFIDENTIAL SUPPORT FORMS

A complete application will include two confidential online forms: (1) Mentorship Form submitted by a designated mentor, and (2) Institutional Commitment Form submitted by the department chair. These forms provide data about the applicant, the designated mentor and plans for mentorship, and the institutional commitment to provide research time protection for the applicant. Outstanding mentorship and institutional environment are critical to success in this competition. Below are descriptions of the mentorship and institutional support expected for this award.

Mentors and department chairs will automatically receive the guide in Attachment 3 on page 23, when you request that they fill out the Mentorship and Institutional Commitment forms, respectively. Attachment 3 is provided here only for reference.

I. Mentorship Form

Mentors are expected to play an active role during the course of the Clinical Scientist Development Award in fostering the applicant's career advancement 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.

The foundation recognizes that the mentor functions described may be more adequately fulfilled by a team rather than an individual mentor. Though not required, applicants may opt to engage a mentorship team rather than a single mentor. Applicants with mentorship teams must, however, designate a mentor to fill out the mentorship form. Designated mentors will be evaluated for their research and mentorship accomplishments, including current research funding, and will be responsible for briefly describing the mentorship team if applicable. Mentors from institutions outside of the applicant's may be included if they would strengthen the applicant's research experience or would expand access to knowledge that will enable a successful research career.

The mentorship form asks for brief remarks about the applicant. Mentors are asked *to avoid* referring to personal circumstances or attributes of the applicant, such as: marital status, age or gender (e.g., young, woman, man), juggling of work-life balance such as child care responsibilities or illness, and roles of the applicant outside of the professional setting (e.g., mother, husband, father).

PLEASE NOTE: The peer-review of pre-proposal applications evaluates the ability of the designated mentor to enable career development of the applicant; therefore, this mentor cannot be switched for another nor replaced after submission of the pre-proposal application. Letters on institutional letterhead will not be accepted in lieu of the mentor form nor in addition to it.

II. Institutional Commitment Form

The institutional commitment online form must be provided by the applicant's department chair to confirm the applicant's appointment term, that the required research time protection (75%) will be provided if selected to receive the Clinical Scientist Development Award, and that there is

commitment to the applicant's research and career advancement. *Division chiefs in the departments of Medicine or Pediatrics may provide this form only if they are authorized to provide the information above.*

Applicants will have an opportunity to ask department chairs (or division chiefs for Medicine and Pediatrics) to write full letters of institutional support if they are invited to submit a full proposal. As with the mentor form, changes to the name of the individual providing the Department Chair Form are not allowed in the second stage of the competition, except when the person in that role changes. Letters on institutional letterhead will not be accepted in lieu of the form nor in addition to it.

Instructions on how to request online confidential forms from a mentor and the Department Chair

- Before going to the site below, applicants will need the following information for both the mentor and the department chair:
 - First name and last name
 - Institutional email address
- Alert the mentor and department chair to expect email requests from the address noreply@mail.smapply.net. It is advisable to add this address to the safe senders list to avoid email requests from being blocked by spam filters.
- Visit https://ddcf.smapply.io/prog/csda_mentorship_and_institutional_commitment_form_request and bookmark the page. We recommend that applicants visit this site as soon as possible and well in advance of the deadline so that the mentor and department chair can complete their confidential electronic support forms ahead of the deadline **November 13, 2020, 3 pm ET. Late submissions will not be accepted.**
- Click "Apply" on the homepage and follow the instructions:
 - For New Applicants:** Click "Register" on the top right corner of the login page next to "Don't have a SurveyMonkey Apply account?" Follow the prompts to create a login using the applicant's email address as the username. We suggest using the same institutional email address as for the online pre-proposal form.
 - Note: if a returning applicant attempts to register, the user will be prompted instead to login with the existing password associated with the applicant's email to access the forms. The applicant can choose to reset their password at this time if necessary.*
 - For Returning Applicants:** Login using your previous credentials, you may also reset your password as needed.

For issues with account logins, contact Apply Customer Support by selecting the "Information (i)" icon on the upper right corner of the homepage and selecting "Having technical issues with this site?" Instructions for login assistance can be referenced [here](#).

- On the landing page, you will see two tasks: 1) Mentorship Form and 2) Institutional Commitment Form. Click on “Mentorship Form” to send a request for the designated mentor to fill out a Mentorship Form. An optional message may be included for the mentor.
- Repeat the previous step to request the Department Chair to complete an Institutional Commitment online form.
- Upon submission of their contact information, an automatic email will be generated for each of the two individuals. This email will include instructions on how to complete electronic confidential support forms for the applicant’s pre-proposal application and a *unique* link to log into the portal for the relevant form.

Please make sure you are confident in your selections so that unnecessary emails are not distributed.

Once the applicant sends requests to the mentor and chair, a half-filled green circle will appear by each of the two tasks as pictured below. The circle indicates a request has been made.



- Applicants will receive a notification email from noreply@mail.smapply.net once each individual agrees to complete their form in support for your application and a confirmation email when they submit their electronic support form. Applicants should receive a total of two notice of acceptance emails and two submission confirmation emails.
- Another way to check if a submission has been made by the mentor and department chair is to click on each of the tasks and look for a green check next to the mentor and department chair name and email address as shown below.



- Once both forms have been submitted by the corresponding individuals, you will receive a third email to confirm that the submissions done through this website are complete. If you do not receive an email, please check your spam folder. Please note that the online confidential support forms are only part of the application. Be sure to also submit a complete Online Pre-proposal Form.
- If necessary, applicants can replace the contact information for the mentor and department chair up to deadline. If any of these individuals did not receive the email with instructions, we recommend that the applicant delete and add them again. We also recommend that email recipients check their junk mail folder or email spam filter.

- It is the applicant's responsibility to ensure that the supporting forms are completed by the deadline. **Late submissions will not be accepted.**
- Pre-proposal applications missing the electronic confidential support forms from their mentor or department chair will be disqualified without notice.

ONLINE PRE-PROPOSAL FORM

Complete the electronic form by entering the following information:

III. Principal Investigator and affiliations

- First name, middle initial and last name
- Telephone number
- Institutional email address; commercial email addresses such as Gmail, Yahoo, etc. are not acceptable
- Office address
- Post-baccalaureate academic degree(s), institution and year
- Current appointment title
- Additional current job titles
- Institution name
- Current faculty appointment start date
- Department name
- Tenure information
- Title of first faculty-level appointment and whether this was full or part-time
- Date of first faculty-level appointment
- Institution where the applicant held her/his first faculty-level appointment
- Date of completion of the most recent fellowship
- Field(s) of research training (select from the list)
- Clinical specialty and subspecialty
- Training completion confirmation
- US Medical license confirmation
- Percent professional effort currently allocated to patient care, research, teaching, administration, and other
- Other funding information (K and R01 level awards)
- Number of first author peer-reviewed original reports
- Confirmation that the applicant does not have other funding as principal investigator for a multi-year research grant with annual direct costs of \$225,000 or higher at the time of application and up to July 1, 2021.
- Annual direct cost dollar amount of your largest current or pending multi-year grant as a principal investigator

IV. Project information

- Project title (up to 255 characters)

- Primary disease area (select from the drop-down list)
- Primary biomedical/health research area (select from the drop-down list)
- Research classification (select from the drop-down list)
- Research approach (select from the drop-down list)
- Abstract (up to 250 words)
- Experimental systems to be used in the proposed experiments and their source
- Project IRB and IND requirement and approval information. IRB approval 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 12, 2021, 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, 2021. Institutional Review Board approval must be in place by October 1, 2021.

V. Mentor information

Please provide the information below about the mentor (or mentors, if applicable):

- First name, middle initial and last name
- Highest academic degrees
- Title
- Department
- Institution
- Office address
- Email address

Applicants with mentorship teams:

- The contact information for up to three mentors may be provided in this online application form. If the team is larger, the designated mentor will be responsible for indicating the composition of the team in the confidential online Mentorship Form.
- Make sure that the information of the first mentor listed matches that of the mentor designated to fill out the Mentorship form, as indicated at the mentorship and institutional commitment form request site.

VI. Department chair or division chief in Internal Medicine or Pediatrics information

Please make sure that this information matches what you provided for the Institutional Commitment Form request.

- First name, middle initial and last name
- Highest academic degrees
- Title
- Department
- Phone number
- Institutional email address

VII. Principal investigator demographic information

DDCF recognizes the value to clinical research of a diverse workforce that is representative of the demographics of the United States. We collect applicant data on race, ethnicity, gender, disability, sexual orientation, and barriers in access to resources that may have limited participation in research. Please help us improve our processes by providing your optional responses. Individual information will be kept on a secure server, will not be provided to the review panel, and will only be described in aggregate.

PRE-PROPOSAL APPLICATION ATTACHMENT

For the review of pre-proposals, the foundation adds a cover page to each pre-proposal attachment. The cover page will include information that you provide through the pre-proposal submission form such as your name and institution, project title, abstract, etc. When assembling your pre-proposal attachment, do not include any additional pages (e.g., cover page, photos of the applicant, table of contents, abstract) beyond the required content. *Including additional pages might result in disqualification from the competition as described in Attachment 2 on page 22.*

The following components must be assembled into one PDF:

VIII. Biographical sketch of the applicant (3-page limit not including funding information, use the [template provided here](#))

Note that this is not the NIH template. ***Applicants are asked to use the DDCF template to provide this information or risk disqualification from the competition.*** Applicants can also download the biographical sketch template upon login to the online pre-proposal application form.

- The default font size in the template is 11-point but may be decreased to a minimum of 10-point font.
- *Do not remove section or sub-section headers if no items are available to list under each one of them. Instead, indicate “none” or “not applicable.”*
- Do not attach copies of publications.

Please complete all sections of the biographical sketch:

- Indicate the applicant name and current faculty position.
- Education and training: Indicate education history in chronological order from oldest to most recent beginning with Baccalaureate degree or equivalent. Indicate the field of study, the name of the degree-granting institution, and the date when the degree was awarded.
- Explanation of gaps in career trajectory or resilience in overcoming obstacles in your path to becoming a physician scientist: This is an optional section for applicants to contextualize their scientific achievements given gaps in career trajectory or resilience in overcoming obstacles encountered in their path to becoming a physician scientist. In no more than 3 sentences, you may also address gaps in training or productivity that resulted from life events such as family or medical leave and the COVID-19 pandemic-related research disruptions.

- Positions and employment: Indicate all positions held in chronological order beginning with the earliest position and ending with the most recent. For each position, indicate the start and end date, position title, name of the institution/organization, and location.
- Other experience and professional memberships: List memberships and advisory roles.
- Honors: List the year and name of recognition awards and honors.
- Peer-reviewed original research reports:
 - First and last author original reports must be listed *separately* from non-first or last author reports. Publications in which the applicant is neither first nor last author should be listed under “additional publications.”
 - No abstracts, reviews, chapters, or publications in preparation may be listed.
 - Publications related to the proposed research plan should be **highlighted in bold font**.
 - Publications must be numbered as indicated in the template.
 - If the limited space does not allow you to fit all your publications, choose those that are most relevant to the pre-proposal application but do not exceed 3 pages and indicate how many out of a total are listed (e.g., 15 of 40 listed).
- Non-peer reviewed original research reports in preprint servers
 - First and last author original preprints must be listed separately from non-first or last author preprints. Preprints in which the applicant is neither first nor last author should be listed under “Additional non peer-reviewed original reports in preprint servers.”
 - To cite preprints, the Digital Object Identifier and any information about the document version (e.g., most recent date modified) must be included in the citation in addition to the authors, title, and preprint server name.
- Original dataset contributions
 - The suggested citation format is: Name of the data creator (publication year). Title. Version. Publisher. Identifier.
 - If available, indicate metrics of use such as number of views or requests to access the dataset, downloads, and citations.

Funding information (no page limit, this information does not count toward the biographical sketch page count)

- Sources of funding should be listed under two headings: Research Support as Principal Investigator and Other Research Support (not as principal investigator).
- Sources of funding include all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional or industry awards.
- List each funding source under the appropriate funding status heading: past, current, pending, or applied.
 - Past: Awards that have ended in the past 3 years.
 - Current: Currently funded awards.
 - Pending: Notification of award was received, but grant agreement is not yet in place.

- Applied: Application was submitted, and the funding status remains to be determined. Please disclose all funding applications clearly indicating the required details below. This information will help reviewers and the foundation assess your research activity and understand if overlap exists between concurrent applications and your plans if overlapping applications are recommended for funding.
- For each source of funding indicate:
 - Principal Investigator name
 - Role: indicate this only for sources of funding where the applicant is NOT the principal investigator
 - Percent effort
 - Award Type and Number: Award type refers to the NIH activity code (K08, U01, etc.), or award name for non-NIH awards.
 - Funding Agency/Institution
 - Annual Direct Costs: For contracts, list only the direct cost amount that supports your research directly and not the full contract amount.
 - Total Award (direct and indirect costs): For contracts, list only the amount that supports your research directly and not the full contract amount.
 - Project Period (start and end dates)
 - Project Name
 - Brief Project Description
 - Indicate if the project is related to or overlaps with the work proposed
 - If yes, indicate the project's relationship to the work proposed in this application. If overlap with the CSDA application exists for sources under the "Applied" category, indicate how you plan to resolve the overlap should both applications become funded.

IX. Biographical sketch of *each* mentor (5-page maximum for each biographical sketch)

The biographical sketch of mentor or each of the mentorship team members (if applicable) must be in NIH format and must include research funding information also in NIH format. Mentor biographical sketches must be prepared using the NIH format, not the DDCF template.

X. Research plan description (2-page maximum)

- **Font:** Use 12-point font size throughout unless noted otherwise. Smaller font sizes are acceptable for use in tables and figure legends.
- **Page Margins:** Page margins must not be smaller than 0.5 inch on all sides.
- **Color Figures:** Applicants may include color figures as reviewers will be provided with the electronic pdf that you submit.

Applicants **must include all five sections** described below in the two-page limit. As you begin to work on your research plan, we strongly recommend that you copy/paste the five section headers below into your working document to ensure that all sections are included. *Pre-proposals with research plan descriptions not including these explicit sections in the order listed, or including additional sections, may be disqualified from the competition:*

1. Career accomplishments and research experience
 - List and describe your three most significant professional accomplishments. If your accomplishments and experience involve collaborative efforts, highlight your original contributions.
2. Significance of the proposed research
 - Why is the proposal important and original?
 - How will the proposed research impact or improve patient care or human health?
 - What is the expected societal impact of the proposed research in the context of your larger body of work?
3. Goal of the proposed project and research specific aims
 - What is the question to be addressed?
 - State the hypotheses that form the basis for the proposed research.
 - State and describe the specific aims that you intend to accomplish with the award.
4. Study design overview
 - Briefly describe the experimental design that would be used to accomplish the specific aims of the project.
 - Detailed methodology description is not required for the pre-proposal application.
5. Role of the CSDA in the transition to independence
 - In one brief paragraph, describe how the CSDA would contribute to your career advancement, research program, and future attainment of R01 funding or equivalent.

XI. Cited literature

Cited literature is required and does not count toward the 2-page limit. 10-point font size may be used.

XII. Letter from the Office of Sponsored Research

Include a signed letter on institutional letterhead from your institution's Office of Sponsored Research to confirm that you are eligible for the award, that the application has been reviewed, and that the office approves of this application.

PLEASE NOTE

- Pre-proposal applications **will not be accepted after 3 pm ET on November 13, 2020**. The online application system shuts down automatically at the deadline.
- After the deadline, applicants with incomplete pre-proposal applications and those not adhering to instructions will be removed from the competition without notice.
- Only pre-proposal applications submitted through the DDCF online pre-proposal form will be accepted.
- Applicants whose mentor or department chair does not provide the electronic confidential support forms will be removed from the competition without prior notice. It is the responsibility of the applicant to ensure that this information is submitted by the deadline. Please note that the

deadline for submission of the confidential forms is the same as for the applicant, **3 pm ET on November 13, 2020**. Late submissions will not be accepted.

- Mentorship or institutional support letters on letterhead will not be accepted in lieu of the electronic confidential support forms. Applications missing electronic confidential support forms will be removed from the competition without notice.
- Pre-proposal applications that do not meet the page limits and formatting instructions will not be considered for review.
- Pre-proposal applications with research plans that do not include the required sections, in the specified order, will not be considered for review.
- The submission of a pre-proposal application is final, and modifications are not usually accepted.
- The maximum size for the attachment is 1000 MB. Please note that files with certain extensions (such as “exe”, “com”, “vbs” or “bat”) cannot be uploaded.
- If you have applied for or plan to apply for another grant that could be funded with a start date before or on July 1, 2021, we strongly encourage you to avoid proposing research with budgetary overlap with your CSDA project.

QUESTIONS?

Please consult our online [Frequently Asked Questions](#) or email Joanne Sullivan at ddcf@aibs.org with “2021 CSDA - your last name” as the subject line. Questions will be answered within two business days. No phone calls, please. Calling may delay your question from reaching the appropriate contact. We can more efficiently address your questions over email.

ATTACHMENT 1

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. If applicant has provided an optional explanation of gaps in career trajectory or resilience in overcoming obstacles encountered in their path to becoming a physician scientist, including impacts of COVID-19, reviewers will consider this information to contextualize the applicant's achievements.
- Evidence and quality 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. Applicants with delayed career trajectories due to justified extraordinary circumstances will not be penalized for the lost time. 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 and Institutional Environment

- Evidence of the mentor's successful research career, including grant support.

- Evidence that the mentor(s) and institution will actively foster the applicant's research and 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.

Significance

- Impact on human health. Does the disease or health issue being studied pose a major clinical burden (with considerable morbidity and mortality for affected individuals, whether it is a rare or common condition) or has the potential to improve the health of marginalized communities?
- Likelihood of the research to influence the field, lead to improvements in human health, and advance the career advancement of the applicant.
- Potential of the research, if carried out successfully, to fill critical gaps in evidence or knowledge.
- Significance of the societal impact of the proposed research in the context of the applicant's larger body of work.

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.

ATTACHMENT 2

2021 Clinical Scientist Development Award Administrative Compliance Criteria

We recommend checking your proposal against this list of items that, if not met, will result in disqualification from the competition. Using this list will ensure that your pre-proposal is reviewed.

- Eligibility criteria: Do you meet all eligibility criteria? Unless an exemption was approved, ineligible applicants' pre-proposals are not reviewed.
- Mentorship form was submitted
- Institutional commitment form from the department chair, or division chief in Internal Medicine or Pediatrics, was submitted
- The instructions for the 2021 competition were used to prepare the application. Using instructions from previous competitions will likely result in disqualification as the instructions are revised annually.
- Pre-proposal attachment is a single document assembled as instructed
- Pre-proposal attachment was uploaded to the online application form
- Biographical sketch of the applicant is no more than 3-pages long (not including funding information)
- Biographical sketch of the applicant used the template provided
- Biographical sketch of the applicant is part of the pre-proposal attachment in the instructed order
- NIH-format biographical sketch of the mentor(s) are included as part of the pre-proposal attachment in the instructed order
- Research plan description is part of the pre-proposal attachment in the instructed order
- Research plan description is no more than 2-pages long
- Research plan description includes all five, labeled, required sub-sections
- Cited literature is included as part of the pre-proposal attachment as instructed
- Sponsored research office letter is included as part of the pre-proposal attachment as instructed
- Extra pages such as cover page, table of contents, publications, abstracts, headshots, etc. are not included. We add a standard cover page to each application for review, so please do not include one. Including any items not requested as part of the application might disqualify applications.

ATTACHMENT 3

Information for Mentors and Department Chair of applicants to the Doris Duke 2021 Clinical Scientist Development Award

The purpose of the Doris Duke Charitable Foundation Clinical Scientist Development Award is to provide research support and enable research time protection for early-career physician scientists in their transition to independent project research grant funding. The award is highly competitive and successful applicants have outstanding research plans, mentors and institutional support to facilitate the transition to independent research funding. Supportive mentoring and institutional environment should be evident as they are critical to building successful careers in research.

The Doris Duke Charitable Foundation recognizes that a diverse workforce that represents the demographics of the population of the United States is better poised to address health issues affecting all communities. Therefore, the foundation values mentor and institutional efforts to achieve diversity, equity, and inclusion in biomedical research.

Applicants to the Clinical Scientist Development Award will request a designated mentor and the department chair each to complete a confidential online form in support for their application by **3 pm ET on November 13, 2020**. The Mentorship Form will be submitted by a designated mentor and the Institutional Commitment Form will be submitted by the department chair. If the designated mentor is the department chair, this person must submit each of the two forms. Please see the corresponding section for specific guidance based on your role in the application.

The mentor, or the designated mentor for applicants with a mentorship team, and the department chair will receive an email message from noreply@mail.smapply.net requesting completion of a Mentorship Form or Institutional Commitment Form, respectively, **by 3 pm ET on November 13, 2020**. It is advisable to add this address to the safe senders list to avoid email requests from being blocked by spam filters.

The email will include instructions on how to complete the corresponding electronic confidential support form for the applicant's pre-proposal application and a *unique* link to log into the portal for the relevant form. Mentors and department chairs will need to create an account to access their respective forms by clicking "Register" on the top right corner of the login page. Please note that the same instructions apply for mentors and chairs who have participated in prior competitions; they will receive the same invitational email but will simply login instead of creating an account. If returning users attempt to register, they will be prompted to login with existing credentials, at which point they may reset their password.

For issues with account logins, contact Apply Customer Support by selecting the "Information (i)" icon on the upper right corner of the webpage and selecting "Having technical issues with this site?" Instructions for login assistance can be referenced [here](#).

Mentorship Form (for mentors)

Mentors are expected to play an active role during the course of the Clinical Scientist Development Award in fostering the applicant's career advancement 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.

The foundation recognizes that the mentor functions described may be more adequately fulfilled by a team rather than an individual mentor. Though not required, applicants may opt to engage a mentorship team rather than a single mentor. Applicants with mentorship teams will designate a mentor to fill out the Mentorship Form **by 3 pm ET on November 13, 2020**. Designated mentors will be evaluated for their research and mentorship accomplishments, including research funding, and will be responsible for briefly describing the mentorship team if applicable. Mentors from institutions outside of the applicant's may be included if they would strengthen the applicant's research experience or would expand access to knowledge that will enable a successful research career.

The Mentorship Form will ask the designated mentors about:

1. Their name, academic title, and field of research
2. Their active research funding
3. Their experience as mentors
4. The applicant's knowledge and ability to direct the project
5. Brief remarks (1500-character limit, including spaces, tabs, carriage returns, etc.) to indicate:
 - Why the applicant's record and accomplishments merit support from this award
 - Why the mentor has taken a mentorship role for this applicant
 - How the mentor, and the mentorship team if applicable, will use their professional influence and scientific knowledge to promote research and career advancement of the applicant in the transition to independent, R01-level funding
6. The mentor's racial equity and mentorship training, and resulting changes to mentoring activities
7. The mentor's role and effort to foster an environment that is inclusive and committed to promoting the career of the applicant, if the applicant is from a group underrepresented in biomedical research.

In the remarks, mentors are asked to avoid referring to personal circumstances or attributes of the applicant, such as: marital status, age or gender (e.g., young, woman, man), juggling of work-life balance such as child care responsibilities or illness, and roles of the applicant outside of the professional setting (e.g., mother, husband, father). Letters on institutional letterhead will not be accepted in lieu of the mentor form nor in addition to it.

Institutional Commitment Form (for department chairs or division chiefs, if applicable)

Department Chairs will receive an email message from noreply@mail.smapply.net requesting completion of an Institutional Commitment Form in support of the applicant by **3 pm ET on November 13, 2020**. It is advisable to add this address to the safe senders list to avoid email requests from being blocked by spam filters. Division chiefs in the departments of Medicine or Pediatrics may provide this form only if they are authorized to provide assurance of the research effort protection required by the award.

The Institutional Commitment Form will ask department chairs, or division chiefs if applicable, to indicate:

1. Their name, academic title, and department
2. The applicant's official current appointment title rank, appointment track, start date, confirmation of full-time appointment, date of the last salary review for the applicant, and where the applicant's salary falls in the salary distribution for faculty at the same faculty level
3. Confirmation of the applicant's current clinical effort
4. Assurance that the department will guarantee 75% time protection for research if an award is made
5. Departmental resources being made available to advance the research and career of the applicant, including the existence of a standing oversight committee to assist the applicant with career and research progress, independent of the mentorship team
6. Additional remarks (1500-character limit, including spaces, tabs, carriage returns, etc.) to confirm:
 - The Department/Division protection of at least 75% research time protection for the applicant
 - How the institution will support the applicant's research and career advancement
7. Information about the department's plans to advance diversity, equity, and inclusion
8. Description of additional resources being provided to the applicant, if from a group underrepresented in biomedical research, to foster an environment that is inclusive and committed to promoting the career of the applicant

In the remarks, department chairs are asked to avoid referring to personal circumstances or attributes of the applicant, such as: marital status, age or gender (e.g., young, woman, man), juggling of work-life balance such as child care responsibilities or illness, and roles of the applicant outside of the professional setting (e.g., mother, husband, father). Letters on institutional letterhead will not be accepted in lieu of the form nor in addition to it. Applicants will have the opportunity to ask department chairs (or division chiefs for Medicine and Pediatrics) to write full letters of institutional support if they are invited to submit a full proposal.