



Doris Duke Medical Research Program Guidelines and Policies

Introduction

The following policies and guidelines apply to the Doris Duke Charitable Foundation's (DDCF) Medical Research Program. Note that this information is provided *for guidance only* to current and potential grantees. It does not supplant the information or terms contained in DDCF grant agreements. In the event of a conflict between these policies and guidelines and the DDCF grant agreement, the provisions in the DDCF grant agreement shall take precedence.

If you have questions regarding these policies, please [contact us](#).

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I. Restriction on use of animals

In her will, Doris Duke expressed her desire to promote medical research designed to effectuate cures of major diseases, provided that no animals are used to conduct such research. In keeping with those wishes, the Doris Duke Charitable Foundation does not fund research that uses non-human animals.

II. Use of human subjects

All research conducted as part of a DDCF Medical Research Program award involving human subjects must comply with appropriate federal, state and local regulations pertaining to the use of human subjects in research, including all requirements of the United States Department of Health and Human Services. No part of the grant may be used to support any research involving human subjects that does not have the approval of the appropriate Institutional Review Boards (IRB). Appropriate IRB approvals must be in place before research involving human subjects commences (with copies of IRB approvals submitted to DDCF) and must thereafter be maintained and in effect throughout the research project. All federal, state and local regulations and policies governing the conduct of research must be followed without exception, including, but not limited to those relating to human subject protection, radiation and environmental health and safety.

The grantee institution is responsible for ensuring that the research conducted as part of this grant is in compliance with all relevant federal, state and local policies and regulations. DDCF must be notified immediately if there are any regulatory issues, protocol violations or policy changes that impact the ability of the grantee to conduct the research as part of this grant.

III. Investigational New Drug approvals

DDCF grant funds cannot be used to support any part of research aims that require Investigational New Drug (IND) approval(s) by the FDA (or its equivalent when the research project is conducted outside the U.S.) until the required approval(s) has been received by grantee. Evidence of IND approvals must be submitted to DDCF before research subject to approval commences.

Generally, IND approval is necessary at the time of application for a DDCF grant. . If you are applying for a DDCF grant, please refer to that program’s Request for Applications for specific details on whether IND approval is required for an application to be accepted for the competition.

IV. Clinical trial registration

All clinical trials supported in part or in full by DDCF must be registered at <http://www.clinicaltrials.gov/>. DDCF uses the NIH definition of a “clinical trial,” which is “A research study in which one or more human subjects are prospectively assigned to one or more intervention (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.”

View source: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html>

V. Allowable costs

DDCF allows the following direct and indirect costs as part of Medical Research Program grants.

Direct costs are those expenses that are clearly identified with and charged to a specific research project. They include:

- Salaries and fringe benefits
- Consultant fees
- Equipment
- Consumable supplies
- Travel (suggested DDCF travel expense guidelines are included below)
- Subcontracts
- Tuition, books, publication fees
- Seminar and small meeting costs
- Data analysis and processing
- Patient costs

Indirect costs, sometimes referred to as facilities and administration costs or overhead, are costs incurred to conduct the standard business activities of an institution and are not readily identified with or attributable to a *specific* research project. The DDCF Medical Research Program generally caps indirect costs at 10% of the total of all direct costs, including equipment. However, we advise that you review your grant agreement and/or the request for proposal (RFP) as this percentage may vary.

The activities of an institution that might fall under indirect costs include:

- Research and grants administration
- Research committees (e.g., Institutional Review Boards, Biosafety Committees)
- Shared facilities

a. Travel Guidelines

DDCF awarded funds may be used towards reasonable and necessary travel expenses **related to the research supported by the grant**. The following table of allowable and non-allowable travel-related costs are given as a guideline; grantees should follow their own institutional policies when applicable. The list is not meant to be all-inclusive. Grantees seeking guidance about a particular expense should contact program staff for clarification.

| Allowable travel expenses | Non-allowable travel expenses |
|---|---|
| Coach or economy class airfare or trainfare Ground transportation, including taxis, public transportation, and services such as Uber Mileage reimbursement for use of personal car Standard or economy car rental Reasonable costs for meals (suggested amounts are \$25 for breakfast, \$35 for lunch and \$65 for dinner per person including tax and tip) Tips for hotel housekeeping, luggage assistance, and parking valets Airline charges for checked baggage and business packages Business office expenses at hotels (fax, copy services, business postage, etc.) Currency conversion fees Health club access fees while traveling Vaccines or prescribed medication required for travel Internet access fees Visas, passports, and country entry and exit fees Telephone charges | Activities primarily social in nature or for personal entertainment, even if business associates are included Frequent traveler program fees; travel paid for with frequent flyer miles; airline club memberships and dues Change/cancellation fees (airline, hotel, car service, etc.) unless due to a business necessity Barbers, hairdressers, shoe shine and spa services Car washes Child care or other family care expenses Expenses not associated with business travel for travelers extending their stay for personal reasons Personally obtained flight and travel accident insurance In-room videos/entertainment Laundry and valet service for trips less than five nights in duration Luggage damaged or lost in transit Normal commuting expenses Pet boarding fees Traffic/parking fines or citations |

- b. **Subcontracts:** Indirect costs are allowed within subcontracts that are part of a DDCF-funded project. Indirect costs that are part of subcontracts will count towards the *total* indirect costs of 10% allowed for the grant. Again, this percentage may vary based on the award program.

Unallowable costs

DDCF Funds cannot be used for the following activities:

- Acquisition, care, and use of experimental non-human animals or their primary tissues
- Lobbying
- Non-allowable travel expenses listed in the table above.

VI. Scientific and budgetary overlap

While DDCF anticipates and encourages grant recipients to apply for research support from other funding sources, the foundation requires that the DDCF grant be the exclusive source of support for budgeted items necessary to achieve the specific research aims described in a proposal and associated budget that is funded by DDCF. The grantee and the associated institution agree to:

- Adhere to the DDCF policy with respect to other funding requests;
- Notify DDCF immediately in writing upon receipt of any other funding for projects on which the DDCF grantee is the principal investigator or co-investigator so DDCF can determine whether or not there is scientific or budgetary overlap; and
- Work with DDCF toward appropriate resolution of overlap if a project with similar aims or budget items is funded.

VII. Progress/financial reporting

Progress and financial reports must be completed using the foundation's web-based application and reporting system. A link to the online report form that includes a template for the financial report and additional instructions will be emailed to the grantee approximately two months in advance of the due date. Please refer to your grant agreement for the specific date requirements of your progress/financial reports.

Generally, progress and financial reports are due on an annual basis. Progress reports should detail the scientific progress made, as well as provide updated IRB approval status, budgetary, expense and other support information. A separate financial report gives a detailed comparison of actual expenses to the approved line-item budget, as well as an explanation for any overages and/or unspent funds and a budget for the following year, when appropriate. The financial report should be signed by the appropriate financial officer of the grantee institution.

VIII. Budget approvals, rollovers, and allocation changes

For multi-year grants, budgets beyond the first year of the grant are generally approved on an annual basis. DDCF will authorize expenditure of funds based upon review of the annual progress and financial reports and proposed budget for the subsequent years. After receipt and review of a satisfactory report, DDCF will provide written notification to the grantee and the grantee institution that DDCF authorizes expenditure of funds, in accordance with the proposed budgets, for the upcoming year and the start of the following year. This allows spending to continue while the grantee awaits the next year's budget approval.

Funds budgeted but not spent in one year of a multi-year grant may be rolled into the following year's budget, with the approval of program staff. Budget revisions of 20% or more per line item of the current year's grant budget require DDCF approval through a written request to the program officer.

IX. Changes to research plan

DDCF grant funds may not be used for any other purpose or research project of the grantee institution without the prior written approval of DDCF.

The foundation must be consulted in advance if there are significant changes to the aims of the funded research project or in the event that any aspect of the research project is changed or redesigned.

X. Institutional transfers

If you are a current DDCF grantee planning a move to a new institution, please [contact us](#) as soon as possible and preferably at least three months prior to the transfer. While most transfers will be approved, DDCF must have confirmation that the new institution is eligible to receive DDCF grants and that it will host the transferred project. Please note that DDCF grants to institutions to run fellowship programs may not be transferred.

Program staff will work with you and your current and new institution to ensure a smooth transfer. Below is a summary of the general transfer process; other supporting documents may be necessary.

1. The grantee requests DDCF approval of a transfer with a letter detailing the last effective day at the current institution as well as the new position and start date at new institution.
2. The grantee submits following document to DDCF:
 - A brief progress report on project aims
3. Documents to be prepared by the grantee's current institution are submitted:
 - A final financial report
 - A refund check payable to DDCF for funds remaining in the grant
4. Documents to be prepared by grantee and institutional officials at the new institution are submitted:
 - Revised cover page for the research project proposal from the new institution, to include principal investigator and institution information, and signatures by grantee and authorized official at the new institution
 - A budget describing how the remaining grant funds will be spent at the new institution and clearly stating the start and end dates of the grant period.
 - IRB approval documentation
 - Official institutional letter confirming grantee's new academic appointment and institutional resources available to the grantee
5. DDCF issues a new grant agreement to the new institution, including a schedule for payment of the remaining grant funds.

The transfer is considered complete once all the steps above have been executed and DDCF has a signed new grant agreement with the new institution. Due to the time needed for the original institution to complete its financial reporting and to send any refund to DDCF, it may take as long as three to six months to complete the transfer process.

XI. No-cost extensions

Generally, if unspent funds are projected to remain at the conclusion of the funding period, DDCF will allow a no-cost extension with prior written permission. The maximum time period for a no-cost extension depends on the grant program. We recommend that you refer to the grant agreement to determine the maximum number of no-cost extension months allowed for your particular grant. During any approved no-cost extension period, indirect costs may be charged to the grant provided that total indirect costs charged over the entire grant period and extension do not exceed the total indirect cost allowance.

XII. Funding acknowledgement

All publications (as well as posters and/or abstracts at scientific meetings) reporting work funded by the grant should acknowledge that support in writing and specify the grant number. Acknowledgment for the grant should include use of the complete Foundation name, "Doris Duke Charitable Foundation," in any public documents pertaining to the grant. DDCF reserves the right to include information relating to the Grant in DDCF's periodic reports, newsletters or news releases or in any other materials issued by or on behalf of DDCF. In their grant agreement, grantees will find specific language to acknowledge funding.

XIII. Attendance and presentations at the Doris Duke meetings

Grantees are expected to attend regular meetings hosted by DDCF during their grant period. These in-person meetings allow DDCF Medical Research Program staff and advisors to meet with grantees and to evaluate whether research projects are progressing as intended. They also give grantees the opportunity to network with each other.

Details regarding meeting logistics and presentation guidelines are provided to the grantee several months in advance of meetings. Meetings generally require one night of lodging, which is paid for by the foundation. Grantees requiring more than one night of lodging are responsible for the additional costs. In addition, grantees must use grant funds to cover the cost of traveling to the meetings.

XIV. Public access publishing

The foundation requires that any publication based on a DDCF-funded research project must be made freely available and downloadable online in a timely manner and with as few restrictions as possible, in order to ensure that DDCF-funded research can be accessed, read and built upon. Starting with grants made in 2013, DDCF grantees and their institutions must agree to fulfill this requirement by depositing all documents accepted for publication resulting from their DDCF-funded research project into the National Institutes of Health's PubMed Central ("PMC") in accordance with the following stipulations:

- Documents are defined to include all authors' final manuscripts accepted for publication, including all modifications from the publishing and peer review process (the "postprints");
- Documents are to be deposited in PMC upon the grantee's receipt of notification of acceptance for publication;
- Grantees may impose an embargo on PMC's public release of the documents that ends no later than 12 months after the official date of publication.

Access to PMC is made available to the grantee through DDCF's membership in the [Health Research Alliance](#) (HRA) (a national consortium of non-governmental, nonprofit funders of biomedical research and training) and DDCF's registration of data about its clinical research grants in the [HRA reporter](#) database. DDCF will provide detailed instructions for depositing documents in PMC to grantees upon DDCF's receipt of a fully executed grant agreement.

XV. Sharing of grant information

DDCF reserves the right to include information relating to the grants that it funds in DDCF's periodic reports, newsletters or news releases or in any other materials issued by or on behalf of DDCF.

DDCF is a member of the Health Research Alliance (HRA) and has agreed to deposit grant information in a database of privately funded grants. The following grant information will be uploaded into this database: investigator name, degree(s), clinical specialty, Open Researcher and Contributor ID (ORCID), institution and institutional information, project title, abstract, grant start date and duration, and grant amount. The Health Research Alliance (HRA) aggregates these data for its member organizations and for periodic publication of findings. View more information on HRA reporter and use of these data by HRA members [here](#) .

XVI. Intellectual property and copyright

If any idea conceived or reduced to practice as a result of a DDCF grant results in material subject to patent or copyright, the disposition of any such rights and income derived therefrom shall be subject to the policies and procedures of the grantee institution, unless otherwise outlined in the grant agreement. In the event that the grantee institution has no such established policy, the foundation reserves the right to review and determine the disposition of any such rights and income.