



CCF RESEARCH GRANT APPLICATION 2018 REQUIREMENTS & GUIDELINES

The Children's Cardiomyopathy Foundation (CCF)'s Research Grant Program has a two-step application process. A letter of intent is required in advance of submitting a full grant application. Only investigators who have submitted a letter of intent and have been invited to submit a formal grant application will be considered for CCF funding. For more information on how to submit a letter of intent, please refer to the Letter of Intent Instructions document available on CCF's website. The 2018 deadline for letters of intent is Wednesday, June 13 by 5:00 p.m. eastern standard time.

The following instructions are for investigators who have already submitted a letter of intent and have been invited to submit a full grant application to CCF. Funding requests are limited to US \$50,000 total (direct costs only) for a one-year period. Requests for time extensions of grants need to be justified in writing and submitted to CCF before the end of the grant period.

Application Requirements

The research grant application should be no more than 16 pages in length including the application form and any figures or tables. The biographical information and publication list will not be counted towards the 16-page limit. Please read the document "CCF Research Funding Considerations" before writing the project abstract, lay person summary and research plan. The grant should be in the following format: single-sided, single-spaced, Calibri 12-point font, and 1-inch margins all around with page numbers at the bottom of the sheet. The application should contain the following sections:

1. **Application Form** (2 pages)

The provided cover sheet should be completed and signed.

2. **Project Abstract & Lay Person Summary** (2 pages)

Briefly and clearly state the nature, objective, procedures and significance of the proposed research and explain how the study furthers knowledge on pediatric cardiomyopathy and/or improves the treatment or diagnosis of the disease in children. The lay version of the abstract should be written for a non-medical person to understand. The lay summary may be used by CCF for communication and publicity purposes.

3. **Research Plan** (10 pages)

The narrative should cover the following areas in detail:

- Title of project
- Background & Significance: This should provide information on the scope of the problem, summary of population or elements to be studied, a critical evaluation of previous research

and existing knowledge, and insight into gaps in knowledge that the study intends to fill. The section should clearly indicate how study findings might impact the evaluation or medical management of children with cardiomyopathy.

- **Specific Aims:** This should present the broader research objectives as well as the specific study hypothesis to be tested in the project.
- **Research Design & Methods:** This should describe the experimental design and methods that are used to accomplish the specific aims. This section should describe how data will be collected, analyzed and interpreted. Any new methodology and its advantages over existing techniques should be mentioned. Potential difficulties and limitations of the proposed procedures along with alternative approaches should be mentioned. If the study involves human subjects, details on the study and control group criteria as well as the recruitment process should be provided.
- **Timetable:** This should specify the time required for study setup or patient recruitment, conducting the experiment, data analysis and evaluation, and dissemination of study findings.
- **Project personnel:** Each researcher's name, title, institution, role in project and percentage effort devoted to the project should be listed.
- **Resources & Environment:** This should describe the research facility, laboratory space and major equipment needed for the study. Any procedures, materials or situation that may be hazardous should be described along with the proposed precautions to be taken.

4. **Budget** (1 page)

- **Budget breakdown:** Include a itemized research budget for the proposed project stating the amount requested from CCF along with other confirmed funding sources. There is no specific budget form, but the budget should list direct cost items such as personnel, supplies and equipment. Project personnel should be listed by name, title, time/percentage effort and requested salary.

If the amount of the study exceeds what is being requested from CCF, please indicate other sources of funding or provide an explanation of how additional funding will be secured to complete the study.

Administrative overhead or indirect costs will not be covered by the grant and therefore should not be included in the budget. CCF does not cover institutional construction or renovation, purchase of capital equipment other than what is needed for the proposed research, office equipment or furniture, equipment service contracts, travel to medical meetings, tuition fees, journal subscriptions, dues or memberships, and publication fees.

- **Budget justification:** The narrative should explain the budget items and reason for the expense. For project personnel, an explanation of their project role should be included.

5. **Research Approval Letter** (1 page)

Biomedical research involving human subjects or animals require an Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC) letter of approval from the investigator's affiliated institution. If one is not available at the time of the application, a general institutional letter of support can be submitted. However, grant funding will be contingent on securing an IRB or IACUC letter of approval prior to the start of the study.

6. **Biographical Information and Publication List** (appendix)

Biographical sketches for key investigators involved with the study should include name, position, education, and training in chronological order as well as research and professional experience in chronological order. The NIH biosketch format is preferred, and an example can be downloaded from <https://grants.nih.gov/grants/forms/biosketch.htm>. Only publications from the past 5 years that are relevant to the proposed research topic should be listed.

Application Submission

A PDF copy of the proposal should be electronically submitted to grants@childrenscardiomyopathy.org no later than 5:00 p.m. eastern standard time on Friday, September 7, 2018. The required format for submission is as follows:

- All documents should be merged into one pdf file. This includes the cover sheet, application, biosketch and supporting documents.
- Documents requiring signatures (cover sheet, IRB or IACUC letter) need to be signed first, scanned and then merged into the full application file.
- The PDF file should be saved as "investigator first and last name_institution_2018." An example would be to name the file "John Smith_Univ of Miami_2018"

No extensions of the deadline can be made. Once submitted, a confirmation email will be sent by CCF.

In addition, one printed copy of the proposal, clipped together and not stapled, should be received no later than Wednesday, September 12, 2018. The proposal should be mailed to: Children's Cardiomyopathy Foundation, 66 Hoover Drive, Cresskill, NJ 07626.

For questions, please contact Lisa Yue, CCF founding executive director, at 866-808-2873 ext. 901 or lyue@childrenscardiomyopathy.org.

Application Review Process

Applications are reviewed in detail by CCF's medical advisors and discussed as a group to determine funding priority based on CCF's research criteria. The document "CCF Research Funding Considerations" provides information on the types of research studies that are commonly funded. Preference will be given to studies on primary cardiomyopathy and where no other funding organization exists for the form of cardiomyopathy being studied. A prioritized list is then forwarded to CCF's Board of Directors for final funding decisions.

Each research grant is carefully evaluated on the basis of:

1. Significance & Scientific Merit

- Does the study focus on understanding the genetic basis or causes of cardiomyopathy and its relationship to disease progression in children?
- What significant contribution will the study make to the understanding and/or treatment of cardiomyopathy in children?
- Is the research in-line with the research priorities of CCF?

2. Approach & Feasibility

- Are the conceptual framework, design, methods and analyses adequately developed, well integrated and appropriate to the aims of the project?
- Are potential risks and problems addressed and alternative methods recommended?
- Will the study be completed in the proposed timeframe and within the proposed budget?

3. Innovation

- Are the aims original and innovative?
- Does the project employ novel concepts, approaches and methods?

4. Investigator Qualification & Environment

- Does the investigator have the expertise and commitment to carry out the proposed work?
- Are all the required elements such as laboratory, technology, equipment, reagents, and human or animal subjects available for the project?

5. Ethical & Regulatory Adherence

- Is the study ethical and does it abide by HIPAA regulations?
- Will the study be conducted properly in accordance to IRB and IACUC regulations?

6. Prospect of long term funding

- What is the likelihood of getting subsequent NIH or other major funding to sustain the project and/or expand the research?

Final decisions on funding will be made by CCF's Board of Directors by January 31, 2018, and grant applicants will be notified by email or U.S. mail. All decisions about grant applications made by CCF are final and are not subject to appeal.

Research Grant Terms

Before CCF disburses funds to a grant recipient, the principle investigator (PI) will be asked to sign a funding agreement letter with the Children's Cardiomyopathy Foundation (CCF) which outlines the below research grant terms:

1. **Grant Period:** Grants are for one year of funding beginning from the time funds are received until the same time the following year. Extensions will be considered for delays if a valid reason is submitted in writing before the end of the grant period.

2. **Grant Payment:** Upon receipt of a signed CCF letter of agreement and letter of approval by the PI's Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC), CCF will award 50% of the grant award amount as start up funds. The remaining payments will be based upon meeting certain milestones and deliverables as outlined in CCF's letter of agreement. An additional 25% of the grant award amount will be provided upon submission of a detailed mid-year progress report. However, for studies that involve patient recruitment or acquisition of tissue/blood samples, additional payments will be contingent on the number of patients enrolled or samples acquired during the study period. Final payment is dependent on achieving the outlined aims in the proposed research study, submission of a detailed final report and confirmation that research findings will be/are presented at a recognized medical conference and/or that a manuscript has been accepted for publication in a peer reviewed medical or scientific journal. The milestones for disbursement of funds will be specified in the funding agreement letter.
3. **Grant Reporting:** The awarded PI shall provide a six-month progress report as well as a twelve-month progress report upon completion of the grant. Each report should include an accounting summary of grant expenditures and a narrative account of what was accomplished by the grant, including a detailed description of progress made towards achieving the research goals and any significant findings. If the grant period is longer than one year, a progress report and accounting summary shall be provided to CCF every six months unless otherwise noted. One year following the completion of the grant, the PI will be asked to provide a list of presentations, publications and/or subsequent funding received as a result of CCF's grant support.
4. **Site of Project:** CCF awards funding to public or private universities, hospitals and biomedical research institutions in the United States or Canada. The research shall take place only in the research facility specified in the submitted research proposal. In the event the PI leaves his or her affiliated institution, the PI shall immediately notify CCF of the changes and submit a status report and accounting of the funds spent to date. It is the responsibility of the PI to make necessary arrangements with their institution to permit transfer of any unused CCF research funds to the PI's new institution.
5. **Expenditures:** The grant is made only for the purposes stated in the research proposal and according to the proposed research budget. Any changes in a budget category equal to or greater than 10% of the total research grant amount must receive prior approval by CCF before funds are expended. The grant covers direct costs only, and funds may not be used for administrative overhead, construction or renovation, purchase of capital equipment other than what is needed for the proposed research, office equipment or furniture, equipment service contracts, non study related travel, tuition fees, journal subscriptions, dues or membership, and publication fees. At the end of the grant period, any unused funds shall be promptly returned to CCF.
6. **Grants Administration:** The grant funds shall be physically segregated, and such funds shall be shown separately on the PI's books for ease of reference and verification. Records of receipts and expenditures under the grant, as well as copies of reports submitted to CCF, shall be kept for a reasonable period of time following completion of such receipts and expenditures.
7. **Institutional Research Approval:** All CCF-funded research projects must conform to federal regulation requiring that all institutions maintain appropriate policies and procedures for the protection of the rights and welfare of human subjects and the safe and humane treatment of

animals used for research. A letter of approval from the PI's Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC) must be provided to CCF before the start of research study.

8. **Liability:** The PI assumes sole responsibility for conducting the research and supervising the work of co-investigators associated with the study and is therefore responsible for any negligent acts or omissions in connection with their research study. The PI and PI's institution shall indemnify and hold harmless CCF, its Board, advisors, agents and constituents from any claim, judgment, award, damage, settlement, liability, negligence or malpractice arising from accepting CCF's grant, expending or applying grant funds, or in carrying out the research study supported by the grant.
9. **Grant Suspension or Cancellation:** CCF reserves the right to suspend or cancel the funding agreement at any time at its sole discretion for failure of the PI to abide by CCF's grant terms. Upon receipt of a written notice of project suspension or cancellation from CCF, the PI should prepare and submit a project status report and accounting summary of funds expended to date. All unused funds must be returned to CCF immediately upon its request. A PI may terminate a grant by sending written notice to CCF stating the reason and providing a project status report and accounting summary of funds expended. The PI should make arrangements to promptly return unused funds to CCF.
10. **Dissemination of Findings:** All findings resulting from research supported by CCF shall be made public, preferably through recognized national medical meetings and peer-reviewed journal articles. Any scientific data resulting from research funded by CCF shall be made available to other researchers and non-commercial laboratories in a timely manner at a no charge or at cost basis. If it has been determined that the findings will not be published, the PI and CCF shall discuss other options for dissemination of the data to the public and medical/scientific community.
11. **Presentation and Publication Acknowledgement:** All presentations and publications related to research funded in part or in whole by CCF's research grant must cite the "Children's Cardiomyopathy Foundation" (full name of foundation) as a source of funding. CCF shall be notified when a presentation or publication related to the funded research has been confirmed, and a PDF file of the final abstract or publication shall be forwarded to CCF when available.
12. **References to Work:** Both CCF and the PI may include general, non-confidential information about the research grant in announcements to the general public and their constituents. For specific print or internet references, such as communication materials or press releases, the PI or PI's institution must acknowledge CCF's involvement and notify the Foundation before distribution. Similarly, announcements about the study findings must be reviewed by the PI before distribution by CCF.

For a listing of past funded studies, visit CCF's Research Grant & Awards page at www.childrenscardiomyopathy.org/site/grantsawarded.php.