Children's Cancer Research Fund®

Application Instructions: Childhood Cancer Survivorship Research Award
Originally published June 2022

Title

Provide a title that is short and descriptive of the proposed research. Maximum space limit is 81 characters, including spaces.

Abstract

The abstract should contain information about the significance, broad objectives, hypotheses, specific aims, and methods to be employed. There should be a statement of how the project relates to the mission of CCRF. The abstract should use lay language as much as possible. Do not include graphs or images in the abstract. The maximum length is 30 lines of text.

Principal Investigator

Name the one person responsible to the applicant organization for the scientific and technical direction of the project. Include degree and email address.

In general, the following positions may be designated as PIs in CCRF applications:

- All tenured and tenure-track Assistant, Associate, and Full Professors
- All Research Assistant Professors, Research Associate Professors, Research Professors, and Clinical Professors
- All Adjunct, Visiting, Emeritus, Lecturers or other faculty with have the approval of their Department and Dean of the relevant School or College

PI Title, Affiliation, Department

Provide these details for the PI

PI address and Telephone number

Provide mailing address and telephone number for the PI.

Dates of Proposed Period of Support

Provide the dates of research support requested.

Costs Requested for Initial Budget Period

Direct Costs ($) Enter the Direct Costs for the Budget Period

Total Costs ($) Enter the total costs for the budget period

Key Personnel/Biosketches

Senior/Key Personnel are defined as all individuals who contribute in a substantive, meaningful way to the scientific development or execution of the project, whether or not salaries are requested. Consultants should be included if they meet this definition. You should not include technicians or junior investigators unless they are providing specific expertise or skills needed to complete the proposed research. If you are awarded the grant, any changes in key personnel must be approved by staff at CCRF. Your application should indicate to reviewers that the key personnel on the application are very well suited to conduct the research. This is reflected in their training and publication record. You don't need to name each person working on the project as key personnel. If collaborators from other institutions are part of key personnel, you will need to include letters of commitment in your application that clearly spell out their roles and commitment to the project. For consultants, letters should include rate/charge for consulting services.

Each person included as Key Personnel must submit an NIH Biosketch which requires a personal statement describing relevant experience and qualifications that makes this person well suited for the role to be played in the project. Any citations should include PMC numbers.

Facilities, Other Resources, Equipment

Reviewers will use the information in this section to assess the capability of the organizational resources to perform the proposed research. Resources include laboratory, animal labs, computer, office, clinical, or other facilities. Provide information on capacities, capabilities, relative proximity, and extent of availability of resources to the project. Describe only those resources that are directly applicable to the proposed research. Discuss the scientific environment of the institution, specifically, ways in which the proposed research will benefit from unique features of the environment, including special populations and investigators, opportunities for collaboration, intellectual discussion, etc. If the research will be conducted in several places, be sure to describe the resources available in each site. There is no page limit for this section. List major equipment available to the project.

Budget

The amount of money requested should reflect the scope of the science proposed. The budget includes investigator time, equipment, supplies, travel expenses, etc. CCRF grant applications require detailed line item budgets and detailed justification for each item. There are no page limits for this section.

Other Support

Applicants for CCRF funding should provide information on active and pending support. Other support includes all resources made available to researchers or key personnel in support of and/or related to all of their research endeavors. Other support does not include training awards, prizes, gifts or start-up support provided to the individual by the applicant organization.

Other support is necessary to verify there is no budgetary overlap, scientific overlap, or commitment of effort greater than 12 person-months for the PI(s) or any **Senior/Key Personnel**.

Specific Aims

The Specific Aims section is limited to 1 page and should provide clear research objectives. Typically, this section begins with a brief narrative that concisely states the issue or problem to be addressed, describes the long-term goals or objectives of the project and clearly states the hypothesis to be tested. This is followed by a numbered list of 2-4 specific aims. Make sure the aims are logical, achievable, and clearly relate back to the primary research or hypothesis.

Research Strategy

The research strategy or research plan is organized into three sections: Significance, Innovation, and Approach. Applicants can choose to address these sections (significance, innovation, approach) separately for each specific aim or collectively across all specific aims. This section has a 6 page maximum.

Significance and Personal Research Plan

In this section, state the research problem, current state of knowledge, and potential contributions of the research to the field. Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses. Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields. Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

Innovation

In this section, explain how the application challenges and seeks to shift current research or clinical practice paradigms. Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions. Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

Approach

In this section, describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Describe how the plan to carry out the research. Include details related to specific methodology, and explain why the proposed methods are the best to accomplish study goals. Describe any novel concepts, approaches, tools, or techniques. The research methods should relate directly to the specific aims. Preliminary studies and experience should be described.

Reviewers will consider preliminary data an essential part of the research grant application and it will establish the likelihood of success of the proposed project. Discuss how the previous work demonstrates feasibility and leads to the current proposal.

State how the data will be collected, analyzed, and interpreted. Describe statistical techniques that will be used.

Data Sharing

Children's Cancer Research Fund is dedicated to data sharing and interoperability. Please describe the data generated by your research, how it will be FAIR (findable, accessible, interoperable, reusable), and your plan for sharing and dissemination. Data include any information generated through the research, including clinical data, sequencing data, real-world evidence, etc. As appropriate, please indicate what data standards will be used, and if none are available, how this will be addressed.

Please describe how the data will be shared both during and after the award. Awardees are encouraged to place data into a publicly accessible repository (e.g., dbGaP for genomics). Or describe your organization/campus data sharing policy.

Please also include a description of any protections for privacy and security, including any data governance considerations.

Discuss any intellectual property considerations and how they will be addressed. For any algorithms or tools developed, please discuss what software license will be leveraged and why. Finally, please describe your plan to share your research findings with the wider scientific community.

Timeline

Include a proposed **timeline** for completing the work. Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims. If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work. Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.

The following sections do not count against the Research Plan page limits.

Human Subjects: Does your research involve human subjects? According to DHHS regulations, the answer is "yes" if you obtain data or biological specimens through intervention or interaction with a living individual or you obtain identifiable private information about a living individual. If you answer "yes" to human subjects' involvement, there are required sections of the application that must be completed. CCRF does not require that you have IRB approval at the time of submission; however, IRB approval is required before the proposal is funded.

For studies involving human subjects the following sections are required:

1. Proposed Use of Human Subjects: Provide information on 6 issues: (1) the characteristics of the subjects; (2) the sources of research materials; (3) recruitment plans and consent procedures; (4) potential risks; (5) procedures for protecting against or minimizing potential risks; and (6) potential benefits to subjects and to humanity.
2. Inclusion of Women and Minorities: Discuss the demographics of the minority populations in the area and the criteria and rationale for selection of gender and racial/ethnic group, as well as your plan for recruiting/ including women and minorities in the research.
3. Targeted Enrollment Table: provide an estimate on participation in the study by gender and ethnicity.
4. Inclusion of Children: Discuss the participation of children and explain the rationale if children are excluded. If they are included, describe the rationale for selecting specific ages, and discuss the qualifications of investigators who will work with children.

If you are doing Human Subjects Research in a Clinical Trial: A clinical trial is a prospective study designed to answer questions about biomedical or behavioral interventions. If you are conducting a clinical trial, you must write all the four sections above PLUS you must write a **data and safety monitoring plan** which will be included in Section 1 above.

If your Human Subjects Research is Exempt under Exemption 4: In this case, you need only describe the human subjects work you will do involving specimens or data, where and how you will collect the data, and clearly justify the exemption. Make sure to refer to the definition of the exemption (above).

If your project is not considered Human Subjects but you are using human specimens or data: In this case, you must justify why the project is not considered human subjects even though you are studying data or specimens from living beings. This determination will have been made by the IRB, which can help you with the justification.

Vertebrate Animals

If vertebrate animals are involved, address each of the five points below. If all or part of the proposed research involving vertebrate animals will take place at alternate sites (such as collaborating

sites), identify those sites and describe the activities at those locations. Although no page limitation applies to this section, be succinct.

1. Provide a detailed description of the proposed use of the animals in the work outlined in the Research Strategy section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.
2. Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.
3. Provide information on the veterinary care of the animals involved.
4. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.
5. Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia. If not, include a scientific justification for not following the recommendations.

Bibliography and References Cited

Provide a bibliography of any references cited in the project narrative and any other parts of the application. There is no page limit for this section. Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. When citing articles that fall under the Public Access Policy (i.e., arose from NIH support), provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the Pubmed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal – In Process."

Appendix

A maximum of 10 PDF attachments is allowed in the Appendix. Surveys, questionnaires, and other data collection instruments; clinical protocols and informed consent documents may be submitted in the Appendix as necessary.