



COMMUNITY RESEARCH COLLABORATION (CRC) INFORMATION AND APPLICATION INSTRUCTIONS

Pilot and Full Awards

Applications Due: February 15, 2012, noon Pacific Standard Time

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LTS and to document the long-term impact of cancer and its treatment over the adult lifespan. No overlap.

PREVIOUS SUBMISSION REVIEW RESPONSE

This form is evaluated in the Peer review.

Limit the text to two pages

Follow the formatting instructions in “General Items” above.

This form is for the applicants to describe their response to the suggestions contained in previous submissions. Provide the page number of the research plan where the most salient changes can be found, if the changes are such that they appear in a specific section or page of the plan (i.e., don't try to identify all the places where your responses are if they are scattered throughout the plan).

RESEARCH PLAN

This form is evaluated in the Peer review.

Limit the text to:

Pilot Award: Ten Pages

Full Award: Fifteen Pages

Page limits are exclusive of bibliographical references, which should follow the research plan.

Follow the formatting instructions in “General Items” above.

Both co-principal investigators' names (last name, first name, middle initial) must be printed in the upper right-hand corner of every page.

We ask that applicants describe the proposed research project in sufficient detail for reviewers to evaluate its scientific merit and collaboration elements, as described below. If you don't use all the pages to describe your research plan, it might be best to review what you have written and explain in more detail anything not fully explained. **However, note that a concise, focused research plan of less than the maximum number of pages is preferable to one less concise and made longer by overly elaborate or unimportant details.**

Supporting materials (such as questionnaires, consent forms, interview questions, letters of collaboration) that are directly relevant to the proposal may be included in the Appendix. **The research plan must be self-contained and understandable without having to refer extensively to supporting materials.**

Note: Recommended format for research plans is included below for the Pilot or Full Award.

1. Statement of Goals, Research Questions, and Specific Aims

For Pilot applications: In a short paragraph, describe goals for the Pilot award in light of the long-term research goals. Describe how the Pilot, if awarded, will be used to prepare the collaborative team to pursue further research and to apply for a CRC Full Research award or funding from another agency. State the goals and research questions for the Pilot award. Follow with the Specific Aims—the specific tasks that will be undertaken to address the question(s). These should have a logical connection, and you need to make clear their relationship to the team's long-term research goals. Do not include tasks that you expect to undertake in the CRC Full Research award project or with future funding from another agency.

For Full Research applications: Briefly state the research question(s) and hypothesis for the Full Research award. Follow with the Specific Aims—the specific tasks that will be undertaken to address the question(s). These tasks should be very clearly defined and should not include exploratory or development undertakings. The research questions, hypothesis, and aims should have a logical connection.

2. Background and Significance

Concisely describe the rationale underlying the proposed research; the hypotheses to be investigated; the methodology to be employed; and the experience, knowledge, and skills of the research team. Emphasize positioning the research in the context of existing relevant scientific literature and preliminary data that the team may have collected in preparing for the research. Demonstrate a grasp of the current state of the knowledge relevant to the problem. Provide up-to-date references, acknowledge controversies and contradictory reports, and be comprehensive and accurate. If there is little literature on the topic, draw on information from related fields. Demonstrate the community interest, participation in the plan development from the beginning, and the potential contribution of the proposed research. Briefly state the long-term potential of the research: the problems, issues, or questions which, through the execution of this award, can be further developed, specified, and sharpened into testable hypotheses; and the methodologic approach (or possible approaches that seem at present most appropriate to be used). Keep discussion of the general problem of breast cancer brief; emphasize the specific problem addressed by your research proposal.

Preliminary Data (Required For Full Application)

Describe in detail the work you performed during the Pilot award, if any, or present relevant data or supporting information. Include a description of different approaches taken, and the results obtained with each approach to justify applying for the Full Research award. Present any data obtained in detail, with a description of how the data was obtained and analyzed. Describe any pitfalls or problems that arose, as well as how they were overcome. Provide justification and support for: (1) the hypothesis and assumptions; (2) the research design; (3) the potential for useful knowledge and/or products to result from the research.

3. Research Methodology: Research Design, Conceptual Framework, and Data Analysis

Describe in detail the exact tasks listed in the Statement of Goals, Research Questions, and Specific Aims. Provide a detailed description of the work you will do during the Award period, exactly how it will be done, and by whom. For instance, if women are to be surveyed, explain how many women will be surveyed; why you chose this number; how the women will be identified and recruited; why you believe you will be able to reach and recruit this many women; what questions you will ask them; whether you will use face-to-face or telephone interviews, or written surveys and why you will use the method chosen; and, how the data will be collected and analyzed. Be as detailed as possible. Provide this information for each specific task cited in the first section. Discuss potential pitfalls and how you will overcome them should they arise, or alternative methods that you will use if the intended methods are not fruitful. Provide a realistic timeline. Be sure to include a hypothesis and conceptual framework.

4. Partnership Collaboration Plan and Community Benefit

Begin this section by describing the community of interest for this study. Is the community distinct because of geography, age, gender, associated by disease status or risk, race, sexual orientation, or socio-economic status? Describe the interest of the community in the research question and how they have participated in identifying it. Discuss the importance and benefit to the community of the research question and expected outcome. Specifically answer how the broader community of interest was involved in developing the research proposal.

Describe the relationship between the community co-PI and their community organization and the community of interest. How will the community of interest be included on the research team? Discuss how the leadership of the community organization (the Executive Director, the Board of Directors, or the individuals of an informal organization) will ensure that the organization or group is committed to the research project? Describe how the Community Co-PI and the community organization will communicate with one another to facilitate input and decision-making.

Describe in detail the plan for carrying out the collaboration. Describe your specific collaboration plans, including how and when the partners will interact; what the specific roles and responsibilities of each partner will be through each step of the research process; how all members will be brought into the design, data analysis, and decision-making process. Briefly summarize collaborative agreements described in more detail in the Collaborative Agreements Form: ownership of data, handling disagreements, how grant funds will be handled; and plans for dissemination of results. Discuss how participating in this research project will build capacity for the community organization (such as through developing research/evaluation skills, answering a question important to the organization, having policy impact, improving programs, etc).

5. Statement of Future Goals

For Pilot applications: Begin with a brief discussion of the long-term research goals of the team, as well as a description of the work the team would like to pursue with a CRC Full Research award or funding from another agency after completing the preliminary research funded by the Pilot award. Be as specific as possible about future research plans.

For Full Research applications: Begin with a brief discussion of the expected outcome of the proposed research. Describe how the research, if awarded, will result in benefit to the community and beyond— what new knowledge will be obtained and how will this knowledge reduce the human and economic costs of breast cancer?

HUMAN SUBJECTS

This form is required for all applications but only needs to be completed if the proposed study will involve human subjects.

Special Note to CRC Applicants: If you are planning on having data from your studies with individual identifiers being accessible and possibly even maintained by both the Community Research Partner and the Scientific Research Partner, please address this issue in your Human Subjects approval application. If you received Human Subjects approval through one partner's IRB, and you did not include in the IRB application that the other partner will receive a copy of the identified data during or after the study, you may be precluded from sharing the data.

Provide sufficient information in response to item (1) below to confirm there has been a determination that the designated exemptions are appropriate. Determination of exemption from DHHS regulations must be made by an approved Institutional Review Board (IRB). Documentation of IRB review must be provided before an award is made. Research designated exempt is discussed in the U.S. Department of Health and Human Services, Public Health Service Grant Application #398 Part II Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan, Pages 4-5. Although a grant application is *exempt* from these regulations, it must, nevertheless, **address the issues of race/ethnic composition of the subject population**, as instructed in item (2) below.