

TRANSLATIONAL RESEARCH AWARD TEMPLATE & FORM INSTRUCTIONS

Step #1: Letter of Intent (Required): the deadline is Wednesday **October 21, 2009**. You must upload the [project outline](#) and [PI biosketch](#) to proposalCENTRAL. If the LOI is approved, then the PI will be notified by November 10th and given access to the remaining application forms.

Step #2: Electronic submission: the deadline for submission of the complete application is Thursday **February 11, 2010** (12 noon Pacific Standard Time = 3 pm Eastern Standard Time as shown on proposalCENTRAL's Web site)

Step #3: Face Page submission with signatures:

- Print your application's Face Page from proposalCENTRAL and obtain the necessary signatures (PI and institutional signing official are required).
- E-mail as a PDF attachment a scanned copy with signatures to: facepage@cabreastcancer.org before 5 pm (PST) by Thursday **February 18, 2010**

Important Reminders

- When preparing your application be sure to use the "validate" function to assure that all required submission items are entered.
- You must select an institution with a tax ID (EIN) number in the Proposal Section called "Institution & Contacts." In addition, the "signing official", "contracts & grants official", and "fiscal contact" must be selected from the pull down menu for that institution or have them register with proposalCENTRAL prior to submission. Work with your signing and contracts officials to both identify your institution (duplicates might be present in proposalCENTRAL).

Note: Portions of the application are prepared using pre-formatted Web pages in proposalCENTRAL. For other portions you must use CBCRP forms that are completed then uploaded as PDF attached files to your application (see below).

PROPOSAL SECTIONS (items pre-formatted on proposalCENTRAL Web pages)

Complete the Web formatted pages with special attention to required items marked with a *.

- **Title Page.** Enter the project title in 60 characters or less. Indicate whether the application is a resubmission of a previous application reviewed and not funded by the CBCRP.
- **Enable Other Users to Access this Proposal.** You should use this page to allow additional people to access your application.

- **Applicant/PI.** You must complete all the required information on this page. Enter the % effort on the project. Translational Research Award PIs have a minimum 10% FTE.
- **Institution & Contacts.** When you first register with proposalCENTRAL you should select an institution with a valid IRS tax ID number (EIN) from the pull-down menu. If done correctly, then you can directly add your institution's "Signing Official", "Contracts & Grants Official", and the "Fiscal Contact" who will handle budget and fiscal reports. If these individuals are not present on the pull down menu, then you need to contact them and have them register with proposalCENTRAL.
- **Abstracts.** Copy both Lay and Scientific abstracts for your project from the downloaded templates (refer to the detailed instructions below). Then, add the CSO Code (1 or 2 items) using the CSO Coding Instructions download. Next, add three (3) key words to describe your project. Finally, select the one CBCRP priority issue that best matches your project from the menu.
- **Budget Summary.** Follow these Translational Research Award Budget Guidelines:
 - The **maximum duration is 3 years and the direct costs budget cap is \$750,000.** The CBCRP will consider direct costs requests over this amount only in special circumstances.
 - **Equipment purchases have no cap amount.** However, equipment must be specific to the project and justified on the "Budget Justification & Facilities" form.
 - We will allow a maximum of \$500/year for travel to **CBCRP symposium** in 2010 (year #1).
 - **Scientific meeting travel** is capped at \$2,000/yr for the PI.
 - Full indirect (F&A) costs are allowed only to non-UC institutions.
- **Organization Assurances.** Add the required information. You must have your Contracts & Grants official add your institutional Federal Wide Assurance (FWA) code or equivalent for Human Subjects and an Animal Welfare Assurance code for Vertebrate Animals.
- **Research Plan and Other Attachments.** The Translational Research Award-specific and CBCRP General Application Requirements instructions are located here. All required items to complete and upload are listed. All uploads must be in PDF format.
- **Validate.** This function allows a check for any missing REQUIRED information or files. All missing required information will be listed on the screen. Please correct any missing information before proceeding to the Face Page and Submit sections.
- **Electronic submission:** the deadline for electronic submission of the complete application is **February 11, 2010** (12 noon Pacific Standard Time = 3 pm Eastern Standard Time as shown on proposalCENTRAL's Web site)

Face Page Submission. Print your application's Face Page from proposalCENTRAL and obtain the necessary signatures (PI and institutional signing official are required). E-mail as a PDF attachment a scanned copy with signatures to: facepage@cabreastcancer.org before 5 pm (PST) by Thursday **February 18, 2010**

RESEARCH PLAN AND OTHER ATTACHMENTS SECTION– CBCRP templates (application forms) to be downloaded, completed, converted to PDF files, and uploaded

List of templates (those marked * are required uploads):

- Lay Abstract*
- Scientific Abstract*
- Program Responsiveness*
- Critical Path & Additional Criteria*
- Distinction from Other Funding*
- PI Biographical Sketch & Other Support*

- Budget Summary* (note: separate .xls & PDF uploads are required)
- Budget Justification & Facilities*
- Key Personnel*
- Other Key Personnel Biosketches & Other Support
- Research Plan*
- Milestones*
- Human Subjects
- Vertebrate Animals
- Appendix List

Instructions – LAY ABSTRACT (required)

This item is evaluated mainly in the programmatic review. **The text is also entered in the appropriate box in the “abstracts” page of the Proposal Sections.** Do not use symbols or other special text, as these will not transfer to the box in the “abstracts” page.

The **Lay Abstract** must include the following sections:

- A **non-technical introduction** to the research topics
- The **question(s) or central hypotheses** of the research in lay terms
- The **general methodology** in lay terms
- **Innovative elements** of the project in lay terms
- **Advocacy involvement and human issues.** Briefly describe the role of advocates in planning and carrying out the research. Describe how the project addresses the human issues associated with breast cancer. We suggest that applicants request assistance from their institution’s public affairs office.

The abstract should be written using a style and language comprehensible to the general public. The scientific level should be comparable to either a local newspaper or magazine article, such as might appear in *Time* or *Newsweek*. Avoid the use of technical terms and jargon not a part of general usage. Place much less emphasis on the technical aspects of the background, approach, and methodology. Ask a family member or friend who is not a scientist to read the abstract and tell you what they don’t understand.

Examples advocacy concerns/human issues can be sourced through web sites, such as:

- <http://www.networkofstrength.org/> Breast Cancer Network of Strength
- <http://www.natlbcc.org/> National Breast Cancer Coalition
- <http://www.bcaction.org/> Breast Cancer Action
- http://www.breastcancerfund.org The Breast Cancer Fund
- <http://www.komen.org> The Susan G. Komen Breast Cancer Foundation

Instructions - SCIENTIFIC ABSTRACT (required)

This item is evaluated mainly in the peer review. **The text is also entered in the appropriate box in the “abstracts” page of the Proposal Sections.** Do not use symbols or other special text, as these will not transfer to the box in the “abstracts” page.

The Scientific Abstract should include:

- A short introductory paragraph indicating the **background** and overall topic(s) addressed by the research project

- The **central hypothesis** or **questions to be addressed** in the project.
- A listing of the **objectives or specific aims** in the research plan
- The major research **methods and approaches** used to address the specific aims
- A brief statement of the **impact** that the project will have on breast cancer.
- **Advocacy involvement and sensitivity to advocacy concerns**

Provide the critical information that will integrate the research topic, its relevance to breast cancer, the specific aims, the methodology, and the direction of the research in a manner that will allow a scientist to extract the maximum level of information. Make the abstract understandable without a need to reference the detailed research plan.

Instructions – PROGRAM RESPONSIVENESS (required)

This item is evaluated in the programmatic review.

Limit the text to two pages.

The information on this template allows the advisory Council to rate the application for adherence to our Priority Issue and Award Type descriptions.

First, indicate the CBCRP Priority Issue (see the CBCRP General Requirements download) that best matches your project topic and discuss this relationship. If your project addresses more than one CBCRP Priority Issue, then concentrate your discussion on the one priority issue that best matches the project.

Address these questions:

- How is your project specific for breast cancer?
- What special aspect of breast cancer is the focus of your research?
- What unique characteristics of breast cancer, especially in the clinical or community settings, make it an ideal target for your research topic?

Second, indicate the Award Type that you are applying for, and discuss why your project and career level matches this choice. Refer to these criteria:

- Translation Research Award applicants should stress how the research and addresses the criteria this funding mechanism. What practical application will be derived from this research? Indicate your background in breast cancer research and previous success in translational efforts.

Instructions – CRITICAL PATH & ADDITIONAL CRITERIA (required)

This item is evaluated in the programmatic and peer reviews.

Limit the text to two pages.

A. Critical Path

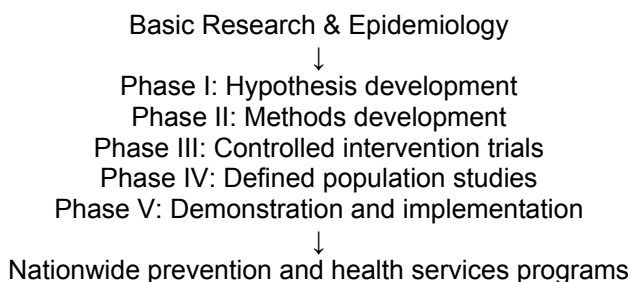
Background:

Breast cancer research has resulted in the creation of new knowledge; however, some believe that the practical application of this knowledge has not been effectively encouraged by funding agencies. In addition, “translational research” RFPs (Request for Proposals) and funding decisions do not always adequately define and distinguish translational proposals from those more appropriately funded by traditional granting mechanisms. **CBCRP believes that identification of a “critical path” from discovery-to-practical application can allow a better selection of grant applications that are responsive to translational research goals.**

In 2003 Best et al. (*Cancer Epidemiology Biomarkers & Prevention*,12:705-712) distinguished two pathways to practical application of research as follows:

, “..... it is important to view "translational research" to encompass not only the pervasive view of transfer of basic science discoveries into clinical applications ("bench to bedside"), but also its transfer into effective interventions at the population level with active community participation in the process ("bench to trench"). Collaboration between research producers and research consumers in this translational approach is critical to reduce the cancer burden at the population level, the ultimate measure of benefit to all people.”

A conceptualization and stepwise model for the “critical path” was published in the context of smoking/tobacco by Greenwald and Cullen (*J. Natl. Cancer Inst.*, 74:543-551, 1985). They distinguished these phases of cancer control research:



CBCRP receives many excellent research proposals, although most are early on the “critical path.” Most research grant applications are incremental plans and do not attempt substantially overcome barriers and advance topics towards translational endpoints. However, the concept of discrete research phases is useful to: (1) identify logical translational steps for a topic, and (2) to make translational efforts understandable across disciplines as described below.

Objectives and Requirements:

To be responsive to CBCRP’s translational research award, the PI should place the proposed project on a “critical path” **leading from basic concept to a measurable impact** for the prevention, detection, diagnosis and treatment, reduction in community and social burden, or improved patient quality of life for breast cancer.

Note: a complete presentation for the critical path would include: (1) the **original concept** and “proof of principle” background related to breast cancer, (2) the **PI’s accomplishments in the research topic** that brings it closer to translation, (3) the specific **barriers to translation** and the PI’s strategy to overcome them, (4) an endpoint of **practical value** that the research would enable (e.g., in the clinic or community), and (5) a “**vision for future implementation**” that extends the expected endpoints and describes the **potential impact** at the patient, community, or policy levels.

The applicant should distinguish the proposed "translational project" from non-responsive research that aims to: (1) focus on exploratory/discovery endpoints, (2) develop new hypotheses, or (3) accumulate additional or “incremental” knowledge in a given topic.

Translational “Critical Paths” for Different Disciplines:

We have identified three separate “tracks” for translational research, and listed some phases of the research within these disciplines. The following examples are not intended to be all-inclusive, but merely to assist researchers in completing this portion of the application.

► #1. Critical Pathway for Translation of Basic Science Discoveries to Clinical Applications:

Over the years, industry and research funding agencies have made major investments in translating basic science discoveries into new detection and diagnostic procedures, drugs, and other clinical treatments. Basic science projects that initiate research along this continuum are appropriate for CBCRP’s IDEA funding mechanism or awards from other agencies (e.g., NIH R01). In addition,

CBCRP supports research in the developmental stage by offering IDEA-competitive renewals. Applicants from the basic sciences for a CBCRP translational research award are expected to have assembled a robust body of background data in the basic science and developmental phases, and will be poised for transition to the pre-clinical and clinical phases. .

Table 1

Position along pathway	Definitions and examples
Basic Science (exploratory) <u>Not appropriate</u> for CBCRP’s translational research award.	Hypothesis testing and exploring novel paradigms. Envisioning a practical application for breast cancer patients or in prevention efforts. Laboratory, basic science studies.
Developmental (first phase of translational research) <u>Not appropriate</u> for CBCRP’s translational research award.	Preliminary “proof-of-concept.” Demonstrating a relationship between basic science work and application potential. Includes: <ul style="list-style-type: none"> • Target validation to define causal connection or definitive correlation with breast cancer • Establishing clear relevance to breast cancer and validation of proposed critical path • Promising work in breast cancer relevant cell models and initial studies in animal models • Lead compound development and testing
Pre-Clinical (testing and validation; “first in man” studies). <u>Eligible</u> for CBCRP’s translational research award.	Definitive “proof of concept”. Pre-clinical development directly leading to testing in human subjects Preparation for direct clinical application, final validation of approach. Final stages of testing of diagnostic or therapeutic modality <ul style="list-style-type: none"> • Obtaining final animal model and initial human subjects data sets for new drugs and biomarkers to confirm the translational strategy and level of opportunity • Final <u>conceptual and testing/validation phases</u> and early phase clinical trials. • Testing of new imaging modalities in the animal → human setting for final proof-of-concept in patients • Establishing clinical protocols and patient study parameters Could be included in a project, but <u>not</u> as the focus of the funding. For example: <ul style="list-style-type: none"> • Toxicity evaluation, pharmacokinetics, formulation and stability testing of therapeutics, scale-up optimization
Clinical Application (application in the human and clinical setting, implementation or “reduction to practice”). <u>Eligible</u> for CBCRP’s translational research award.	Testing of a therapeutic, diagnostic or prognostic for efficacy or utility in humans. Includes: <ul style="list-style-type: none"> • Clinical trials • Demonstrating impact of the therapeutic, detection, prognostic or chemopreventive approaches in breast cancer • Use of diagnostic tools to define patient population or guide treatment decisions

► **#2. Critical Pathway for Interventions to Change Behavior or Provide Supportive Services:** In many respects research leading to public health interventions follows a similar

“critical path” as the basic science-clinical track described above. Table 2 illustrates the key phases that flow from the Cullen and Greenwald model described earlier.

Table 2

Position along pathway	Definitions and examples
Hypothesis development. <u>Not appropriate</u> for CBCRP’s translational research award.	Hypothesis testing and exploring novel paradigms. Develop hypotheses to link new research findings and an intervention to change behavior. Includes: <ul style="list-style-type: none"> • Conceptualizing possible interventions • Identifying target populations and delivery systems
Methods development. <u>Not appropriate</u> for CBCRP’s translational research award.	Developing a more detailed model of a proposed intervention and field methodology. Includes: <ul style="list-style-type: none"> • Formulating a strategy for practical application • Identification of outcome and process measures • Identification of data collection and analysis procedures • Refining the proposed intervention and evaluation methods
Controlled intervention trials and defined population Studies. <u>Eligible</u> for CBCRP’s translational research award.	Larger scale testing of intervention hypotheses in a well-defined population enabling generalization to ultimate target populations. Including: <ul style="list-style-type: none"> • Testing intervention outcomes in an efficacy trial (intervention delivered under “ideal conditions”) or an effectiveness trial (intervention delivered under “real world” conditions) • Conducting process evaluation to test the underlying theoretical framework and/or to identify factors that mediate outcomes
Demonstration & implementation. <u>Eligible</u> for CBCRP’s translational research award.	Larger scale studies of adaptation, dissemination and diffusion to other populations and communities

► **#3. Critical Pathways for Translational Research in Other Disciplines:** The critical pathways for translating research discoveries into medical practices, health systems changes, health policies, or environmental modifications are largely uncharted and may be highly variable. Examples of studies relevant to breast cancer research include:

Table 3

Position along pathway	Definitions and examples
<p>Early phase research. <u>Not appropriate</u> for CBCRP’s translational research award.</p>	<p>Identifying public health, social, environmental or community concerns and needs related to breast cancer and developing the initial strategies to enable translational research. Includes developing researcher-community organization collaborations. Examples include:</p> <ul style="list-style-type: none"> • Assessing individual community needs and the effectiveness of current breast cancer practices at the community level • Cost-effectiveness studies of new approaches to preventing, detecting, diagnosing, or treating breast cancer • Examining how methods of disseminating knowledge about new research discoveries influence change in health services and identifying facilitating or impeding factors • The development of models to simulate effects of a proposed public health or policy changes specific to breast cancer
<p>Mid-level research. <u>Eligible</u> for CBCRP’s translational research award.</p>	<p>Developing practical applications of previous research findings. Examples include:</p> <ul style="list-style-type: none"> • Directly engaging “stakeholders” at the community or other levels to test the early application of new health policy and services models • Policy research leading to implementation • Testing interventions to increase dissemination and diffusion of evidence-based practices
<p>Advanced studies. <u>Eligible</u> for CBCRP’s translational research award.</p>	<p>Demonstration projects to test and refine the effectiveness of different methods and models for the final phases of translating research knowledge into health services delivery, policy, and environmental modifications</p>

B. Additional Criteria

Limit the text to one page.

Part #1. Address the project’s (i) focus on underserved populations, and (ii) advocacy involvement in the research and sensitivity to advocacy concerns. Do not address these issues with “n/a.” Take the time to study the human issues of breast cancer and the extra burden the disease places on different communities, and consider how your project might address the needs of the underserved (including those that are underserved due to factors related to race, ethnicity, socioeconomic status, geographic location, sexual orientation, physical or cognitive limitations, age, occupation and/or other factors) in prevention, detection, prognosis, and treatment.

Part #2. Indicate your intentions to interact with advocates and advocacy organizations and involve them in planning and carrying out the research project. Here are some suggestions:

- Contact an advocate/activist group in your area to discuss your research project with them and receive feedback and suggestions.
- Use advocates/activists as a resource to find the “human link” between your project and their experience as breast cancer survivors to better appreciate the social/community issues related to breast cancer.
- Visit advocate/activist displays and posters at cancer meetings (e.g., San Antonio Breast Cancer Symposium) to discuss your research interests. Many advocates welcome interactions with researchers.

- Examine the literature and Web sites of advocate/activist organizations to get a sense of their social/research concerns and needs.
- Obtain a “letter of collaboration” from an advocate/activist organization describing their role in your project.

Instructions – DISTINCTION FROM OTHER FUNDING (required)

This item is evaluated mainly in the programmatic review.

Limit the text to one page.

Overview: Applicants should highlight the unique aspects of the proposed research compared to their other current and previously funded projects. The peer review committee considers this information when evaluating “innovation”, “impact.”, and “translational potential.” For the programmatic review the information is used to rate the criteria “Underfunded.”

Detailed instructions: Discuss the unique properties of the current application from, (i) other current and past grant support to the PI, (ii) the current CBCRP portfolio as shown on our Web site (<http://www.cabreastcancer.org/>) under the link “Research Portfolio”, and (iii) general research in the topic under investigation on display on the International Cancer Research Portfolio (ICRP) Web site: <http://www.cancerportfolio.org/>

Instructions – BUDGET SUMMARY (required)

Follow these Translational Research Award Budget Guidelines:

- The **maximum duration is 3 years and the direct costs budget cap is \$750,000**. The CBCRP will consider direct costs requests over this amount only in special circumstances.
- **Equipment purchases have no cap amount.** However, equipment must be specific to the project and justified on the “Budget Justification & Facilities” form.
- We will allow a maximum of \$500/year for travel to **CBCRP symposium**.
- **Scientific meeting travel** is capped at \$2,000/yr for the PI.
- Full indirect (F&A) costs are allowed only to non-UC institutions.

Instructions – BUDGET JUSTIFICATION & FACILITIES (required)

This item is evaluated in the peer review.

Limit the text to two pages

Follow the instructions on the template.

Instructions – KEY PERSONNEL (required)

This item is evaluated in the peer review.

Limit the text to one page

Follow the instructions on the template.

Instructions–BIOGRAPHICAL SKETCH & OTHER SUPPORT (required)

This item is evaluated in the peer review.

Limit the length of each biosketch to *no more than four(4) pages*.

The information provided is evaluated to assess the expertise, training, and background relative to the methods employed in the project. For career development, the biosketch is evaluated to determine the additional training or benefit the research will contribute to the PI's capabilities in breast cancer research.

Use the Form provided or substitute the current [NIH Form 398](#) for biosketch and include the requested information:

- Name
- Role in Project
- Education. Include steps from baccalaureate through postdoctoral training.
- Research and professional experience. List positions in chronological order.
- Publications. List the relevant publications for this application first, then list others as space permits. Do not include items 'submitted' or 'in preparation.'
- Other grant support. List all items of current and pending grant support with the grant title, agency, role in project, percent FTE devoted to grant, a brief summary of aims, and overlap/resolution with the present application.

Instructions – RESEARCH PLAN (required)

This section is the **most important** for the peer review. Note carefully the page limits, format requirements, and suggested format.

Page limit, exclusive of references, is:

Translational Research Award12 pages

An additional 3 pages is allowed for References.

Format issues: Begin this section of the application using the download template. Subsequent pages of the Research Plan and References should include the principal investigator's name (last, first, middle initial) placed in the upper right corner of each continuation page.

The Research Plan and all continuation pages must conform to the following four format requirements:

1. The height of the letters must not be smaller than 11 point; Times New Roman or Arial are the suggested fonts.
2. Type density, including characters and spaces, must be no more than 15 characters per inch (cpi).
3. No more than 6 lines of type within a vertical inch;
4. Page margins, in all directions, must be at least ½ inch.

Use the appendix to supplement information in the Research Plan, not as a way to circumvent the page limit.

Suggested content:

Introduction and Hypotheses: Provide a brief introduction to the topic of the research and the hypotheses/questions to be addressed by the specific aims and research plan. The relationship of the project to the CBCRP Priority Issue should be clear. Identify the translational endpoint (practical application of the research at the patient or population level), the main barriers to be overcome, and the basic strategy to be employed to achieve success.

Specific Aims: List the specific aims, which are the steps or increments deemed necessary to address the central hypothesis of the research. The subsequent research plan will detail and provide the approach to achieving each of these aims.

Background and Significance: Make a case for your project in the context of the current body of relevant knowledge and the potential contribution of the research. Identify work by yourself and others that has set the stage for translational project for this topic.

Preliminary Results: Describe the recent work relevant to the proposed project. Emphasize work by the PI and data specific to breast cancer. If the project is new to breast cancer, then this section should illustrate the capabilities of the research team to develop practical applications focused on breast cancer.

Research Design and Methods: Provide an overview of the experimental design, the methods to be used, and how data is to be collected and analyzed. Recognition of potential pitfalls and possible alternative approaches is recommended. How will technical barriers be overcome or mitigated? Cover all the specific aims of the project in sufficient detail. Identify the portions of the project to be performed by any collaborators. Match the amount of work to be performed with the budget/duration requested. A timeline at the end will demonstrate how the aims are interrelated, prioritized, and feasible. Explain the use of human subjects and vertebrate animals and show their relationship to the specific aims.

Common criticisms of Research Plans that arise in the peer review include:

Project is still in the developmental stage and is not yet poised for translation. Lack of focus on the central topic or hypothesis. Preliminary data and aims do not address the hypothesis. PI is not current with the literature. Sample size is too small to test the research hypothesis with sufficient power. Control group not well defined. Data management not described. Inadequate information on ongoing studies that are the basis for the project. “Cut-and-paste” from another grant application, and the presence of language (e.g., prostate or lung cancer) that indicates a lack of specificity to breast cancer. PI and research team lack expertise and collaborations to tackle the technical issues of the project.

As you prepare the research plan, be sure to address the *scientific merit scoring criteria* specific for each award type.

Instructions - MILESTONES (required)

Follow the instructions on the form.

Limit the text to one page.

Instructions – HUMAN SUBJECTS (only if needed)

This item is evaluated in the peer review.

This form is required only for applications that use Human Subjects, including those in the "Exempt" category.

Use additional pages, if necessary.

For applications requesting “Exemption” from regular IRB review and approval. Provide sufficient information in response to item #1 below to confirm there has been a determination that the designated exemptions are appropriate. The final approval of exemption from DHHS regulations must be made by an approved Institutional Review Board (IRB). Documentation must be provided before an award is made. Research designated exempt is discussed in the NIH PHS Grant Application #398 http://grants2.nih.gov/grants/peer/tree_glossary.pdf. Most research projects funded by the CBCRP falls

into Exemption category #4. Although a grant application is exempt from these regulations, it must, nevertheless, *indicate the parameters of the subject population* as requested on the form.

For applications needing full IRB approval: If you have answered “YES” on the Organization Assurances section of the application and designated no exemptions from the regulations, the following **seven points** must be addressed. In addition, when research involving human subjects will take place at collaborating site(s) or other performance site(s), provide this information before discussing the seven points. Although no specific page limitation applies to this section, be succinct.

1. Provide a detailed description of the proposed involvement of human subjects in the project.
2. Describe the characteristics of the subject population, including its anticipated number, age range, and health status. It is the policy of the State of California, the University of California, and the CBCRP that research involving human subjects must include members of underserved groups in study populations. Applicants must describe how minorities will be included and define the criteria for inclusion or exclusion of any sub-population. If this requirement is not satisfied, the rationale must be clearly explained and justified. Also explain the rationale for the involvement of special classes of subjects, if any, such as fetuses, pregnant women, children, prisoners, other institutionalized individuals, or others who are likely to be vulnerable. Applications without such documentation are ineligible for funding and will not be evaluated.
3. Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records or data.
4. Describe the plans for recruiting subjects and the consent procedures to be followed, including: the circumstances under which consent will be sought and obtained, who will seek it; the nature of the information to be provided to the prospective subjects; and the method of documenting consent.
5. Describe any potential risks—physical, psychological, social, legal, or other. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.
6. Describe the procedures for protecting against, or minimizing, any potential risks (including risks to confidentiality), and assess their likely effectiveness. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects on the subjects. Also, where appropriate, describe the provision for monitoring the data collected to ensure the safety of subjects.
7. Discuss why the risks are reasonable in relation to the anticipated benefits to subjects, and in relation to the importance of knowledge that may be reasonably expected to result.

Documentation of Assurances for Human Subjects

In the appendix, if available at the time of submission, include official documentation of the approval by the IRB, showing the title of this application, the principal investigator's name, and the approval date. Do not include supporting protocols. Approvals obtained under a different title, investigator or organization are *not* acceptable, unless they cross-reference the proposed project. Even if there is no applicant institution (i.e., an individual PI is the responsible applicant) and there is no institutional performance site, a USPHS-approved IRB must provide the assurance. If review is pending, final assurance should be forwarded to the CBCRP as soon as possible, but **no later than Sept 1, 2010**. Funds will not be released until all assurances are received by the CBCRP. If the research organization(s) where the work with human subjects will take place is different than the applicant organization, then approvals from the boards of each will be required.

Data and Safety Monitoring Boards (DSMB)

Applications that include Phase I-III clinical trials may be required to provide a data and safety monitoring board (DSMB) as described in the NICI policy release, <http://deainfo.nci.nih.gov/grantspolicies/datasafety.htm>. This ensures patient safety, confidentiality, and guidelines for continuing or canceling a clinical trial based on data collected in the course of the studies. The CBCRP may require documentation that a DSMB is in place or planned prior to the onset of the trial.

Instructions – VERTEBRATE ANIMALS (only if needed)

This item is evaluated in the peer review.

This form is required only for applications that use Vertebrate Animals.

Limit the text to two pages.

If you have answered “**YES**” to the Vertebrate Animals item on the Organizations Assurances page of your application, then following **five points** must be addressed. When research involving vertebrate animals will take place at collaborating site(s) or other performance site(s), provide this information before discussing the five points.

1. Provide a detailed description of the proposed use of the animals in the work outlined in the Research Plan. 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 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 methods of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If it is not, present a justification for not following the recommendations.

Documentation of Assurances for Vertebrate Animals

Grants will not be awarded for research involving vertebrate animals unless the program for animal care and welfare meets the standards of the AAALAC or the institution has a U.S. Public Health Service assurance. In the appendix, if available at the time of submission, include official documentation of institutional review committee approval showing the title of this application, the principal investigator's name, and the inclusive approval dates. Do not include supporting protocols. Approvals obtained under a different title, investigator or institutions are not acceptable unless they cross-reference the proposed project. If review is pending, final assurances should be forwarded to the CBCRP as soon as possible, but **no later than Sept 1, 2010**. Funds will not be released until all assurances are received by the CBCRP.

Instructions – APPENDIX LIST (only if needed)

Follow the instructions and items list on the template.

The appendix may not be more than 30 pages in length.

Note that the *research plan must be self-contained* and understandable without having to refer to the appendix. Only those materials necessary to facilitate the evaluation of the research plan or renewal report may be included.