

**NIEHS and NCI Breast Cancer and the
Environment Program (BCERP):
Technical Assistance Webinar for
RFA-ES-14-011 and RFA-ES-14-012**

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NIH Staff

- Caroline Dilworth, Program Director, NIEHS
- Gary Ellison, Program Director, NCI
- Sally Tilotta, Scientific Review Officer, NIEHS
- Molly Puente, Grants Management Specialist, NIEHS

Questions?

Please type questions into the Q&A box.

We will read out the questions we receive.

Two weeks after the webinar, FAQs related to the Breast Cancer and the Environment Research Program will be available online at:

<http://www.niehs.nih.gov/research/supported/dert/programs/breast-cancer>

BCERP Goals

- Support transdisciplinary scientific research to enhance our knowledge of environmental and genetic factors underlying breast cancer risk over the lifespan of a woman
- Ensure new research findings are disseminated to girls and women at risk to advance breast cancer prevention

Definition of Transdisciplinary Research

Research that involves scientists from multiple disciplines, as well as community partners, working interactively on a common problem to develop novel cross-disciplinary methods, insights, and research approaches that would not have occurred with a traditional single-disciplinary investigation

BCERP Program Structure

- Individual transdisciplinary research projects (RFA-ES-14-012)
- Coordinating Center (RFA-ES-14-011)
- NIH cooperative agreement mechanism

Tip: review both RFAs, even if you are just planning to apply to one of them!

Key Dates

- Posted: November 3, 2014
- LOI: December 28, 2014
(Letter of Intent)
- Due Date: January 28, 2015
- Review Date: May/June 2015
- Council Date: August 2015
- Earliest Start Date: September 1, 2015

Environmental Influences during
Windows of Susceptibility (WOS) in
Breast Cancer Risk (U01)

RFA-ES-14-012

Windows of Susceptibility Project Objectives

- Support transdisciplinary research to investigate the influence of environmental exposures during specific windows of susceptibility on breast cancer risk
- Foster community-academic partnerships to ensure community concerns are represented and research findings are appropriately translated/disseminated
- Accelerate understanding of the contribution of environmental factors to breast cancer risk, the underlying mechanisms, and the potential for prevention strategies

Required Elements

- Include a community-academic partnership and community engagement activities
- Address a specific window(s) of susceptibility
- Propose a transdisciplinary research approach
- Focus on priority environmental exposure(s) for the program

Community-Academic Partnership and Activities

Applicants must:

- Partner with breast cancer organization(s) and/or members of the engaged community
- Focus on community-identified concern related to environmental stressors and breast cancer risk
- Include collaborative activities that are jointly conducted by the researcher(s) and community partner(s)

Window of Susceptibility

- **Definition**: specific time periods in which an individual is particularly susceptible to breast cancer risk associated with environmental exposures
- Applicants **must** identify one or more specific windows of susceptibility of focus

Transdisciplinary Research Approach

Applicants must:

- Focus on an identified common research theme related to the role of environmental exposures in breast cancer
- Propose novel transdisciplinary hypotheses that will be tested using both:
 - Experimental research aim(s) (*in vivo* or *in vitro models*)

AND

- Human research aim(s) (directly involves individuals or groups of individuals or that uses data/tissue from humans)
- Describe how the integration of the experimental and human research aims will collectively increase understanding

Types of Environmental Exposures

Applicants must include focus on one or more: Chemical substances that people are exposed to in their environment (such as industrial chemicals or manufacturing byproducts, metals, pesticides, herbicides, air pollutants, and personal care product contaminants) as well as physical factors (such as radiation from environmental sources and light at night)

Encouraged to also consider: how lifestyle and behavioral factors (such as physical activity and weight gain in adulthood) and social and cultural influences (such as family, community, psychosocial/social, and societal factors) contribute to breast cancer risk in combination with environmental exposures

Contact NIH Program Staff to Clarify!!

Encouraged Element

- Focus on intermediate risk factors that precede breast cancer:
 - Established risk factor for breast cancer that may be associated with etiological pathway linking environmental exposure with future disease
 - Should be observable in humans prior to breast cancer occurrence and potentially serve as predictive markers of environmentally induced breast cancer risk
 - Include, but are not limited to, markers of pubertal development and growth, breast density, and benign breast disease

Special Eligibility Requirements

- PIs for an application submitted under this FOA may not be the PI for a Coordinating Center application (but may be members of the same institutions)
- Applicant organizations may submit more than one application, provided that each application is scientifically distinct

Application Package Requirements

(in addition to/in place of standard NIH instructions)

Specialized Budget Requirements:

- Funds to cover travel for PI and Community Partner to annual BCERP meeting
- Support for Community Partners' level of effort proposed within the current application as well as to participate in BCERP Consortium-wide activities

Specialized Research Plan Instructions:

- Research Strategy section is limited to 30 pages
- Specific requirements listed for Specific Aims and Research Strategy components (see RFA)
- Must include Resource Sharing Plan

Anticipated Funding and Potential Number of Awards

\$6.2 million – combined budget from NIEHS and NCI per year for five years

6-8 awards – potential number of research projects

\$600,000 direct cost/year for up to 5 years – budget limit for applications per year; can request up to 5 years of support

Specialized Review Criteria

(in addition to the Standard NIH Review Criteria)

Overall Impact Score

- **Scored Review Criteria**

- Significance
- Investigator(s)
- Innovation
- Approach
- Environment
- **Assessment of the Community-academic Partnership**

- **Additional Review Criteria**

- **Collaborative Strengths**
- Protections for Human Subjects
- Incl. Women, Minorities and Children
- Vertebrate Animals
- Biohazards

- **Additional Review Considerations**

- Resource Sharing Plans
- Budget and Period of Support

- Each assigned reviewer provides scores (1-9) for each criterion. The Overall Impact Score is **NOT** an average of these Criterion Scores.
- This RFA includes additional questions for some criterion categories
- This RFA includes an additional scored criterion category to assess the community-academic partnership
- This RFA includes an additional review criterion to collaborative strengths of the applicant.

Additional Scored Criterion Questions

Significance: Are the proposed transdisciplinary research activities likely to accelerate understanding of the impacts of environmental exposures during specific windows of susceptibility on breast cancer risk, the underlying mechanisms, and the potential for prevention strategies?

Investigator(s) : Do the investigators have experience working in transdisciplinary teams?

Innovation: Does the application propose novel transdisciplinary methods, insights, and research approaches that would not have occurred with a traditional single-disciplinary investigation?

Approach: Are the proposed laboratory and human research aims well integrated and do they address the proposed common research theme related to the role of environmental exposures in breast cancer? Are steps proposed to disseminate applicable findings in appropriate formats to relevant stakeholders?

Assessment of the Community-academic Partnership: Is there evidence of an active partnership between research scientists and community members, including evidence that community partners have been involved in formulating research questions? Does the proposed study benefit from the strengths and expertise of all members of the collaborative research team? Is the partnership adequate to ensure success of the proposed project?

Additional Review Criteria Questions

Collaborative Strengths:

Does the application and/or history of the research team suggest that the investigators are willing to collaborate and share information among members of the BCERP Consortium, including the BCERP Coordinating Center, and abide by the priorities and policies agreed upon by the Steering Committee for collaborative studies? Do investigators bring particular expertise, facilities, research models, study populations, etc., that could potentially be leveraged to enhance the overall BCERP Consortium?

- Reviewers will evaluate **collaborative strengths** in determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for this item

Coordinating Center for the
Breast Cancer and the Environment
Research Program (U01)

RFA-ES-14-011

Coordinating Center Objectives

- Provide intellectual leadership as well as logistic support for the BCERP Consortium
- Identify opportunities for cross-BCERP collaborations and extend the transdisciplinary activities of the BCERP Consortium
- Assist in disseminating BCERP research findings and facilitating an internal evaluation of the Consortium

Required Responsibilities

Applicants must include plans to:

- Provide leadership and logistical support for the BCERP consortium
- Develop cross-BCERP coordinated research approaches and other activities
- Facilitate resource and data sharing and provide bioinformatics and data management support (as needed)
- Facilitate educational and outreach activities for the consortium
- Conduct ongoing internal evaluation of the Consortium

Leadership and Logistical Support

- Facilitate interactions among the BCERP Consortium and NIH
- Bring experience in leading team science initiatives to promote cross-disciplinary collaboration
- Provide scientific guidance on how to maximize the overall transdisciplinary nature of the program
- Provide logistical support for all aspects of the Consortium

Cross-BCERP Coordination

- Identify commonalities in research directions and methods being used across the Consortium to promote cross-BCERP collaborative efforts
- Facilitate the identification of new scientific questions that could be explored by the Consortium
- Coordinate development of collaborative projects
- Oversee a pilot project fund, referred to as the “BCERP Opportunity Funds”

Resource and Data Sharing, and Bioinformatics

- Facilitate the development of Consortium-wide policies in coordination with the BCERP Steering Committee and NIH program staff
- Establish and maintain secure websites for the public and for internal BCERP uses
- Facilitate access to individuals with specialized expertise in biostatistics and bioinformatics
- Serve as a clearing house for data storage and management (as needed)

Outreach and Education

- Facilitate integration of findings across the consortium and promote BCERP research
- Organize sessions to present BCERP outcomes at relevant national and international scientific meetings
- Promote the BCERP Consortium by actively synthesizing and disseminating relevant BCERP results to diverse audiences

Internal Evaluation

- Enable timely internal evaluation of the BCERP Consortium to identify and promote effective self-correcting actions
- Track the relative contribution of each individual Windows of Susceptibility research project to the overall goals of the BCERP Consortium
- Facilitate external evaluation of the program

Special Eligibility Requirements

- PIs for an application submitted under this FOA may not be the PI for a Windows of Susceptibility application (but may be members of the same institutions)

Application Package Requirements

(in addition to or in place of standard NIH instructions)

Specialized Budget Requirements:

- Funds to cover travel for PI and other essential staff to annual BCERP meeting
- BCERP Coordinating Center applicants must budget appropriate pilot project funds as “BCERP Opportunity Funds”

Budget for Pilot Project Funds: A recommended minimum of \$100,000 direct cost per year (or \$500,000 direct cost over the entire project period) should be requested in the budget with a clear plan for how potential projects will be identified, selected, and managed.

Application Package Requirements (cont'd)

Specialized Research Plan Instructions:

- Research Strategy section is limited to 30 pages
- Specific instructions provided for structure and content of the Research Strategy section (see RFA)
- Must include Resource Sharing Plan

Special Requirement for Research Personnel:

- The Biosketch of the PI should demonstrate experience and expertise in team science and conducting coordinating functions for multi-site projects

Anticipated Funding and Potential Number of Awards

\$1 Million – combined budget from NIEHS and NCI per year for five years

1 Award – one Coordinating Center

\$600,000 direct cost/year for up to 5 years – budget limit for applications per year; can request up to 5 years of support

Specialized Review Criteria

(in addition to the Standard NIH Review Criteria)

Overall Impact Score

- **Scored Review Criteria**
 - Significance
 - Investigator(s)
 - Innovation
 - Approach
 - Environment
- **Additional Review Criteria**
 - Protections for Human Subjects
 - Incl. Women, Minorities and Children
 - Vertebrate Animals
 - Biohazards
- **Additional Review Considerations**
 - Resource Sharing Plans
 - Budget and Period of Support

- Each assigned reviewer provides scores (1-9) for each criterion. The Overall Impact Score is **NOT** an average of these Criterion Scores.
- This RFA includes additional questions for some scored criterion categories

Additional Scored Criterion Questions

Significance: How well will the proposed Coordinating Center serve the goals of the BCERP Consortium?

Investigator(s) : Are the PDs/PIs and BCERP Coordinating Center investigators and key personnel well-qualified for participating and managing multi-site collaborations and facilitating and coordinating interactions and communication among investigators and staff from multiple institutions? Are the backgrounds, expertise, and commitments of the PDs/PIs and other key personnel sufficient for the proposed scope of activities and in line with the overall goals for the BCERP Coordinating Center?

Approach: Are new approaches proposed that would streamline research processes, improve communication, collaboration, creativity and performance within the BCERP Consortium? Does the plan for resource and data sharing and bioinformatics describe a program that will efficiently support the sharing of data and information resources across the BCERP Consortium? Are the proposed educational and outreach activities appropriate and adequate to support the BCERP goals? Is the proposed plan to synthesize and disseminate BCERP research results adequate to provide meaningful information to both researchers and community stakeholders? Does the evaluation plan demonstrate a capacity for the BCERP Coordinating Center to collaborate within the BCERP Consortium and NIH program staff on critical evaluation of the transdisciplinary nature of the program and dissemination of research findings?

Electronic Application

- Please start the application process early!
- Recommend to submit at least **three to five business days before due date**
- Check for confirmation email**
- Avoiding common errors:

http://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm



Cooperative Agreement Terms and Conditions of Award

- RFAs use NIH Cooperative Agreement (U01) Mechanism
- Each RFA has special terms of award (in addition to standard NIH Policy Statement)
- Outlines primary responsibilities and requirements of the PIs, role of NIH Staff and areas of joint responsibility
- Please review the RFA for full details!