Breast Cancer and the Environment Research Program (BCERP) Single-Site Data Use Policy

August 29, 2018

Purpose: The BCERP Consortium places strong value on sharing knowledge, data, research materials, and any other resources necessary and relevant to our work. This Single-Site Data Use Policy is intended to cover all data derived from work funded under the BCERP Funding Opportunity Announcement (RFA-ES-14-012), hereafter referred to as "BCERP Single-Site Data." (Data originally derived from work funded by non-NIH sources are not subject to this policy.) BCERP Single-Site data includes but is not restricted to published and unpublished data that are reported in any publication, including those presented in journal publications, conference talks, or poster presentations. Data generated by collaborative BCERP work are subject to the consortium's Collaborative Data Use Policy. Within 30 days of completing a BCERP study (i.e., the study's primary aims are published and available online), the Principal Investigator (PI) will submit a protocol and data description to the Coordinating Center to share with the Consortium. These descriptions will also be made publicly available to encourage use of BCERP data with external investigators.

BCERP Data Management: The Coordinating Center will maintain a description of each BCERP Single-Site data set on the public website, including any accompanying protocols, links to methodology publications about the data, and a data dictionary. Sites may either maintain a clean BCERP data set for distribution or may submit a clean BCERP Single-Site data set to the Coordinating Center. We recommend that scripts and software configuration information are also stored with the BCERP Single-Site data.

Process for BCERP data sharing: Investigators interested in using BCERP Single-Site data should submit a written request directly to the site using the BCERP Data Sharing and Reuse Proposal form. Sites will be expected to work with the requester to secure the necessary human and/or animal subjects approvals and data use agreements. It is expected that investigators requesting BCERP Single-Site data will cover reasonable costs for data sharing preparation.

Deposition of BCERP Single-Site **data:** When appropriate and/or required by NIH policies, BCERP investigators are expected to deposit data sets into approved repositories, such as dbGaP. Please notify the Coordinating Center of any such deposits, which can then be noted on the BCERP website.

Dissemination of information about available BCERP Single-Site **data:** The Coordinating Center will maintain a list of all available BCERP Single-Site data sets on the public website. Please inform the Coordinating Center at info@bcerp.org of all sharing of BCERP Single-Site data with either internal or external investigators. The Coordinating Center will track the sharing and should be notified of any resulting publications.

This policy applies to data generated by BCERP investigators while they are supported by BCERP grant funds. After the grants are finished and the Coordinating Center is no longer supported to facilitate data sharing, investigators interested in obtaining BCERP Single-Site data will need to work directly with WOS PIs.

BCERP PIs are expected to follow NIH policies for sharing research data (See:
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html) and sharing specimens including
model organisms (See:
https://grants.nih.gov/grants/policy/model_organism/model_organisms_faqs.htm)

From BCERP Coordinating Center RFA-ES-14-011:

III. Resource and Data Sharing, and Bioinformatics.

The BCERP Coordinating Center will facilitate data sharing and results dissemination across BCERP
awardees and between the BCERP and the NIH. It is expected that this aspect will involve resources and
personnel at individual BCERP project sites. Responsibilities of the BCERP Coordinating Center will
include, but are not limited to,:

- facilitating the development of publication, biospecimen, and data use policies in coordination with
  the BCERP Steering Committee and NIH program staff;
- establishing and maintaining secure websites for the public and for internal BCERP uses;
- facilitating access to individuals with specialized expertise in biostatistics and bioinformatics, as
  needed to support cross-BCERP projects; and providing data management functions for the
  Consortium, as appropriate.

From BCERP WOS Sites RFA-ES-14-012:

To the extent that common data elements can be collected across multiple research projects, BCERP
members may be expected to share such data with the BCERP Coordinating Center to serve as a clearing
house for data storage and management if it is determined that centralization of such data would be
beneficial to the BCERP Consortium by the BCERP Steering Committee (see section below on BCERP
Consortium Governance below).

All PD(s)/PI(s) of the BCERP Consortium (Coordinating Center and Windows of Susceptibility research
projects) will have the primary responsibility for:

- Sharing data, protocols and other research resources generated through the BCERP award.

All BCERP Consortium awardee institutions/organizations will be expected to share with other BCERP
awardees knowledge, data, research materials, and any other resources necessary and relevant to the
BCERP Consortium.