Breast Cancer Surveillance Consortium (BCSC)
Guide to Working with BCSC Data

I. Purpose: Describe how to apply for BCSC data and requirements for using BCSC data.

II. Applying for and Working with BCSC Data

Step 1: Develop your research question

Investigators must contact the Statistical Coordinating Center (SCC) and/or other BCSC investigators while developing their research proposal to confirm that the BCSC data can meet their needs. Other topics important for planning can be discussed at this time, including the feasibility of data release to investigators who wish to analyze data themselves. Information to assist with proposal preparation such as a list of BCSC investigators, distribution of key variables, and mammography performance benchmarks are on the public website (https://www.bcsc-research.org/about/working-with-bcsc). Other information, such as sample data collection forms and BCSC proposal forms, are available from the SCC (email KPWA.scc@kp.org).

Investigators must include at least one BCSC investigator as a collaborator on their proposed project, given their expertise and experience with the data. We recommend that you contact BCSC investigators with whom you wish to collaborate while you are developing your research question. If you are uncertain who to invite to collaborate, contact the SCC.

Step 2: Submit a BCSC Concept Proposal Form to the SCC at KPWA.scc@kp.org

Complete the BCSC concept proposal form and send it to the SCC at KPWA.scc@kp.org. Provide a succinct description of your proposed research project. The SCC will use this information to identify potential overlap with approved proposals, determine whether the project would conform to BCSC data sharing policies, and identify BCSC investigators to facilitate development of the full proposal. The form may also be used to request de-identified data to assess feasibility. Most investigators will receive a decision on their concept proposal within six weeks.

Please note that approval of a concept proposal does not guarantee approval of the full proposal. Full proposals must be submitted within **six months** of concept proposal approval; otherwise, the proposal will be classified as inactive, opening the possibility that another investigator can move forward with that research idea.

Step 3: Submit a BCSC Full Proposal Form to the SCC

If your concept proposal is approved, the BCSC will work with you to prepare your full proposal. We can help you to develop your research ideas, assist you in choosing data variables, and suggest potential collaborators.

The SCC will send you a full proposal form after your concept proposal is approved. This form asks about your research plans, including collaborators, main hypotheses and research questions, inclusion criteria, years, key variables and outcomes, analytic methods, table shells, and a timeline. The Steering Committee will review the proposal. They will also

determine whether analyses are best performed by the SCC or whether de-identified data can be given to the investigator for analysis. We usually respond within 6 weeks.

If you are planning on submitting a grant using BCSC data, you must submit your proposal to the SCC **at least** 6 weeks before the due date.

Draft budgets and staffing plans should be discussed with your BCSC collaborators and the SCC while you develop your proposal. Final agreement to participate will depend on agreement with the budget and staffing plans, as well as approval of your BCSC proposal.

For grant proposals, please note that each manuscript using BCSC data that you plan to produce under the grant will need its own approved manuscript proposal. So if your original proposal was for a grant, then after you are funded you must submit a manuscript proposal form for each manuscript. This allows the SCC to adequately plan for your needs.

Step 4: Sign a BCSC collaborative research agreement and read or sign additional documents

If your full proposal is approved, you and anyone else working directly with the data will be asked to sign a BCSC Collaborative Research Agreement. The agreement sets forth the terms and conditions to which you must agree before the BCSC provides you with a dataset or data tables. Additional documents may need to be read or signed, depending on the data requested.

For data requests, please note: Everyone who works with the data is required to sign a collaborative agreement before accessing the data. If the analyst(s) or method of storing the data changes during your project, you need to report this to the SCC so we can update our records and obtain additional signatures as needed.

Step 5: Work with the SCC to obtain data or define analyses

When your proposal is approved, you will be assigned an SCC analyst. The investigator and analyst will work with you to complete the data or analysis request. For data analyses, you will discuss and establish the analytic design, table format, and other details.

Significant changes to approved proposals must be approved by the BCSC Steering Committee before analyses are conducted or findings disseminated. Examples of changes that **require** Steering Committee approval include:
- New specific aims or scientific questions
- Change in the study outcomes
- Change in the main exposures or predictors of interest
- Substantial change in inclusion criteria (e.g., change from women with cancer to all women, or from screening only to both screening and diagnostic exams)
- Addition of an adjustment variable to the analysis if the results after adjusting are shown in tables or figures or reported in the text
- Change in the statistical analysis that requires additional data

Examples of changes that do **not** need Steering Committee approval include:
- Small changes in inclusion criteria (e.g., change start year from 1998 to 1996)
- Addition of an adjustment variable to the analysis if results using this variable are not shown in tables or figures or reported in the text

- Change in the statistical analysis method that does not require use of additional data (e.g., use a log-binomial instead of logistic regression model)
- Addition or deletion of a table or figure without changing the question under study

If you think you may have made changes to your proposal that require Steering Committee approval, please notify your SCC analyst or the SCC (KPWA.scc@kp.org).

Step 6: Submit a BCSC Project Update to the SCC

Every 6-12 months you will be asked to complete a brief project update. The SCC will e-mail you to request the update and ask that you return it within 2 weeks. The purpose of this update is to assist the SCC in tracking data requests and progress.

Step 7: Submit your manuscripts, conference abstracts, posters and slide decks to the SCC before submission or presentation

All manuscripts, conference abstracts, posters and slide decks must be submitted to the SCC **before submission or presentation**.

The Manuscript Approval Checklist must be submitted to the SCC with your **manuscript**. The checklist is available from the SCC (KPWA.scc@kp.org).

We recognize that **abstracts** for scientific meetings are typically prepared close to their due date. If you cannot send your abstract to the SCC for Steering Committee review at least two weeks before the submission date, you may send it for review when you submit the abstract to the conference. In this case, the investigator must agree to withdraw the abstract if s/he does not receive approval from the BCSC.

Because many **posters and slide decks** are completed close to the time of presentation, investigators may submit an early but solid draft rather than the final version. Projects with a BCSC collaborator do not need SCC review (provided that the BCSC coauthors have approved the presentation), but final presentations must be submitted to the SCC at KPWA.scc@kp.org.

The main purpose of review is not to critique the science or methods; it is to ensure that confidentiality of the women, physicians, facilities, and sites is maintained, that BCSC data are not misrepresented, and to confirm proper BCSC acknowledgment. If you believe that your manuscript or presentation may contain something of concern, please contact the SCC for guidance.

Step 8: Send analytic datasets to the SCC for archiving

As part of the Collaborative Research Agreement, investigators who received BCSC data are required to delete all data files, tables and paper copies within **six months** after publication or project completion. You may send your analytic datasets to the SCC for archiving. You are encouraged to send the SCC a final analytic dataset along with the documented program you used to generate the dataset. The SCC will archive the data for at least 5 years. To track this, the SCC will send you a letter seeking confirmation that you have destroyed the BCSC data.

If you would like to use the data for another purpose, you must submit a new proposal to the BCSC.

III. Collaborative Writing Guidelines

The BCSC has developed guidelines for efficiently and successfully creating and publishing collaborative scientific papers. The guidelines describe how to facilitate manuscript development and submission for publication and are available on the public BCSC website *(https://www.bcsc-research.org/about/working-with-bcsc, under "Guidelines for developing manuscripts").* We strongly recommend use of these guidelines for collaborative manuscripts with an SCC analyst.

IV. Requirements for Using BCSC Data for Publication

1. **Collaborate** with designated members of the SCC in data preparation and analysis.

2. **Acknowledge** the BCSC for its contributions to the manuscript. (Information available from KPWA.scc@kp.org.)

3. Submit final draft of the manuscript, with the **manuscript checklist,** to the Steering Committee for approval before submission for peer review. Review usually takes 2 weeks. If the author group includes an NCI scientist, clearance from NCI must also be obtained before submission for peer review. (Checklist available from KPWA.scc@kp.org.)

V. Frequently Cited BCSC Publications

A list of BCSC publications is available on the public BCSC website: https://www.bcsc-research.org/about/media.

VII. Suggested Language about HIPAA Compliance, Confidentiality, and IRB Approval
"Each BCSC registry and the Statistical Coordinating Center (SCC) have received institutional review board approval for all study procedures, including passive permission (one registry), a waiver of consent (six registries), or both depending on facility (one registry), to enroll participants, link data, and perform analytic studies. All procedures are Health Insurance Portability and Accountability Act (HIPAA) compliant. All registries and the SCC have received a Federal Certificate of Confidentiality and other protections for the identities of women, physicians, and facilities who are subjects of this research."

VIII. Submit Publication to PubMed Central

NIH requires that publications that arise from an NIH award be submitted to PubMed Central. NIH provides sample language that can be used in a copyright agreement between the author or institution and publisher: *"Journal acknowledges that Author retains the right to provide a copy of the final peer-reviewed manuscript to the NIH upon acceptance for Journal publication, for public archiving in PubMed Central as soon as possible but no later than 12 months after publication by Journal."* For more information, see *http://www.nihms.nih.gov/help/* or *http://publicaccess.nih.gov/*.