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 are strongly encouraged to contact the Statistical Coordinating Center (SCC) and/or other BCSC investigators while developing their research question to confirm that the BCSC data can meet their needs. Other topics important for planning can be discussed at this time, including the likelihood of data release to investigators who wish to analyze data themselves. Information is available on the public BCSC website (*http://www.breastscreening.cancer.gov/index.html*) to assist with proposal preparation: (1) list of BCSC investigators, (2) data collection forms, (3) distribution of key variables, (4) mammography performance measures (such as sensitivity, specificity, and positive predictive value) by patient characteristics, and (5) the BCSC concept proposal form.

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

Please provide a succinct but complete description of your idea. The SCC will use this information to identify potential overlap with approved concept or full proposals, determine whether the project would conform to BCSC data sharing policies, and identify BCSC investigators to facilitate development of the full proposal.

Most investigators will receive a decision on their concept proposal within six weeks of its submission. 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. The BCSC can help you to further develop your research ideas, assist you in choosing BCSC 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 and outcomes of interest, key variables, analytic methods, table shells, and a timeline. Budgets and detailed staffing plans are not necessary.

The Steering Committee will review the proposal and will determine whether analyses are best performed by the SCC or whether de-identified data can be given to the investigator for analysis. A response will typically occur 2-6 weeks after submission.

If necessary, refine the proposal to address comments from Steering Committee.

For grant proposals, please note that each manuscript using BCSC data that you plan to produce under the grant needs its own approved manuscript proposal. This means that if your original proposal was for a grant, then after you are funded you must submit a manuscript proposal form for each manuscript. The additional detail 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 will be asked to sign a BCSC Collaborative Research Agreement before activity begins. 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 and/or signed, depending on the data requested.

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

When your proposal is approved, you will be assigned an SCC analyst. The investigator and SCC analyst will work with you to complete the data or analysis request and develop a timeline for completion. For analyses, you will discuss and establish the analytical design, table format, and models for data analysis.

Significant changes to approved proposals and projects must be approved by the BCSC Steering Committee before analyses are conducted or research findings disseminated. Examples of changes that **require** Steering Committee approval include:

- New specific aims or scientific questions not included in the approved proposal
- Change in the primary or secondary outcome (dependent variable)
- Change in the main exposures or predictor variables 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 mammograms)
- Addition of an adjustment variable to the analysis if the results obtained after adjusting for this variable are shown in tables or figures or reported in the text
- Change in the statistical analysis method 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., using 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 (scc@ghc.org).

Step 6: Submit a brief BCSC Project Update Form to the SCC

Every 6-12 months, you will be asked to complete the Project Update Form (PDF). The SCC will e-mail the form to you and will ask that you return it within two weeks. The purpose of this form is to assist the SCC in tracking data requests and progress in general.

Step 7: Submit your manuscripts, conference abstracts, posters and slides to the SCC prior to submission or presentation

All manuscripts, conference abstracts, posters and slides must be submitted to the SCC prior to submission or presentation. The Manuscript Approval Checklist must be submitted along with a **manuscript**.

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 at the same time you submit it to the conference of interest. In this instance, the investigator must agree to withdraw the abstract if s/he does not receive approval from the BCSC.

Projects without a BCSC collaborator should submit **posters and slides** to the SCC for review at least two weeks before presentation. As many posters and slides 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 need to be submitted to the SCC at scc@ghc.org.

The 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 as early as possible.

Step 8: Send analytic datasets to the SCC for archiving

As part of the Collaborative Research Agreement, investigators performing their own analyses using BCSC data are required to delete all data files, tables and paper copies within **six months** after publication of results. To ensure reproducibility of your analyses, the SCC serves as the repository for analytic datasets using BCSC data. You are encouraged to forward a final analytic dataset along with the documented program you used to generate the dataset to the SCC for archiving; datasets will be archived by the SCC for at least 5 years. The SCC will send a letter asking that you forward the final analytic datasets to the SCC if you would like them archived, and seeking confirmation that you have destroyed the BCSC data. Please return this letter to the SCC within 2 weeks.

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 (*http://www.breastscreening.cancer.gov/index.html*). We strongly recommend use of these guidelines for collaborative manuscripts with an SCC analyst.

IV. Requirements for Using BCSC Data for Publication

1. Work with your designated SCC analyst.

2. Acknowledge the BCSC for its contributions to the manuscript.

3. Submit the final draft of your abstract or manuscript to the Steering Committee for approval before submission for peer review. This review process usually will be completed within two weeks. If the author group includes an NCI scientist, clearance from NCI must also be obtained before manuscript submission for peer review.

V. Frequently Cited BCSC Publications

1. Public BCSC website: http://breastscreening.cancer.gov/

2. BCSC descriptive paper:
Ballard-Barbash R, Taplin SH, Yankaskas BC, Ernster VL, Rosenberg RD, Carney PA, Barlow WE, Geller BM, Kerlikowske K, Edwards BK, Lynch CF, Urban N, Chrvala CA, Key CR, Poplack SP, Worden JK, Kessler LG. Breast Cancer Surveillance Consortium: a national mammography screening and outcomes database. AJR Am J Roentgenol 1997;169:1001-8.

3. Confidentiality paper:
Carney PA, Geller BM, Moffett H, Ganger M, Sewell M, Barlow WE, Stalnaker N, Taplin SH, Sisk C, Ernster VL, Wilkie HA, Yankaskas B, Poplack SP, Urban N, West MM, Rosenberg RD, Michael S, Mercurio TD, Ballard-Barbash R. Current medicolegal and confidentiality issues in large, multicenter research programs. Am J Epidemiol 2000;152:371-8.

4. Cancer Data Completeness paper:
Ernster VL, Ballard-Barbash R, Barlow WE, Zheng Y, Weaver D, Cutter G, Yankaskas B, Rosenberg R, Carney PA, Kerlikowske K, Taplin S, Urban N, Geller B. Detection of DCIS in women undergoing screening mammography. J Natl Cancer Inst. 2002;94:1546-54

VII. Suggested Language about HIPAA Compliance, Confidentiality, and IRB Approval

"Each registry and the Statistical Coordinating Center (SCC) have received institutional review board approval for either active or passive consenting processes or a waiver of consent to enroll participants, link data, and perform analytic studies. All procedures are Health Insurance Portability and Accountability Act (HIPAA) compliant and 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/.