

## **Breast Cancer Surveillance Consortium (BCSC) Data Request Process Guide**

I. Purpose: Define the process of applying for use of BCSC data and for manuscript development that arises from the use of the requested data.

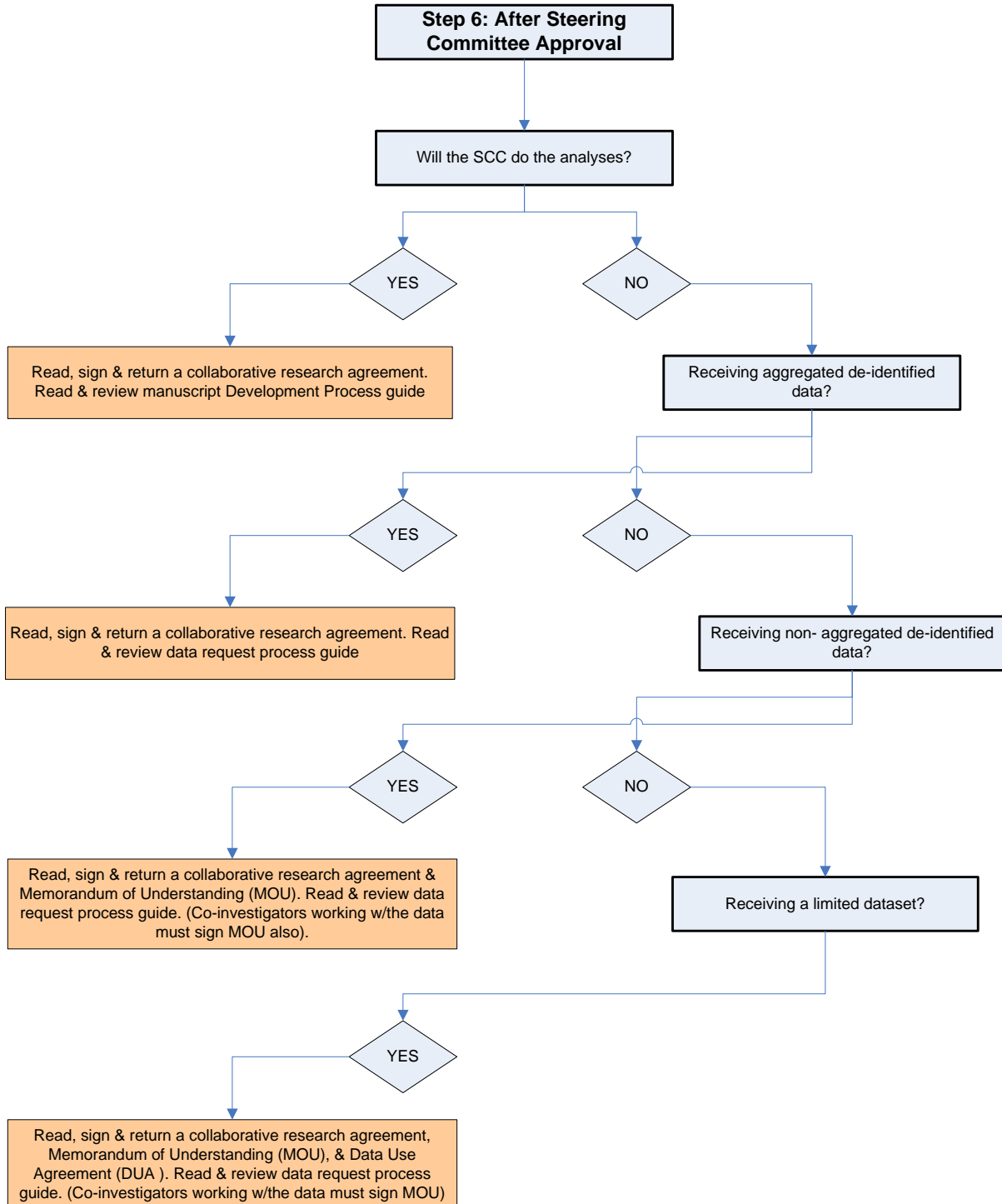
### II. Overview of Application Process for Working with the BCSC to Use BCSC Data:

- **Step 1:** Develop research question(s) that can be answered using BCSC data.

To ensure the project is feasible using BCSC data, investigators are encouraged to work closely with a Statistical Coordinating Center (SCC) and/or BCSC member when developing their project proposal (See Step 2 below). The following are available on the public BCSC website to assist with analytic plans and manuscript preparation: (1) data dictionary, (2) site-specific questionnaires, (3) tables describing the distributions of some key variables, (4) mammography performance measures such as sensitivity, specificity, and positive predictive value by patient characteristics, and (5) BCSC proposal form. The Steering Committee or designee(s) will determine whether data analyses are best performed by the SCC or whether deidentified data can be given to an investigator(s) for analysis.

- **Step 2:** Contact the SCC ([scc@ghc.org](mailto:scc@ghc.org)) or review the list of investigators on the BCSC website (<http://breastscreening.cancer.gov/index.html>) to identify an individual who can facilitate completion and review of the BCSC proposal form. Please indicate reason(s) for data request (manuscript, preliminary data for grant proposal, inputs for simulation models, development of statistical methodology, etc.)
- **Step 3:** Prepare a preliminary proposal, using the BCSC proposal form, to outline the scientific background, research question, relevant variables, and timeline. This proposal will be presented to the BCSC Steering Committee for initial approval to continue with the application.
- **Step 4:** Present the final version of the BCSC proposal form for review to the SCC ([scc@ghc.org](mailto:scc@ghc.org)). A response to requests will occur within 2-4 weeks of submission to the SCC.
- **Step 5:** If necessary, refine proposal to address comments from Steering Committee or designee(s).
- **Step 6:** Following Steering Committee approval, several documents need to be read, signed and/or returned to the SCC before the analyses may begin. These documents may include
  1. BCSC collaborative agreement
  2. Memorandum of Understanding (MOU)
  3. Data request process guide
  4. Manuscript development process guide
  5. Data Use Agreement

The following flow-diagram has been developed to help you determine which documents are required. Documents requiring signatures must be signed and returned to the SCC before analysis may begin. For the MOU, only the signature page needs be returned and it may be faxed to 206.287.2871(Attention: Diana Miglioretti).



- **Step 7:** Plan analyses with SCC member and develop timeline for data analysis.
- **Step 8:** Complete a brief progress report biannually. (The BCSC tracks data requests to determine how investigators use BCSC data for research. A project update form will be sent to by e-mail in March and September. To assist us with tracking data requests, please complete the brief progress update form by checking the appropriate boxes and submit the form to the SCC at [scc@ghc.org](mailto:scc@ghc.org) within 2 weeks.)
- **Step 9:** As analyses near completion, presentation of findings at a semi-annual BCSC meeting is encouraged.
- **Step 10:** Submit project results (abstract for scientific meeting presentation, manuscript, preliminary data for grant proposal, statistical methodology, etc.) to SCC at [scc@ghc.org](mailto:scc@ghc.org) for review by Steering Committee or designee(s). Investigators who wish to submit results to scientific meetings should allow at least two weeks prior to an abstract deadline for the Steering Committee or designee(s) to review an abstract and provide feedback. If necessary, refine analyses to address Steering Committee or designee(s) feedback and submit final analyses to the SCC for final BCSC approval.

**III. Guidelines for Manuscript Development:** The BCSC has developed guidelines for successfully creating and publishing collaborative scientific papers for its own use. These guidelines describe procedures for facilitating efficient manuscript development and submission for publication, and are available on the BCSC web site.

#### **IV. Requirements for using BCSC data for publication**

1. Collaborate with designated members of the SCC in data analyses.
2. Acknowledge BCSC for their contributions to the manuscript (see below).
3. Submit final draft of abstract or manuscript to the Steering Committee or Designee (s) for approval prior to submission for peer-review. If the author group includes an NCI scientist, clearance from NCI must also be obtained prior to manuscript submission for peer-review. This review process usually will be completed within 2-4 weeks.

#### **V. Manuscript Acknowledgements**

##### **Acknowledgment of Funding Source**

Manuscripts that used pooled data must cite the following grant numbers according to the sites that contribute data for their project. A SCC member can assist investigators with the appropriate numbers to site. For example, if all sites contribute data to a project the acknowledgement would read: "Data collection for this work was supported by a NCI-funded Breast Cancer Surveillance Consortium co-operative

agreement (U01CA63740, U01CA86076, U01CA86082, U01CA63736, U01CA70013, U01CA69976, U01CA63731, U01CA70040).”

Diana L. Miglioretti  
Group Health Cooperative  
U01CA86076

Karla M. Kerlikowske  
University of California, San Francisco  
U01CA63740

Patricia A. Carney  
Oregon Health and Science University  
U01CA86082

Robert D. Rosenberg  
University of New Mexico Health Sciences Center  
U01CA69976

Gary Cutter  
UAB School of Public Health  
U01CA63736

Diana SM Buist  
Group Health Cooperative  
U01CA63731

Berta M. Geller  
University of Vermont  
U01CA70013

Bonnie C. Yankaskas  
University of North Carolina at Chapel Hill  
U01CA70040

#### Acknowledging the BCSC and investigators

The BCSC and investigators appreciate acknowledgement of efforts to collect and make available this valuable data resource. If journals will allow acknowledgements, the BCSC suggest the following two options in addition to listing grant numbers described above:

“We thank the BCSC investigators, participating mammography facilities, and radiologists for the data they have provided for this study. A list of the BCSC investigators and procedures for requesting BCSC data for research purposes are provided at: <http://breastscreening.cancer.gov/>.”

AND/OR

If one or more authors are BCSC members, the BCSC may be acknowledged at the end of the authorship list with the following: Smith A, Jones B, .....for the Breast Cancer Surveillance Consortium.

#### VI. References For Frequently Cited BCSC Papers

1. 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, Chvala 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. Completeness of Cancer Data

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 describing HIPAA compliance, Certificate of Confidentiality, and IRB approval:

“Each registry and the SCC have received IRB 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 HIPAA compliant and all registries and the SCC have received a Federal Certificate of Confidentiality that protects the identities of research subjects.”

#### **VIII. BCSC Data Destruction**

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 six months after publication of results and/or completion of the grant funding. To ensure reproducibility of analyses, the SCC serves as the repository for all analytic datasets using BCSC data. The SCC will send a letter asking that you forward the final analytic datasets and also seek confirmation that you have destroyed the BCSC data. Please return this letter to the SCC as soon as possible. If you would like to use the data for another purpose, we encourage you to submit a new data request form to the BCSC.