



## Breast Cancer Surveillance Consortium Collaborative Research Agreement

1. Project Title and Abstract Number:
  2. Project Leader:
  3. SCC Contact:
  4. Co-investigators:
  5. BCSC Abstract Approval Date:
  6. Purpose of data request (check all that apply):
    - Data analysis for manuscript
    - Preliminary data for grant proposal
    - Inputs for simulation model
    - Development of statistical methods
    - Other \_\_\_\_\_ (describe)
- 

### Agreement

This Breast Cancer Surveillance Consortium (BCSC) Collaborative Research Agreement (“Agreement”) is made and entered into as of \_\_\_\_\_ (day/month/year) by and between the BCSC and \_\_\_\_\_ (“Data Recipient”). This Agreement sets forth the terms and conditions pursuant to which the BCSC will disclose the Data Set or Data Tables to the Data Recipient.

The Data Recipient(s) may use the data set/tables to conduct research on the approved project named above and described in the attached project proposal. However, the data set/tables may **not** be used for any other purposes than this approved research. This is always true unless it is otherwise stated in the agreement document.

Only the project investigator, co-investigators, or designated individual(s) are permitted to use or receive the Data Set/Tables for approved purposes. These individuals are responsible for using this information subject to the terms and conditions of this Agreement.

### Obligations of Data Recipient

1. Data Recipient agrees to not use or disclose the Data Set/Tables for any other purpose than as permitted by this Agreement. If the recipient would like to use the data for another purpose other than what is stated in their data request form, s/he is required to submit a new proposal form to the BCSC.
2. Data Recipient agrees to use appropriate security to prevent the use or disclosure of the Data Set/Tables, other than as provided for by this Agreement.
3. Data Recipient will establish and maintain the appropriate administrative, technical, and physical safeguards to protect the confidentiality of the data and to prevent unauthorized use or access to it, as described in the proposal. If the Data Recipient becomes aware of any use or disclosure of



the Data Set/Tables not permitted by this Agreement, s/he agrees to report it to the Statistical Coordinating Center (SCC).

**4.** Data Recipient agrees to obtain IRB approval at their institution for any requests of individual-level data (i.e., not aggregate data). The SCC will not release individual-level data until proof of IRB approval or exemption is obtained.

**5.** Data Recipient will not permit others to use the data except for collaborations within their institution involved with the research, as described in the proposal. Collaborators outside of the data recipient's institution must sign a Collaborative Research Agreement if they are custodians of the data.

**6.** If Data Recipient moves to another institution, s/he needs to destroy the Data set/tables and notify the SCC in writing within 30 days that this has been done. If Data Recipient takes these BCSC data to the new institution, then s/he must provide the SCC with updated contact information and a copy of the new IRB approval for the new institution. If the data remain at the initial organization, then the Data Recipient must designate who is responsible for the files and ensure that s/he signs a copy of the Collaborative Research Agreement.

**7.** Data Recipient will not attempt to link (nor permit others to link) the BCSC data with individually identified records in another database.

**8.** No one having access to the BCSC data will attempt to learn the identity of any persons, radiologists, facilities, or BCSC sites. In the event that Data Recipient or collaborator is able to deduce the identity of a specific patient, radiologist, facility, or BCSC site s/he agrees to not attempt to contact these individuals or institutions.

**9.** No findings or information derived from the BCSC data may be released if they contain any combination of data elements that might allow the deduction of a patient's, radiologist's, facility's, or BCSC site's identity. In tables, cell sizes less than 5 must be suppressed. The BCSC proposal review committee will be the sole judge as to whether any finding derived from the BCSC data would, with reasonable effort, permit one to identify an individual, radiologist, facility, or BCSC site, or to deduce the identify of an individual or provider to a reasonable degree of certainty.

**10.** Before submitting **ANY** manuscripts for submission or formal presentation, the Data Recipient agrees to give the Steering committee copies of these manuscripts for review. The Steering committee agrees to review the manuscript(s) and make a determination about approval. The Steering committee agrees to notify the user within 2 weeks after the review. Data Recipient also agrees not to submit such findings to any third party until receiving approval to do so.

The primary purpose of the Steering committee review is to assure that data confidentiality is maintained and that individual patients, radiologists, facilities, or BCSC sites cannot be identified. Thus, the Steering committee may withhold approval for publication if it determines that the format in which data are presented may result in identification of individual patients, radiologists, facilities, or BCSC sites.

Data Recipient agrees that if the Steering committee determines (or has reasonable belief) that s/he has violated any terms of this agreement, the BCSC may request that s/he return the data and all derivative files to the SCC. Additionally, as a result of the BCSC's determination or



reasonable belief that a violation of this agreement has taken place, the BCSC may refuse to release further BCSC data.

11. Significant changes to approved proposals and projects need to be reviewed and approved by the BCSC Steering Committee before any analyses may be conducted or research findings may be disseminated. If the Data Recipient is unsure whether there is a significant change please ask the BCSC Steering Committee to review it.

12. Data Recipient agrees to complete a brief progress report biannually and return it to the SCC within two weeks.

13. Any publications and/or presentations will properly acknowledge the contributions of the BCSC, as described in more detail in the Data Request Process Guide.

14. As of April 7, 2008, NIH requires that any publications, which arose from an NIH award, be submitted to PubMed Central, as described in more detail in the Data Request Process Guide.

15. The Data Recipient will destroy all BCSC datasets six months after publication of their results and/or completion of grant funding period. A copy of all datasets will be archived by the SCC until at least 2015.

IN WITNESS WHEREOF, the parties have executed this Agreement on the date first written above.

**Signature from the Breast Cancer Surveillance Consortium:**

\_\_\_\_\_  
(Signature of SCC Principal Investigator or Designee)

\_\_\_\_\_  
(Title)

\_\_\_\_\_  
(print name)

**Signature of Project Leader:**

The person signing below represents and warrants that s/he has authority to execute this Agreement on behalf of the Data Recipient (in the case of students and fellows, the department chair or advisor from the student’s academic institution must also sign the data request). Your signature indicates that you agree to comply with the above stated provisions.

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Title)

\_\_\_\_\_  
(print name)

Institution/Organization: \_\_\_\_\_

Street Address: \_\_\_\_\_

City/State/ZIP code: \_\_\_\_\_

Phone: \_\_\_\_\_

E-Mail: \_\_\_\_\_



**Signature of the Custodian of the Data:**

*Complete this if the data will be stored by someone other than the Principal Investigator. Your signature indicates that you agree to comply with the above stated provisions.*

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Title)

\_\_\_\_\_  
(print name)

Institution/Organization: \_\_\_\_\_  
Street Address: \_\_\_\_\_  
City/State/ZIP code: \_\_\_\_\_  
Phone: \_\_\_\_\_  
E-Mail: \_\_\_\_\_

**Required for Students and Fellows: Signature of Department Chair or Advisor:**

The person signing below represents and warrants that s/he has authority to execute this Agreement on behalf of the Data Recipient. Your signature indicates that you agree to comply with the above stated provisions.

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Title)

\_\_\_\_\_  
(Print name)

\_\_\_\_\_  
(Relationship to project leader)

Institution/Organization: \_\_\_\_\_  
Street Address: \_\_\_\_\_  
City/State/ZIP code: \_\_\_\_\_  
Phone: \_\_\_\_\_  
E-Mail: \_\_\_\_\_