



## Breast Cancer Surveillance Consortium Collaborative Research Agreement

1. Project Title and Proposal Number:
  2. Project Leader:
  3. Other Data Recipients:
  4. BCSC Facilitator:
  5. SCC Contact:
  6. BCSC Proposal Approval Date:
  7. 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)
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### Agreement

This Breast Cancer Surveillance Consortium (BCSC) Collaborative Research Agreement ("Agreement") is entered into as of \_\_\_\_\_ (day/month/year) by and between the BCSC and \_\_\_\_\_ ("Project Leader"). This Agreement sets forth the terms and conditions under which the BCSC will disclose the data set or data tables to the Data Recipient(s).

The term "Data Recipient" encompasses the Project Leader and all individuals who will access and/or store the data for this approved purpose. The Project Leader accepts primary responsibility for ensuring compliance to this Agreement by other Data Recipients and collaborators. The Project Leader and other Data Recipients are responsible for signing this Agreement and using the data subject to the terms and conditions stated below.

The Data Recipient(s) may use the data to conduct research on the approved project named above and described in the corresponding project proposal. The data may **not** be used for any other purpose.

### Obligations of Project Leader and other Data Recipients

1. Data Recipient(s) will not use or disclose the data for any purpose other than permitted by this Agreement. If s/he would like to use the data, including data tables, for another purpose, s/he is required to submit a new proposal form to the BCSC.
2. The Project Leader will obtain an approved manuscript proposal for each planned manuscript, even if the manuscripts originate from the same parent grant.



3. The Project Leader will obtain IRB approval at his/her institution when requesting individual-level data containing Personal Health Information (PHI) (i.e., a HIPAA-defined limited dataset). The Statistical Coordinating Center (SCC) will not release individual-level data containing PHI until proof of IRB approval or exemption is obtained.
4. Data Recipient(s) will use appropriate security to prevent use of the data, other than permitted by this Agreement. S/he will establish and maintain appropriate administrative, technical, and physical safeguards to protect data confidentiality and prevent unauthorized use or access of the data. If the Data Recipient(s) becomes aware of any use or disclosure of the data not permitted by this Agreement, s/he will report it to the SCC.
5. Data Recipient(s) will not attempt to link (or permit others to link) the BCSC data with individually-identified records in another database.
6. No one having access to BCSC data will attempt to learn the identity of any patient, radiologist, facility, or BCSC registry. In the event that Data Recipient(s) or collaborators are able to deduce the identity of a specific patient, radiologist, facility, or BCSC registry, s/he will not attempt to contact these individuals or institutions or reveal this information to anyone else.
7. Data Recipient(s) will not release findings or information derived from BCSC data if they contain any combination of data elements that might allow one to deduce the identity of a patient, radiologist, facility, or BCSC registry. Small cell sizes may be displayed in tables if the data do not threaten confidentiality. If linked BCSC-Medicare data are shown, no cell size less than 11 (or percentage or other formula that would result in a cell size less than 11) may be displayed. The BCSC Steering Committee will determine whether any finding derived from BCSC data could, with reasonable effort, permit one to identify an individual, radiologist, facility, or BCSC registry or deduce the identity of an individual or provider to a reasonable degree of certainty.
8. If a Data Recipient moves to another institution, s/he must either (1) destroy the data and notify the SCC in writing within 30 days that this has been done **or** (2) take the data to the new institution and provide the SCC with updated contact information and a copy of the IRB approval from the new institution (if IRB approval is required as described above). If the data remain at the initial institution, then the Data Recipient must designate the person responsible for the data and ensure that this person signs a copy of the Collaborative Research Agreement.
9. The Project Leader will obtain approval from the BCSC Steering Committee for significant changes to proposals before analyses are conducted or research findings disseminated. Examples of changes requiring review are in the *Guide to Working with BCSC Data*. If the Project Leader is unsure whether a change is significant, s/he may ask the SCC.
10. The Project Leader will complete a brief progress report every 6-12 months at the SCC's request, and will return the report to the SCC within two weeks.
11. The Project Leader will not submit study findings using unpublished BCSC data to a third party until obtaining approval from the BCSC. Before submitting a manuscript that uses unpublished BCSC data for publication, the Project Leader will submit the manuscript, with the Manuscript Approval Checklist, to the SCC for Steering Committee review. The Steering Committee will typically review the manuscript within 2 weeks.



The Project Leader will submit conference abstracts, posters and slides using unpublished BCSC data to the SCC before submission or presentation. If the Project Leader lacks time to send an abstract to the SCC for review at least two weeks before conference submission, s/he may send it at the time of submission to the conference of interest. In this instance, the Project Leader must withdraw the abstract if s/he does not receive BCSC approval. Because posters and slides are often completed close to the time of presentation, the Project Leader may submit an early (but solid) draft rather than the final version.

The primary purpose of the review is to assure that confidentiality is maintained. The BCSC may withhold approval if it determines that the data presented may result in identification of individual patients, radiologists, facilities, or BCSC registries.

12. The Project Leader will properly acknowledge the contributions of the BCSC in all publications and presentations, as described in the *Guide to Working with BCSC Data*.
13. The Project Leader will submit all publications using BCSC data to PubMed Central, as required by NIH (for publications arising from an NIH award) and described in the *Guide to Working with BCSC Data*.
14. Data Recipient(s) will destroy **all** BCSC data sets and unpublished data tables within six months after publication of results. The Data Recipient may forward the final analytic dataset to the SCC for archiving. Datasets will be archived by the SCC for at least five years.

The Project Leader and other Data Recipients agree 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.



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)

Principal Investigator of the SCC  
(Title)

Diana L. Miglioretti, PhD  
(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 collaborators. Your signature indicates that you agree to comply with the provisions of this Agreement (in the case of students and fellows, the department chair or advisor from the student's academic institution must also sign this Agreement).

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

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

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

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

**Signature of Other Data Recipient(s):**

Complete this if the data will be accessed and/or stored by someone other than the Project Leader. Your signature indicates that you agree to comply with the provisions of this Agreement.

\_\_\_\_\_  
(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 provisions of this Agreement.

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

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

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

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

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

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

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

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

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