

BREAST CANCER SURVEILLANCE CONSORTIUM MANUSCRIPT AND GRANT PROPOSAL FORM

ADMINISTRATIVE

1. General information about the proposal

Date proposal submitted to the BCSC	
Project title:	
Short title (5 words or less):	
Is this project associated with a previously approved BCSC concept, grant or manuscript proposal?	<input type="checkbox"/> No <input type="checkbox"/> Yes: please provide tracking number: _____
Project leader name:	
Affiliation/ organization:	
Address:	
E-mail address:	
Phone number:	

2. List all collaborators associated with this proposal (add rows if more than 8):

Name	Affiliation	Email Address	Will s/he be part of the small working group? ** YES/NO/N/A

****Only applicable** for a manuscript that arises from the use of pooled BCSC data from one or more consortium sites that use the SCC to conduct analyses (or the lead investigator is a member of the BCSC).

3. Proposed Timetable:

Date of proposed initiation: _____

Proposed completion dates: _____

Anticipated deadlines (if applicable): _____

- NO, I would like a dataset sent to me with minimal consultation** with the Statistical Coordinating Center
Please explain how you will store and protect BCSC data from unauthorized access:

Please list the members of your project who will have access to the data:

- Other** (please describe):

7. If you would like a dataset sent to you, please indicate the type of data request. *Any data request that includes dates, zip codes, or specific ages >89 years will require completion of a HIPAA data use agreement after approval of your proposal. The SCC can't release masked BCSC site identifiers or facility-level information. Analyses that require these variables must be done by the SCC.*

- De-identified data/ **aggregate** data
- De-identified **individual level** data (without dates, zip codes, specific ages >89 or BCSC site IDs)
- Limited dataset:** De-identified individual level data with: **(mark all that apply):**
- Dates
 - Specific age >89 years
 - Zip codes *(will generally not be released without careful consideration & protection in place)*
- Other (please describe) _____

8. Supplemental funding

Does this study involve grant or other supplemental funding?
<input type="checkbox"/> NO
<input type="checkbox"/> YES, we have funding from _____ Start & end dates (mo/yr – mo/yr) _____
_____ Start & end dates (mo/yr – mo/yr) _____
<input type="checkbox"/> YES, we plan to apply for a grant from _____ (due date _____)
Does this study involve the support or collaboration of a for-profit entity?
<input type="checkbox"/> NO
<input type="checkbox"/> YES, we have support from and/or are collaborating with _____
Do you intend to use the data to patent any process, aspect, or outcome of the analysis?
<input type="checkbox"/> NO
<input type="checkbox"/> YES

RESEARCH OBJECTIVES & METHODS:

9. Please fill out the content areas of your proposed research below. Proposal length should preferably be no more than 3 pages, excluding mock tables, and should not exceed 10 pages.

Specific Aims

Brief Background (one or two paragraphs)

Study Years

Inclusion/exclusion criteria

Outcome variable(s)

Main exposure variables(s)

Other covariates/possible confounders

Statistical Approach

Power analyses, if applicable

Mock Tables

10. Key words (Double-click boxes to mark all that apply):

- | | |
|--|---|
| <input type="checkbox"/> Breast biopsy | <input type="checkbox"/> Health services research |
| <input type="checkbox"/> Breast MRI | <input type="checkbox"/> Hormones |
| <input type="checkbox"/> Breast ultrasound | <input type="checkbox"/> Imaging facilities |
| <input type="checkbox"/> Breast density | <input type="checkbox"/> Imaging performance |
| <input type="checkbox"/> Comparative effectiveness | <input type="checkbox"/> Radiologists |
| <input type="checkbox"/> Cost Analysis | <input type="checkbox"/> Risk factors |
| <input type="checkbox"/> Digital mammography | <input type="checkbox"/> Risk modeling |
| <input type="checkbox"/> Diagnostic mammography | <input type="checkbox"/> Screening mammography |
| <input type="checkbox"/> Disparities | <input type="checkbox"/> Statistical methods |
| <input type="checkbox"/> Film mammography | <input type="checkbox"/> Treatment |
| <input type="checkbox"/> Geographic access | <input type="checkbox"/> Other: |

11. Indicate the name of the project which will use BCSC data (Check all that apply):

- Comparative Effectiveness of Breast Cancer Screening and Diagnostic Evaluation by Extent of Breast Density (BCSC-ADVANCE)**
- Comorbidity and Screening Outcomes among Older Women Undergoing Mammography (SNOW; Braithwaite)**
- Risk-based breast cancer screening and surveillance in community practice (BCSC-P01 -- "P01 Renewal").** Which Project/Core is this proposal affiliated with? *(Double-click boxes to mark all that apply and indicate which is primary. If this proposal uses data collected under the P01 but isn't related to the P01 project or CE Core aims please check "Core B".)*
- Project 1 (New Risk Assessment Paradigm to Predict Screening Detection, Failures & False Alarms) Primary?
- Project 2 (Breast Cancer Screening Strategies in the Era of New Technologies) Primary?
- Project 3 (Risk-based Imaging Strategies to Improve Breast Cancer Surveillance) Primary?
- Core B ("BCSC registries and/or the SCC") Primary?
- Core C (Comparative Effectiveness Core) Primary?
- Other: _____ Primary?
- Risk-based breast cancer screening in community settings (BCSC-P01 -- the "original P01").** Which Project/Core is this proposal affiliated with? *(Double-click boxes to mark all that apply and indicate which is primary. If this proposal uses data collected under the P01 but isn't related to the P01 project or CE Core aims please check "Core B".)*
- Project 1 (Risk Assessment in Community Practice: developing better models) Primary?
- Project 2 (Comparative effectiveness of imaging strategies for BC screening in community practice) Primary?
- Project 3 (Community-based utilization of breast imaging) Primary?
- Core B ("BCSC registries and/or the SCC") Primary?
- Core C (Comparative Effectiveness Core) Primary?
- Other: _____ Primary?
- Other:** _____

12. Data sets (Double-click boxes to mark all that apply)

- BCSC Research Resource (archived BCSC data – exams and events from 2009 or earlier)
- BCSC-P01 data (exams and events occurring 2010-2016; includes MRI, advanced imaging data)
- BCSC-P01 Renewal data (exams & events occurring 2017& later; includes MRI, advanced imaging data)
- AIM data (e.g., test set data)
- FAVOR data (radiologist survey)
- P01 Project 1 data (SNPs, hormones, volumetric breast density)
- P01 Project 3 data (geocoded census data, travel time data)
- BCSC Medicare data, original linkage (years 1998-2006)
- BCSC Medicare data, new linkage (years 2005-2010)
- Related to EMPRESS aims?
- Related to P01 aims?
- Other: Specify _____

If you are not sure how to answer these questions, please contact the SCC facilitator who is helping you with this proposal form.

Administrative Items that will be completed by the Statistical Coordinating Center:

Assigned Project Number? (Same as above, if number previously assigned) _____

Date of Steering Committee Review: _____

Steering Committee Action:

- Approved
 Not Approved
 Conditionally Approved (state reason): _____

Is this proposal a:

- Grant – Title: _____
 Manuscript
 Other – Describe: _____

Is this proposal a data request (Defined as a data request if answer to #6 is NO)

- YES
 NO

Is the lead investigator from:

- The BCSC-P01 The BCSC-P01 Renewal BCSC-ADVANCE
 On the Steering Committee
 Not on Steering Committee
 External to BCSC with SCC involvement (Name of BCSC Facilitator _____)
 External to BCSC without SCC involvement (Name of BCSC Facilitator _____)
 Part of an ancillary grant:
 What is the name of this grant? (e.g., EMPRESS, SIMBA, CISNET, Braithwaite) _____
 What is the name of BCSC Facilitator _____

Is this grant using BCSC data?

- YES
 NO

Is this grant using Chicago Registry data?

- YES (SCC will follow-up to make sure the data is acknowledged)
 NO

What is the current status of the project:

- In Analysis
 In Queue
 Completed
 Track for grant funding

SCC analyst needed?

- YES (who?) _____ Should s/he be added to the author list? _____
 NO

SCC Programmer needed?

- YES (who?) _____
 NO

Type of data requested:

- N/A – data not requested – no analysis needed at this time (e.g., grant proposal)
- N/A – data not requested – SCC will do the analysis OR is a site-specific analysis
- Aggregated de-identified data
 - Data contains reader, site, and/or facility IDs
- De-identified individual level data (w/o identifiers – e.g., no zip codes, ages >89 or site identifiers)
- De-identified individual level data with dates, specific age >89, or zip codes

Complexity of the project

- Simple
- Average
- Complex

If data was requested, has a call been made delineating points in the Synopsis document?

- YES
- NO
- N/A