

Breast Cancer Family Registry (BCFR) Cohort Collaboration & Publication Guidelines

1. Summary

Forms completed by the Applicant	Processing and Tracking	BCFR Review
<p>Contact BCFR PIs and the Administrative Coordinating Center for potential collaboration. See #8, below.</p> <p>Assignment of BCFR collaborator/liaison (for external applicants)</p>	The BCFR Steering Committee (SC) will assign a collaborator/liaison to each applicant	
BCFR Concept	BCFR Review Coordinator (Ms. Jenny Nguyen)	BCFR site PIs to be involved in proposed collaborative project will decide whether or not to participate in proposed collaboration
BCFR Full Application	BCFR Review Coordinator (Ms. Jenny Nguyen)	BCFR site PIs sites to be involved in proposed collaborative project will decide whether or not to participate in proposed collaboration
BCFR Amendment	BCFR Review Coordinator (Ms. Jenny Nguyen)	BCFR site PIs involved in an already approved project will review amendment request
DUA with Informatics Center, must have project IRB approval at local institution to initiate DUA process	BCFR Informatics Center	
Data Request Form (variable list)	BCFR Informatics Center	
MTA with each BCFR institution providing biospecimens	BCFR site PIs	
Annual Progress Report is due at the end of January of each year	BCFR Review Coordinator (Ms. Jenny Nguyen)	
Publications Checklist and final manuscript (by lead or senior author)	BCFR Review Coordinator (Ms. Jenny Nguyen)	BCFR Review Coordinator (Ms. Jenny Nguyen)
<p>Return of newly acquired data</p> <p>All newly-acquired data (genotype data, other data) will be returned to the BCFR Informatics Center and the collaborating BCFR site(s)</p>	BCFR Informatics Center	

2. Initiating a New Collaboration with the BCFR Cohort

As investigators learn about the BCFR through the website or other ways, they will contact the BCFR site PIs and the Administrative Coordinating Center to discuss a new project and potential collaboration. BCFR investigators expect to be active collaborators (see #5, below) which may involve subcontracts, consultant fees, or other arrangements to be worked out for each project. A BCFR collaborator/liaison will be determined by the BCFR Steering Committee (SC) based on interest, expertise, and availability. The collaborator/liaison will assist the applicant in the evaluation of the feasibility of the project in the BCFR. Collaborating investigators are expected to work closely with the BCFR liaison, including at the design phase.

First, the applicant will prepare the **Concept** and briefly describe the proposed research project and the nature of the proposed collaboration. The BCFR Review Coordinator may assist with the preparation of the Concept. The completed Concept will be submitted to the BCFR Review Coordinator for tracking and processing.

The completed Concept will be sent to the BCFR site PIs for review. Individual BCFR sites will determine whether or not they will participate in the proposed collaboration and contribute data and/or biospecimens. As stated, BCFR investigators expect to be active collaborators; therefore approval will depend on whether there is/are interested collaborator(s)/liaison(s) available for the proposed project.

Upon approval of the Concept, the applicant will be asked to complete the **Full Application**. The BCFR Review Coordinator may assist with the preparation of the full application. Completed applications will be submitted to the BCFR Review Coordinator for tracking and processing.

The completed Full Application will then be sent to the BCFR site PIs for review. The applicant may be invited to present the application at one of the BCFR PI calls which take place monthly. Individual BCFR sites will determine whether or not they will participate in the proposed collaboration and contribute data and/or biospecimens. The review of the **Full Application** will be completed within one month following the receipt of the application. The BCFR Review Coordinator will inform the applicant of the PI decision.

3. Applications by Doctoral or Master's Students

For student applications, the **Concept**, the **Full Application**, and the **Data Use Agreement (DUA)** with the Informatics Center must be submitted by the student's supervisor, academic advisor, or PI. On the Concept or Full Application, please indicate in the checkbox provided that this is a student project. We highly recommend that for dissertation projects or master's thesis BCFR approval is obtained before beginning the proposal process at the academic institution. Please be aware that the timing of approval of the Concept and the Full Application, as well as the release of data and/or biospecimens, may not correspond to the calendar requirements for individual university's dissertation or master's thesis schedules.

4. Receipt of Data/Biospecimens for Approved Projects

For approved projects, the applicant will complete a **Data Use Agreement (DUA)** with the Informatics Center. Applicants need to submit all research to their local IRB and receive IRB approval before the DUA process can be initiated. The applicant will complete the **Data Request Form** that specifies the variables needed to carry out the approved analysis.

For projects that involve biospecimens, a **Material Transfer Agreement (MTA)** with each BCFR site that contributes biospecimens will need to be executed.

5. Active Collaboration with the BCFR

- a. PIs of participating BCFR sites will determine which site co-investigators wish to be actively involved in the project and participate in the development of the project and project-related manuscripts as co-authors. The BCFR Review Coordinator will inform the applicant.
- b. The collaborating investigator is required to keep the BCFR collaborator/liaison and co-investigators / co-authors informed of the analysis plans and results while the analysis is in progress. The collaborating investigator is expected to share results, tables and manuscript drafts at an early stage. All abstracts, manuscripts and presentations should be circulated to BCFR site PIs before submission. Failure to keep the BCFR co-authors informed throughout the analysis, presentation, and publication stages may result in publication delays. The BCFR reserves the right to suggest changes to the method of data analysis and to the interpretation of results.
- c. The collaborating investigator will submit an annual Progress Report due at the end of January of each year. The report will be submitted to the BCFR Review Coordinator.

6. Publication and Authorship

- a. When the manuscript is at an advanced stage, the lead author will submit the manuscript to the BCFR Review Coordinator for administrative review (please see below), along with the **Publication Checklist**. The lead author will also circulate the manuscript to all participating BCFR site PIs in addition to collaborating authors who have participated in earlier drafts of the manuscript.
- b. Failure by the lead author to keep the BCFR collaborating authors informed during the conduct of the project may lead to publication delays. The lead author has the right to expect responses from collaborating BCFR authors in a reasonable defined timeframe and may contact non-responding authors to confirm collaborating authorship.
- c. The BCFR reserves the right to suggest changes in the manuscript.
- d. The BCFR reserves the right to add relevant authors to the final authorship list for final review and approval of the manuscript.

6.1. Referencing the BCFR Cohort in Methods, Title and Tables

All manuscripts should refer to the Breast Cancer Family Registry as follows:

- a. Methods Section: reference individual BCFR sites as follows:
 - Australian site of the Breast Cancer Family Registry
 - New York site of the Breast Cancer Family Registry
 - Northern California site of the Breast Cancer Family Registry
 - Ontario site of the Breast Cancer Family Registry
 - Philadelphia site of the Breast Cancer Family Registry
 - Utah site of the Breast Cancer Family Registry

- b. Title: reference the Breast Cancer Family Registry or BCFR, within the limitations of the journal policy. For multi-center publications, reference the Breast Cancer Family Registry or BCFR if more than 50% of the subjects/samples are from the BCFR.
- c. Tables: reference Breast Cancer Family Registry or BCFR, within the limitations of the journal policy.

6.2. Acknowledgements

At an appropriate place in the article (title-page, foot note, or appendix to the text; see the journal's requirement), abstract, poster or presentation, one or more statements should specify:

- a. Scientific or other contributions that deserve acknowledgement, but do not justify authorship (including technical help).
- b. NCI and other sources of financial support for individual BCFR sites.
- c. NCI financial acknowledgements

All manuscripts, abstracts, posters, and presentations shall acknowledge the federal funding of the BCFR as follows:

“This work was supported by grant UM1 CA164920 from the USA National Cancer Institute. The content of this manuscript does not necessarily reflect the views or policies of the National Cancer Institute or any of the collaborating centers in the Breast Cancer Family Registry (BCFR), nor does mention of trade names, commercial products, or organizations imply endorsement by the USA Government or the BCFR.”

6.3. Manuscript Administrative Review

- a. Manuscripts: All manuscripts will be submitted to the BCFR Review Coordinator for administrative review prior to submission to a journal. The manuscript will be accompanied by the Publication Checklist completed by the first or senior author. The review will be completed within 14 days of submission.
- b. Abstracts, posters and presentations: Abstracts may be submitted to a conference without prior review by the BCFR Review Coordinator.

7. Return of Newly Acquired Data to the Informatics Center and individual BCFR sites

All recipients of BCFR resources (data, biospecimens) who generate new data as part of their approved project (e.g., genotype, biochemical assay, additional questionnaire or other data) are required to return the newly generated data to the BCFR Informatics Center and the collaborating BCFR site(s) within 6 months of publication.

8. BCFR Contacts

BCFR Principal Investigators:

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