Revised 4-19-2013

Breast Cancer Family Registry Cohort
Collaboration and Publication Guidelines

1. Summary

Forms completed by collaborating PI	**Processing and tracking**	**Review**
Contact BCFR PIs and the Administrative Coordinating Center for potential collaboration. See #7, below. Assignment of BCFR liaison (for external applicants)	 The BCFR Steering Committee (SC) will assign a liaison to each applicant	
BCFR Application Form	BCFR Review Coordinator (Mike Burgio)	PIs from sites to be involved in proposed collaborative project will decide whether or not to participate in proposed collaboration
BCFR Amendment Form	BCFR Review Coordinator (Mike Burgio)	PIs from sites involved in proposed project will review and approve amendment
DUA with Informatics Center, must have project IRB approval at local institution to initiate DUA process	Informatics Center	
Data Request Form (variable list)	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 (Mike Burgio)	
Publications Checklist and final manuscript (by lead or senior author)	BCFR Review Coordinator (Mike Burgio)	BCFR Review Coordinator (Mike Burgio)
Return of newly acquired data All newly-acquired data (genotype data, other data) to be returned to Informatics Center as outlined in Collaboration Agreement	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 #4, below) which may involve subcontracts, consultant fees, or other arrangements to be worked out with each project. A BCFR liaison will be determined by the BCFR Steering Committee (SC) based on interest and expertise. The liaison will assist the applicant regarding the feasibility of the project in the BCFR. Collaborating investigators are encouraged to work closely with the BCFR liaison, including at the design phase.

The applicant will prepare the **Application Form** describing the proposed research project and the nature of the proposed collaboration. The BCFR Review Coordinator may assist with the preparation of the application. Completed Application Forms will be submitted to the BCFR Review Coordinator for tracking and processing.

The completed Application Form will be sent to the BCFR SC for review. 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 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. Receipt of Data/Biospecimens for Approved Projects

For approved projects, the applicant will complete a **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, an **MTA** with each site that contributes biospecimens will also be initiated.

4. Active Collaboration with the BCFR

a. PIs of participating sites will determine which site co-investigators wish to be actively involved in the project and participate in development of projects and project-related manuscripts as co-authors. The BCFR Review Coordinator will inform the applicant.

b. Collaborating investigators are required to keep the BCFR liaison and co-authors informed of the analysis plans and results while the analysis is in progress, and to share tables and manuscript drafts at an early stage. All abstracts, manuscripts and presentations should be circulated to BCFR PIs before submission. Failure to keep the BCFR co-authors informed throughout the analysis, presentation, and publication stages may result in publication delays.

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.

5. 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 PIs in addition to collaborating authors who have participated in earlier drafts of the manuscript.

b. Failure by the lead author to keep BCFR collaborating authors informed during the conduct of the project may lead to publication delays. The lead author has a 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.

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

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

a. Methods Section references to individual BCFR sites:

- 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. Titles and Tables: Either BCFR or Breast Cancer Family Registry

5.2. 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. Acknowledgements of the BCFR in the title, as discussed below.

c. NCI and other sources of financial support for individual sites.

d. BCFR acknowledgements in title

Multi-site manuscripts, abstracts, posters, and presentations whose subjects/samples include more than 50 percent BCFR participants/samples should reference the BCFR in the title, within the limitations of the journal policy.

e. 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 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 US Government or the BCFR."

5.3. 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.

6. Return of Newly Acquired Data to Informatics Center

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 Informatics Center. The timeline for the return of data is established by the Collaboration Agreement.

7. BCFR Contacts

BCFR Principal Investigators:

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