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

Summary

The primary mechanism for sharing BCFR data and/or biospecimens is to conduct collaborative multinational, interdisciplinary and translational studies organized through the BCFR. This process entails the following steps:

1. **Concept Submission**
2. **Concept Feasibility Review**
3. **Concept MPI Review**
4. **Data and/or Biospecimen Application**
5. **Data and/or Biospecimen Fulfillment**
6. **Active Collaboration with the BCFR**
7. **Manuscript Preparation, Publication and Authorship**
8. **Return of Newly Acquired Data to the Data Coordinating Center and individual BCFR sites**

BCFR Contacts

Data Coordinating Center:

- Inquiries: bcfamilyregistry@cumc.columbia.edu
- Data Coordinating Center Director: Jeanine Genkinger, jg3081@cumc.columbia.edu
- Project Director: Susan Lloyd, sl4279@cumc.columbia.edu

Principal Investigators:

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Website: http://www.bcfamilyregistry.org/

1. Initiating a New Collaboration with the BCFR Cohort

Investigators who are interested in initiating a new collaboration with the BCFR should submit a concept application to the BCFR Data Coordinating Center (DCC). Potential collaborators should contact the DCC at bcfamilyregistry@cumc.columbia.edu with any questions about the application process, or if there are any data queries that would help inform a concept proposal (e.g., sample size, missingness of a key variable, general availability of types of biospecimens).

BCFR investigators expect to be active collaborators which may involve subcontracts, consultant fees, or other arrangements to be worked out for each project. A BCFR liaison can be pre-selected in the Concept application, or if not yet determined, will be assigned by the BCFR PIs based on interest, expertise, and availability. Collaborating investigators are expected to work closely with the BCFR liaison, including at the design phase.

1.1. Concept Submission

All concept proposals for a research collaboration with the BCFR must be submitted through the Data Coordinating Center (DCC) online collaboration system. Concept application progress can be saved and the concept submitted at a later time.

Create a new user account: https://www.sac-cu2.org/bcfrdata/share/newacct

Login: https://www.sac-cu2.org/BCFRData/Login

1.2. Applications by students

For student applications, the Concept and Data Use Agreement (DUA) with the DCC must be submitted by the student's supervisor, academic advisor, or PI. On the Concept Form, please indicate in the checkbox provided that this is a student project. We highly recommend that for dissertation projects or master's thesis that 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 Data 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.

1.3. Applications related to a grant submission

Investigators interested in collaborating with the BCFR on a grant application should submit a concept and obtain BCFR approval **before** submitting a grant application that proposes the use of BCFR resources. Depending on the project and participating institutions, the collaboration may require subcontracts with BCFR sites. We strongly recommend submitting a concept at least three months prior to a grant submission deadline.

2. Concept Feasibility Review

Concept proposals are reviewed by the DCC for feasibility on a rolling basis. Concept proposals must be complete and include responses to all fields prior to moving forward to MPI review. If the concept proposes utilization of biospecimens, the concept will also be reviewed for feasibility by the Biospecimens Working Group.

3. Concept Review by BCFR MPIs

Concept proposals are reviewed by the BCFR MPIs on a monthly basis, and each BCFR site will determine whether or not to participate in the proposed collaboration. PIs may request that a collaborator present their project at a BCFR PI or Analytics Working Group meeting prior to approving

it. The collaborator will receive an email notification when all of the relevant PIs have made a decision to approve or reject the concept.

4. Data and/or Biospecimen Application

Once a project has been approved, collaborators should submit a Data and/or Biospecimen Application. Through the DCC, collaborators can review BCFR data dictionaries, specify inclusion criteria in detail, and select variables relevant to the approved concept.

5. Data and/or Biospecimen Fulfillment

Data applications are reviewed by the DCC to ensure the requested variables match the approved concept. The DCC may suggest additional variables to include in the study and will assist with deriving new variables as needed for a project. Once a data application is submitted, it will be added to the fulfillment queue. The timeline for data fulfillment depends on the complexity of the data being requested and the status of other existing collaboration projects.

Prior to receipt of any data, collaborators must provide **1) documentation of IRB approval or waiver** and **2) a fully executed Data Use Agreement (DUA).** Most projects will require a single DUA between the collaborating institution and the DCC located at Columbia University. If a project involves the use of any biospecimens, collaborators will need to execute Material Use Agreements (MTAs) with each BCFR site supplying biospecimens. Biospecimen products and fees are listed in **Appendix 1**. These fees are subject to change and should be confirmed with each BCFR site at the time of biospecimen application.

For projects involving the generation of new data from biospecimen resources, epidemiological data will be provided after the return of laboratory results to the DCC.

6. Active Collaboration with the BCFR

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 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. Collaborators may be asked to present results to the BCFR investigative team. All abstracts, manuscripts and presentations should be submitted to the DCC for circulation to BCFR PIs and co-investigators prior to 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.

The collaborating investigator will submit an Annual Progress Report to the DCC, due January 30 each year.

Collaboration projects may remain active for up to five years from the date of concept approval, with the option to request a renewal.

7. Manuscript Preparation, Publication and Authorship

When the manuscript is at an advanced stage, the lead author will submit the manuscript to the DCC for administrative review and to circulate the manuscript to all participating BCFR site PIs in addition to collaborating authors who have participated in earlier drafts of the manuscript.

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.

The BCFR reserves the right to suggest changes in the manuscript.

The BCFR reserves the right to add relevant authors to the final authorship list for final review and approval of the manuscript.

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

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

7.1.1. 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

7.1.2. 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.

7.1.3. Tables: reference Breast Cancer Family Registry or BCFR, within the limitations of the journal policy.

7.2. 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:

7.2.1. Scientific or other contributions that deserve acknowledgement, but do not justify authorship (including technical help).

7.2.2. NCI and other sources of financial support for individual BCFR sites.

7.2.3. 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 U01 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 BreastCancer Family Registry (BCFR), nor does mention of trade names, commercial products, or organizations imply endorsement by the USA Government or the BCFR."

7.3. Manuscript Administrative Review

7.3.1. Manuscripts*:* All manuscripts will be submitted to the DCC for administrative review prior to submission to a journal. The review will be completed within 14 days of submission.

7.3.2. Abstracts, posters and presentations*:* Abstracts may be submitted to a conference without prior review by the DCC.

8. Return of Newly Acquired Data to the Data Coordinating 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 DCC and the collaborating BCFR site(s) within 6 months of publication.

Appendix 1: BREAST CANCER FAMILY REGISTRY BIOSPECIMEN PRODUCT FEES: 2025*

Biospecimens are stored and dispatched from each BCFR site and their respective institution. The cost of acquisition and limited processing of the BCFR biospecimen collections has been covered by BCFR grants. However, maintaining and dispatching biospecimens to researchers generates additional costs that must be paid for by the requesting researcher. Each BCFR site providing biospecimens will prepare and send an invoice. Payment may be requested before biospecimens are dispatched.

*The prices charged will correspond to the date the data and/or biospecimens are requested for delivery *and* all necessary assurance documentation (IRB/ethics, Data Use Agreements, Material Transfer Agreements) has been submitted to the BCFR Data Coordinating Center.

Prices shown are U.S. dollars, are inflated approximately 3% annually, and are subject to change.

Administrative fees[1] (site specific)	$ **SEE NOTE[1]**

EDTA Blood Product	**Number requested**	**Cost per specimen**	**Subtotal $**
DNA distribution[2, 3]	N = _____	@ $24.00/specimen	$ _____
Plasma distribution	N = _____	@ $29.00/specimen	$ _____
Guthrie (dried blood spot) distribution	N = _____	@ $24.00/specimen	$ _____
DNA extraction from WBC Buffy Coat	N = _____	@ $58.00/specimen	$ _____
		EDTA Blood Subtotal	$ _____

Buccal, Mouth Wash or Saliva	**Number requested**	**Cost per specimen**	**Subtotal $**
DNA distribution[2, 3]	N = _____	@ $24.00/specimen	$ _____
DNA extraction from Buccal, Mouth Wash or Saliva	N = _____	@ $58.00/specimen	$ _____
		Buccal Wash or Saliva Subtotal	$ _____

Lymphoblast Cell Line Product	**Number requested**	**Cost per specimen**	**Subtotal $**
DNA distribution from cell-line[2, 3]	N = _____	@ $19.00/specimen	$ _____
DNA extraction from cell-line	N = _____	@ $58.00/specimen	$ _____
Frozen cell-line distribution *(available only if a cell line has already been established and there are at least 4 vials of LCLs in storage. Otherwise a cell line will need to be thawed and re-grown (see cost to re-grow))*	N = _____	@ $25.00/specimen	$ _____
Re-growth to provide frozen LCL for distribution *(required if there is a cell line already established but there are fewer than 4 vials of LCLs in storage)*	N = _____	@ TBD	$ _____
EBV transformation and QC *(required if a cell line has not already been established)*	N = _____	@ TBD	$ _____
		Lymphoblast Cell-Line Subtotal	$ _____

Tumor Tissue Product	**Number requested**	**Cost per specimen**	**Subtotal $**
Paraffin-embedded tissue (PET) slide distribution	N = _____	@ $25.00/specimen	$ _____
Fresh frozen tissue[5] distribution (excised piece)	N = _____	@ $48.00/specimen	$ _____
PET block sectioning *(if all stored slides are exhausted and block is in-house)*	N = _____	@ $56.00/specimen	$ _____
PET block sectioning *(if all stored slides are exhausted and block is not in-house and must be requested)*	N = _____	@ $170.00/specimen	$ _____
Additional sections from PET blocks	N = _____	@ $21.00/specimen	$ _____
Pathology review & H&E marking for macrodissection	N = _____	@ $24.00/specimen	$ _____
Macrodissection for DNA extraction	N = _____	@ $26.00/specimen	$ _____
DNA distribution from tissue (PET or fresh frozen)[2, 3]	N = _____	@ $24.00/specimen	$ _____
DNA extraction from PET tissue	N = _____	@ $66.00/specimen	$ _____
DNA extraction from fresh frozen tissue	N = _____	@ $66.00/specimen	$ _____
Scanned H&E without a scanned image already in house	N = _____	@ $27.00/image	$ _____
		Tumor Tissue Subtotal	$ _____

DNA QUANTIFICATION[2, 3, 4]	**Number requested**	**Cost per specimen**	**Subtotal $**
Fluorescent dye DNA quantification[4]	N = _____	@ $13.00/specimen	$ _____
Spectrophotometry DNA quantification[4]	N = _____	@ $9.00/specimen	$ _____
Re concentrating DNA to increase concentration[3]	N = _____	@ TBD	$ _____
		DNA Quantification Subtotal	$ _____

INVOICE TOTAL

Biospecimen Subtotal	$ _____
Administrative fees[1] (site specific)	$ _____
Institutional indirect cost (site-specific)	$ _____
Packing costs for shipment (including shipment containers, dry ice, etc)	$ _____
Courier (if Applicant is not providing a courier account number)	$ _____
TOTAL (USD)	$ _____

[1] Administrative fees include local administrative and programming (non-laboratory) costs including IRB/ethics approval, MTA preparation, inventory management, sample selection and QC, dataset preparation, requests for data not available at the BCFR Data Coordinating Center and must be provided by individual BCFR sites, and special requests. Administrative fees are determined by each respective PI and typically range $1,000 - $2,000 per site and per dispatch request.

[2] DNA stock concentrations vary. Requests for concentrations requiring a dilution will be provided at the distribution cost.

[3] Requests for DNA concentrations requiring re-concentration *may* be available for a per sample fee. When not available, the sample volume will be adjusted to meet the total DNA quantity.

[4] Standard method of quantitation is spectrophotometry (e.g., Nanodrop). Stock DNAs may need to be re-quantified for dispatching. Fluorescent dye DNA quantification (e.g., Picogreen, Qubit) may be requested.