

Breast Specimen Repository & Registry Specimen Allocation and Registry Use Policy

Background

Since its founding in 2001, the FHCRC/UW Breast Specimen Repository (BSR) has greatly enhanced basic and translational research opportunities for Consortium investigators by providing high-quality, data-rich tissue and blood samples from consented breast patients to IRB-approved studies. Given the success of the BSR in meeting its initial objectives and the growing need for additional research support mechanisms within the Consortium, in 2005 the repository expanded its role to include the assembly of a registry of consented individuals interested in actively participating in breast research. This expanded effort is now known as the **Breast Specimen Repository & Registry (BSRR)**. The primary purpose of the repository did not change as a result of this expansion, i.e., to impact basic and clinical research on the etiology, biology and treatment of breast cancer. Rather, the repository is now able to serve a broader segment of the research community and to make current research initiatives and education related to breast health accessible to a greater segment of the public at large.

Repository Introduction

The BSR currently houses a collection of biologic specimens from breast care and cancer patients who have generously agreed to donate material to this research repository. The repository and associated database represent a collaborative effort among researchers and physicians at the Fred Hutchinson Cancer Research Center (FHCRC), the University of Washington Medical Center (UWMC), Harborview Medical Center (HMC), Seattle Cancer Care Alliance (SCCA), and Overlake Hospital and Medical Center (OHMC). All specimens and the database are housed at the Fred Hutchinson Cancer Research Center.

Tissue specimens in the repository have been obtained from breast biopsies, mastectomies, lymph node dissections, metastatic tumor biopsies and reduction mammoplasties and represent material that was not needed for pathologic diagnosis at the time of surgery. Many specimens have associated blood samples that were drawn immediately prior to surgery and processed into serum and white blood cells. Other blood samples were drawn at clinic appointments from both breast care and breast cancer patients and processed into plasma and white blood cells. Those from breast cancer patients have been drawn either before or after surgery. The repository also collects specimens prospectively using research-specific protocols for IRB-approved studies.

Because these specimens and their associated data are extremely valuable and limited in number, the following guidelines have been formulated to ensure that use of the collection best serves the interests and needs of all cancer researchers. In developing these guidelines, consideration was given to policies instituted by other major tissue bank collections.

Requests for Repository Samples

All qualified researchers at non-profit and for-profit organizations, both public and private (e.g., universities, hospitals, laboratories, government agencies) are encouraged to request specimens for research. Requests for repository material should be submitted in writing to a member of the BSRR oversight committee (see below). Those from postdoctoral associates must be co-signed by the director of the laboratory.

Requests for material should contain:

- a) A brief summary of the research. This statement should specifically address the following: objectives of the project and its potential scientific value; clinical relevance and impact on the

detection, treatment and/or cure of breast cancer; feasibility and time frame of the study; method(s) of analysis; qualifications of the investigator(s) to perform the laboratory work; and availability of funding to complete the project.

b) Information on the nature of material needed, including specimen type, number of samples, stage of patient, tumor grade, etc.

c) Copies of all applicable Human Subjects/Internal Review Board (IRB) approvals associated with the proposed project.

d) A Federal Express recharge number to allow shipping of specimens on dry ice, if applicable.

Requests will be reviewed on a case-by-case basis by the BSRR Oversight Committee according to the following criteria:

- The value of the study in furthering translational breast cancer research
- The nature and extent of the request, including whether it duplicates previous efforts
- Demonstrated ability of the investigator(s) to perform the work and complete the project
- Financial support for the project
- Amount of needed material in the repository

Priority will be given to researchers affiliated with institutions contributing specimens to the repository.

Repository Acknowledgment

Use of repository specimens or their associated data in publications or grant proposals should be acknowledged as follows:

Breast Specimen Repository, a collaboration among the Fred Hutchinson Cancer Research Center, the University of Washington Medical Center, and Harborview Medical Center, Seattle, WA and Overlake Hospital and Medical Center, Bellevue, WA.

Complete citations of any publications, including abstracts, resulting from studies involving repository specimens or their associated data, or information on research projects funded with use of repository specimens or their data, should be sent to: Breast Specimen Repository, Fred Hutchinson Cancer Research Center, 1100 Fairview Avenue North, Mail Stop C1-015, Seattle, WA 98109.

Registry Introduction

Creation of the Breast Registry was viewed as a natural extension of the BSR's original objective, i.e., to impact basic and clinical research on the etiology, biology and treatment of breast cancer. Although the registry will not bank any samples, it enhances the BSR's capability to do so by populating and maintaining a database of individuals devoted to active participation in breast research. Initially, the registry will provide a centralized system for obtaining technically-specific research samples efficiently and in a timely fashion. Over time, it will result in a cohort of individuals willing to actively participate in a much broader range of research studies than the BSR is currently able to serve. The registry is also intended to provide a streamlined mechanism by which individuals in the community can become educated about and involved in a wide variety of breast research protocols, if they so wish.

Use of the Registry

Like the repository, the registry will only be available to researchers who present IRB approval for their studies and whose studies have been approved by the BSRR Oversight Committee. Accordingly, the following phased use of the registry and access to registrants has been implemented:

Phase 1: Assist feasibility studies

To determine the number of participants a given research protocol could potentially accrue from the registry, an investigator should submit a request for a generalized search of registry participants to determine the number of individuals who meet an initial set of study criteria with respect to breast cancer risk factors and/or disease history.

Phase 2: Assist participant accrual

After completion of Phase I, the study will be included in the next issue of the periodic newsletter sent to registrants and the investigator will be invited to give a brief description of the study at the next registry public meeting. Through the newsletter and at the public meeting, individuals will be given information on how to contact *the registry* to express interest in participating in that study.

Phase 3: Confirmation of eligibility of interested registrants, followed by consented release of personal information to investigators

Once interested persons have contacted the registry and expressed interest in participating in a specific study, registry staff will confirm their initial eligibility and written permission will be obtained from the registrant to release her or his contact information to the study's Principal Investigator (PI). At this point, interaction between registrant and investigator will be dictated by the IRB protocol for the investigator's specific research study.

Phase 4: Targeted invitations to accrue participation in a specific study

If accrual for a given study is low despite good feasibility or if the feasibility study shows that only a minority of registry participants would be initially eligible for a given study, then a letter specifically describing the research study and requesting participation will be sent to those individuals in the registry who appear to be eligible. If this mechanism results in a registrant's expressing interest in the study, the registry will confirm eligibility and written permission will be obtained from the registrant to release his or her contact information to the PI, as described above.

Registry Use Agreement

In both Phases 3 and 4, any investigator who recruits a participant from the registry agrees to provide follow-up information back to the registry on the general outcome of their studies. Such information must be provided in writing and will appear in a subsequent issue of the newsletter.

In addition, use of the registry for participant accrual should be acknowledged in publications or grant proposals. Complete citations of any publications, including abstracts, resulting from studies involving use of the registry should be sent to: Breast Registry, Fred Hutchinson Cancer Research Center, 1100 Fairview Avenue North, Mail Stop C1-015, Seattle, WA 98109

Recharge Associated with BSRR Services

A fee per specimen will be calculated based on personnel and supply costs associated with an individual's request and charged to users of IRB-approved research projects.

BSR&R Oversight Committee

The BSR&R Oversight Committee is comprised of members representing the needs of the entire community, including patient advocates, basic scientists and clinicians with expertise in breast health and cancer research. Currently, they are as follows:

Peggy Porter, MD, Head, Breast Cancer Research Program, FHCRC
Amanda Paulovich, MD, PhD, Asst. Member, Clinical Research Division, FHCRC
Julie Gralow, MD, Assoc. Prof. Oncology, Department of Medicine, UWMC
Thomas Lawton, MD, Asst. Prof. Pathology, Department of Pathology, UWMC
Kristi Harrington, MD, Ph.D., Overlake Hospital and Medical Center
Emily White, PhD, Member, Public Health Sciences Division, FHCRC
Stanley Riddell, MD, Member, Clinical Research Division, FHCRC
Steve Schwartz, PhD, Member, Public Health Sciences Division, FHCRC
Trish May, founder and CEO of Athena Partners, breast cancer survivor

Specimen requests approved by the committee are then forwarded to the Fred Hutchinson Cancer Research Center Internal Review Board (IRB) for final review and approval. Recipients will be required to sign a usage agreement and certificate of confidentiality (see attached).

Specimens received from the repository, or extracts from these samples, cannot be transferred to a third party without the expressed written permission of the Oversight Committee. Specimens may be used only for the purposes described in the original application. Uses for other purposes require written permission from the Oversight Committee. Only data which do not reveal the identities of the donor/subjects, or through which donor/subject identities cannot be readily ascertained, will be provided.

With respect to the registry, if demand from the research community overwhelms the supply of participants in the registry, competition may develop among investigators to access registrants. The BSR&R Oversight Committee will ensure fair use of the registry. If more studies want to access the registry than can be accommodated, the Oversight Committee will prioritize the studies based on scientific merit. Additionally, if demand is this high, the registry will have been wildly successful and measures will be taken to increase resources and staff with the goal of meeting the needs of all investigators.

Agreement for Investigators Receiving Specimens from the BSR

As the recipient of specimens and associated data from the Breast Specimen Repository, I acknowledge that the conditions for use of this research material are governed by the Institutional Review Board (IRB) of the Fred Hutchinson Cancer Research Center, Seattle, WA, in accordance with Department of Health and Human Services regulations at 45 CFR 46. Accordingly, I agree to comply fully with all such conditions and to report promptly to the Breast Specimen Repository Oversight Committee any proposed changes in the research project and any unanticipated problems involving risks to subjects or others. I also understand that I remain subject to applicable State or local laws or regulations and institutional policies which provide additional protections for human subjects.

This research material may only be used in accordance with the conditions stipulated by the Breast Specimen Repository IRB (IR 5306). Any additional use of this material requires prior review and approval by the repository IRB and, where appropriate, by an IRB at the recipient site, which must be convened under an applicable OPRR-approved Assurance.

Signature of recipient

Date

Print name

CONFIDENTIALITY PLEDGE

In consideration of my access to the records and information described below and maintained at or belonging to Fred Hutchinson Cancer Research Center ("FHCRC"), I agree as follows:

1. "Confidential Information" means the following records, data and information: [Describe information in detail]

2. I agree not to make use of, disseminate, disclose or in any way circulate any Confidential Information except as expressly permitted by this Confidentiality Pledge. Confidential Information may be published or otherwise disclosed in connection with the study entitled,
"_____
_____" ("Study"),
Protocol number _____, Institutional Review number _____;
provided, however, that no disclosure may be made which permits identification of any individual patient or the patient's physician unless permitted by applicable law and approved by an Institutional Review Board of FHCRC. Confidential Information may also be disclosed to other persons working on the Study who have signed a Confidentiality Pledge.

3. I agree not to disclose any computer password or otherwise provide access to Confidential Information to any unauthorized person.

4. I agree to indemnify, defend and hold FHCRC harmless from any causes of action, claims, damages or liabilities arising or alleged to arise from my failure to comply with any of the provisions of this Confidentiality Pledge.

5. I agree not to remove any Confidential Information from FHCRC. I also agree to maintain appropriate procedures to ensure that Confidential Information remains confidential to the extent required by this Confidentiality Pledge.

6. I agree to destroy all individual identifiers contained in any Confidential Information which would serve to identify a patient or physician as soon as the purposes of the research for which I have been given access to the Confidential Information have been accomplished and to notify FHCRC to this effect in writing.

7. I agree to comply with all applicable laws and regulations regarding the confidentiality of individually identifiable health care information, including, without, limitation the Washington version of the Uniform Health Care Information Act, RCW Chapter 70.03.

8. I understand and acknowledge that this Agreement may not be amended and that use of Confidential Information in a manner not permitted by this Confidentiality Pledge is not permitted without the prior written consent of the chair of the approving Institutional Review Board and Dr. Peggy Porter.

Dated: _____ Title: _____
Name of Individual (Print): _____ Phone Number: _____
Signature: _____

ORIGINAL TO: P.I. RESPONSIBLE FOR REPOSITORY OF CONFIDENTIAL INFORMATION
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