

Accessing the BWH/Harvard Cohorts Biospecimens

The BWH/Harvard Research Cohorts have a proud history of successful collaborations with investigators external to the BWH/HSPH community. We welcome new collaborations and strive to make the process of establishing new collaborations simple and transparent, while maximizing the scientific yield. To this effect, we have developed the following biospecimen access policy with the approval of the Cohort Advisory Boards, and in compliance with our NIH approved plan for data-sharing.

Submitting a Proposal

Letter of intent: Investigators wishing to develop a collaboration with the Nurses' Health Study (NHS) Research Group, the Health Professionals Follow Up Study Research Group (HPFS), or Growing Up Today Research Group to use biospecimens are asked to submit a brief (2 pages) description of the proposed project ("letter of intent") to Dr. Francine Grodstein, NHS Director (fgrodstein@partners.org), Dr. Heather Eliassen, NHSII Director (nhah@channing.harvard.edu), or Dr. Eric Rimm, HPFS Director (erimm@hsph.harvard.edu), as applicable. The letter of intent should briefly outline the following;

- Hypothesis being proposed,
- Scientific significance of the project,
- Proposed use of the biospecimens (assays),
- Participant data variables required for analysis,
- Reasons for proposing use of cohort biologic samples, rather than another source, and a
- Discussion of foreseeable ethical implications of the analyses proposed.

Our cohort biospecimens are a unique and finite resource, therefore, access will only be granted for investigations where other biologic samples cannot provide adequate or similar information. Of note, the assessment of markers of disease prognosis will generally not be considered an appropriate use of the biospecimen archive. Similarly, proposals to evaluate highly speculative hypotheses are not considered appropriate. A letter of intent may be submitted at any time throughout the year.

Review: Letters of intent will be reviewed by a team of investigators at a regular bi-weekly cohort study meetings. Investigators should be aware that analyses which identify women at very high risk of disease may pose ethical implications which may be reviewed by an external advisory panel.

Proposals will be reviewed for merit in the following general categories;

- Technical Feasibility
- Substantial Scientific Interest/Impact
- Uniqueness (not currently being pursued within the Channing)
- Appropriateness of the Assay/Approach to the Biospecimens (e.g. biomarker stability, assay quality, range of data, etc.)

The applicant will be notified of the decision within a month of submission.

Appeals: If the proposed research is not approved for access and the applicant does not agree with the reason for this decision, the applicant can appeal the decision by submitting a proposal to the NHS External Advisory Committee. Submission deadlines are February 15, June 15, and October 15. The format of the proposal should be similar to an NIH grant (i.e. specific aims, background and significance, preliminary studies and methods) but should be no longer than 10 pages in length.

It is anticipated that the Advisory Committee's decision will be made within four to eight weeks of proposal submission. The Advisory Committee will decide to accept, accept pending revisions, or reject a proposal. For either of the latter two outcomes, a summary of the reasons for the decision will be provided. An "accept pending revisions" will be given if the proposal has considerable scientific merit, yet one or more issues need to be addressed before the project can proceed. Arrangements will be made to provide an expedited review of a revised proposal, which addresses the concerns of the Advisory Committee.

For proposals that will require the development of funding outside the proposing organization, the approval process described above must be factored into the timing of any grant application. The Advisory Committee and Cohort investigators do not take responsibility for missed deadlines.