Updated September 2016

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.

The overriding objective of the Access Policy and Process is to encourage the extensive and appropriate use of the Resource through a simple streamlined process to maximally leverage the existing specimens and data without undue delays. The procedures derive from the following key principles:

- The Biorepository Specimens and/or Data are available to all *bona fide* researchers for all types of health-related research that is in the public interest. All researchers, whether in universities, non-profit organizations government agencies or commercial companies, will be subject to the same application process and approval criteria.

- Applications to use the Resource will be reviewed by the Access Board to determine validity of scientific aims, evaluate the fit of the Resource for the proposed methodology, and verify that proposed use meets the guidelines of the Ethics & Governance Framework and the consent that was provided by the participants.

- Different models exist for access to the Resource including but not limited to, funding sponsored research at the Biorepository parent organizations, joint collaboration between outside entities with cohort researchers at parent organizations, or fee for service. The access mechanism will be established to fit the need of the project and will be determined in discussion with individual applicants.

- Access to the biological samples that are limited and depletable will be carefully controlled and coordinated. The quantity of sample that is required will be judged against the potential benefits of the research project, with advice from appropriate experts as required.

- Safeguards will be maintained to help ensure the anonymity and confidentiality of participants' data and samples. Researchers will enter a legal agreement with the parent organizations governing the Biorepository not to make any attempt to identify participants, and data and/or samples provided to researchers from the Biorepository will not identify any particular participant (i.e. they will be de-identified).

- Researchers will have to pay for access to the Resource on a cost-recovery basis. In accordance with Parent Institution policies, charges will be dependent on what is requested and variable in accordance with request.

- Researchers granted access will be expected to agree to the terms and conditions of the standard MTA and DUA utilized by the Biorepository Program and parent organizations.

- Researchers granted access to the Resource will be required to publish their findings and return their raw results to the Biorepository so that they are available for other researchers to use for health-related research that is in the public interest. Embargo periods of 6 months to 1 year on release of returned data to the public data portal will be negotiated at the time of application.

- The Biorepository will seek active engagement with participants, researchers and society in general throughout the Resource's lifetime (which is intended to be some decades), in particular regarding the research that is being conducted on it and the research findings that emerge.

Submitting a Proposal

Letter of intent: Investigators wishing to use biospecimens and related data 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 (nhahe@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. Similarly, proposals to evaluate highly speculative hypotheses are not considered appropriate. A letter of intent may be submitted at any time throughout the year. Proposals will be reviewed in accordance with the Policy described above.