Chapter 9

BIOREPOSITORY AND BIOSPECIMEN USE GUIDELINES FOR PHN STUDIES (PHN BIOSPECIMENS COMMITTEE)

The PHN Biospecimens Committee is responsible for assisting with the development of projects and for reviewing proposals involving biospecimens use. All biospecimens collected for future research or leftover from a primary genetic study are deemed a central PHN resource. Biological data is defined as sequencing, genotyping, gene expression, proteomics, metabolomics or other biological data generated from biospecimens collected in the PHN.

9.1 Development of PHN study proposals involving biospecimens

PHN proposals involving biospecimens collection will be sent to the Biospecimens committee chair/s for input during the development stage before protocol finalization. This will help ensure that standard biorepository language is used in the proposal consistent with best practices and appropriate budget has been included. For studies involving biobanking of samples for future research, investigators are encouraged to refer to the PHN biorepository consent template available through NERIConnect. The consent can be offered as a stand-alone consent or the required elements can be incorporated into the main study consent at the discretion of the parent study committee.

9.2 Primary genetic study or genetic aim of a parent study (including studies involving biomarkers)

For a primary genetic study / aim that is clearly developed and integrated into the parent study and funded by the PHN, the biospecimens will be used as described in the parent protocol and the established procedures for developing a writing committee at the conclusion of the parent study will be pursued.

9.3 Request for use of stored biospecimens or biological datasets

The guidelines below refer to studies proposing use of stored biospecimens that were not fully integrated within the parent study. The PI(s) for the parent study will work with the Biospecimens Committee to develop strategies for testing and analysis of the secured biospecimens. In some cases, optimal testing strategies will require coordination across multiple studies to achieve adequate power.

9.3.1 *Who can propose a study?*

Any PHN member or an external PI in collaboration with a PHN member can propose studies using the stored biospecimens or associated biological datasets. Prior consultation with the parent Study Chair and the Biospecimens Committee Chairs is encouraged. The proposal must be submitted in writing to the PHN Biospecimens Committee using the Ancillary Study Application Form and the supplemental Biospecimens / Biological Data Request Form. Both forms can be

accessed in the Policies and Templates section of the PHN Administrative website NERIConnect.

9.3.2 *Administrative review for feasibility*

NERI will perform an administrative review to ascertain if requested samples are available, and if there are any restrictions on sample use based on individual consent. This information will be released to the Biospecimens Committee Chairs along with the study application. Expected turnaround time for administrative review from receipt of request = 2 weeks.

9.3.3 *Biospecimens Committee Review*

If the biospecimens related study is relevant to a primary or secondary aim of one/more parent PHN studies, the chairs of the parent studies will be consulted to ensure alignment and responsible use of study data and determine the timeline for release of clinical data if the data are unpublished. The application will then be circulated to the Biospecimens Committee which will determine if a request for samples or biological data is appropriate, if funding is available, if the study is scientifically meritorious and feasible, and ensure there is no overlap with ongoing studies in the PHN. Expected turnaround time for Committee Review from receipt of application = 2 weeks.

9.3.4 *Ancillary Study Committee Review*

For a new biospecimens related study that is independent of the primary or secondary aims of a parent study, or if the genetic study involves the collection of additional biospecimens or generation of additional data from existing biospecimens that were not part of the parent study, it will be considered an ancillary study and will require approval by both the PHN Biospecimens and the Ancillary Study committees (and by the PCGC Clinical outcomes working group if involving the PCGC). The results of the Biospecimens Committee review will be submitted to the Ancillary Study Chairs. If the proposed study is limited to the use of biospecimens or biological data only, the Ancillary Study Chair and Co-chair may administratively approve the proposal. If the proposed study involves use of PHN study data in addition to the biospecimens or biological data, the proposal may be reviewed by the full Ancillary Studies Committee. The Ancillary Study Chairs will determine the level of review needed based on these criteria. Please refer to Chapter 7.10 for detailed PHN-PCGC clinical and genomic data sharing policy.

9.3.5 *PHN-PCGC collaborative studies*

For studies proposed jointly by the PHN and PCGC, and/or where sequencing or genotyping costs of PHN samples are covered by the PCGC, the proposal will need approval by both the PHN Biospecimens committee and the PCGC Clinical Outcomes working group before review by the Ancillary Study Committee.

9.3.6 *Biospecimens and Data release*

Biospecimens and/or data release for approved projects will be done after NERI confirms that appropriate IRB approval and Material Transfer Agreements are in place as needed.

9.3.7 *Public use datasets*

In cases where either the clinical data or the biological data are already in public databases, the Biospecimens Committee will review any request for linking clinical and biological datasets. If approved, NERI will link the datasets in a de-identified manner that protects subject identity.

9.4 Funding

For biospecimen studies not budgeted within the parent PHN study, funding for biological characterization and analysis is the responsibility of the study proposer although the Biospecimens committee may assist in securing funding through the PHN, PCGC or from external funding sources if appropriate.

9.5 Biological Data Storage

The biological datasets generated with funding from the PHN or PCGC will be stored in a PHN or PCGC central repository with regulated access limited to investigators with approved studies within the scope of the original consent. For studies funded by external sources, it is expected that the investigator will return the biological datasets to the PHN after study completion for broader use as appropriate.

9.6 Requirements for Writing Committees

The Biospecimens committee will assist in the formation of writing committees.

1. If the manuscript is primarily methodological, it is not required that all PHN Centers be invited to participate in the Writing Committee.
2. For all other studies, all PHN Centers that contributed data and biological samples will be given the opportunity to participate in Writing Committee(s). The Center PIs will be invited to extend this opportunity to a qualified individual. Centers may opt out of participation. The Requirements for Authorship will be used to determine the membership of the Writing Committee.
3. If the opportunity for authorship is not extended to all centers, clear written justification must be submitted and reviewed by the Biospecimens and Ancillary Study Committee Chairs who may administratively approve or refer for review by the entire committee membership.
4. For studies involving the PCGC, the PCGC will also be invited to nominate members.
5. The PHN in general and the names of PHN centers that contributed data or biological samples must be included in the manuscript Methods and Acknowledgement sections, respectively. Individual investigator names from the centers are not required. If the origin of the data or biological samples cannot be determined, then acknowledgement of only the PHN is required.