SOP 502H: Categories of Research Banking of Biologic Specimens, Genetic Testing, and Gene Transfer

1. POLICY

The IRB shall review all research projects involving the collection and/or storage of any human biologic specimen for use in future research studies. An investigator must have an approved research project to collect and bank such specimens and a separately-approved research project for the distribution of these specimens.

The IRB shall review all human research projects involving genetic testing. The type of review is at the discretion of the IRB Chair or IRB designee based on the level of risk to the participant. Generally, the greatest risk for participants who participate in genetic research (except for gene therapy research) involves breach of confidentiality.

Gene transfer research projects shall be reviewed independently by the convened IRB and the Institutional Biosafety Committee (IBC).

Specific Policy

1.1 Clinical Research Involving Banking of Biologic Specimens

Research projects involving the collection and banking of human biologic specimens may be approved under either expedited or convened IRB review, depending on the design of the research project and the degree of potential risk for participants. Research projects that are principally drug-treatment in design but have a specimen-banking component are also subject to this SOP.

The IRB adopts the Office for Human Research Protection’s (OHRP) recommendation that recipient-investigators not be provided access to the identities of donors or to information through which the identities of donors may be ascertained in clinical research involving banking of biologic specimens.

1.2 Genetic Testing of Biologic Specimens

The IRB shall review all research projects involving genetic testing and modifications to approved research projects that include genetic testing. The IRB Chair or IRB designee shall determine the type of review based on the level of risk to the participant using the following table as a general guideline:

<table>
<thead>
<tr>
<th>LEVEL OF ANONYMITY</th>
<th>RESEARCH PROJECT DESIGN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anonymous / Anonymized</td>
<td>Exempt/Expedited</td>
</tr>
<tr>
<td>Identifiable (linked or coded)</td>
<td>Expedited/Full Board</td>
</tr>
<tr>
<td>Identified (direct identifiers)</td>
<td>Expedited/Full Board</td>
</tr>
</tbody>
</table>

1.3 Gene Transfer

The convened IRB and the IBC shall review gene transfer studies independently. Such studies may also require review by external microbiologists, virologists,
molecular biologists, or other consultants with relevant expertise to provide guidance to the IRB and IBC. If the research project involves gene transfer to human participants for other than clinical purposes, the National Institutes of Health Recombinant DNA Advisory Committee (RAC) must approve the research project prior to IRB approval.

1.4 GINA-Genetic Information Nondiscrimination Act

GINA is a Federal law that prohibits discrimination in health coverage and employment based on genetic information. GINA, together with already existing nondiscrimination provisions of the Health Insurance Portability and Accountability Act, generally prohibits health insurers or health plan administrators from requesting or requiring genetic information of an individual or an individual's family members, or from using such information for decisions regarding coverage, rates, or preexisting conditions. GINA also prohibits employers from using genetic information for hiring, firing, or promotion decisions and for any decisions regarding terms of employment.

Given that GINA has implications regarding the actual or perceived risks of genetic research and an individual's willingness to participate in such research, investigators and the IRB should be aware of the protections provided by GINA, as well as the limitations in the law's scope and effect. The IRB shall consider the provisions of GINA when assessing whether genetic research satisfies the criteria required for IRB approval of research, particularly whether the risks are minimized and reasonable in relation to anticipated benefits and whether there are adequate provisions in place to protect the privacy of participants and maintain the confidentiality of their data. GINA is also relevant to informed consent. When investigators develop and the IRB reviews the consent processes and documents for genetic research, they shall consider whether and how the protections provided by GINA should be reflected in the consent document's description of risks and in the provisions for assuring the confidentiality of the data.

2. SCOPE

This SOP applies to all research involving banking of biologic specimens, genetic testing, and gene transfer.

3. RESPONSIBILITY

3.1 The HRPP Director or designee is responsible for maintaining up-to-date review tools for review of this type of research.

3.2 The IRB Chair or IRB designee is responsible for providing IRB members adequate submission review training and ongoing guidance and for selecting one primary and one secondary reviewer with the relevant expertise to perform reviews and make necessary recommendations on approval decisions by the IRB. If the IRB Chair or IRB designee cannot select primary and secondary reviewers with the relevant expertise, the IRB Chair or IRB designee defers the review to another IRB with primary and secondary reviewers with the relevant expertise or obtains consultation for that expertise.
3.3 The IRB Reviewer is responsible for conducting appropriate review of research planned for this category, in consultation with appropriate experts and resources.

3.4 The IRB is responsible to assure there are adequate safeguards for the confidentiality and safety of the participant.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46
21 CFR 50, 56
OHRP Guidance Document, IRB Guidebook
Office for Protection From Research Risks-Issues to Consider in the Research Use of Stored Data or Tissues, November 7, 1997

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301: Research Submission Requirements
SOP 402: Expedited Review
SOP 403: Initial Review – Criteria for IRB Approval

6. ATTACHMENTS

203-A HSC Reviewer Checklist
701-A Informed Consent Template
701-C Tissue Consent Template
701-D Patient Information Sheet – Tissue Banking

7. PROCESS OVERVIEW

7.1 The Investigator or Investigator staff submits a new study application and uploads all applicable documents into the IRB electronic information system.

7.2 The submission is received in the IRB Office and processed (see SOP 301: Research Submission Requirements and SOP 403 – Initial Review – Criteria for IRB Approval). The submission with all applicable documents made available to all IRB members.

7.3 The IRB Administrator conducts a pre-review of the submission and verifies all necessary documents are received as applicable, including documentation of a valid IND and Investigator’s Brochure or drug package insert (if applicable), or if additional institutional committee review or information is required. The IRB Administrator communicates with the investigator and/or research staff to obtain any addition information and/or reviews.
7.4 The IRB Administrator assigns the submission either to (1) the appropriate Board agenda or (2) to the IRB Chair/IRB designee

7.4.1 If to an IRB agenda, the process follows SOP #403: Initial Review – Criteria for IRB Approval.

7.4.2 If to IRB Chair / IRB Designee, the process follows SOP #402: Expedited Review

7.5 Modifications may be required before final approval. When the modifications are received by the IRB, the IRB Administrator verifies all changes are made before assigning the submission to the IRB Chair or IRB designee for final review.

7.6 When IRB review is completed, the IRB Administrator generates the appropriate letter to notify the Investigator of the results of the review, and reports the final approval by posting to the next IRB agenda.

7.7 Enrollment into the research project may not commence until all required institutional committees have completed their review and the contract is signed, if applicable

APPROVED BY: __________________________ DATE: 08/31/2014

NEXT ESTABLISHED REVIEW DATE: AUGUST 2016