

SOP: 502H
CATEGORIES OF RESEARCH BANKING OF BIOLOGIC SPECIMENS, GENETIC TESTING, AND GENE TRANSFER

1. POLICY

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

The IRB shall review all research involving genetic testing. The type of review is at the discretion of the IRB Chair or 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 studies) involves breach of confidentiality.

Gene transfer studies 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

Protocols 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 study and the degree of potential risk for participants. Studies that are principally drug-treatment in design but have a specimen-banking component are also subject to this policy.

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.

1.2 Genetic Testing of Biologic Specimens

The IRB shall review all research studies involving genetic testing or amendments to already approved research studies that include genetic testing. The IRB Chair or designee shall determine the type of review based on the level of risk to the participant using the following table:

LEVEL OF ANONYMITY	STUDY DESIGN	
	RETROSPECTIVE	PROSPECTIVE
Anonymous / Anonymized	Exempt/Expedited	Exempt/Expedited
Identifiable (linked or coded)	Expedited/Full Board	Usually Full Board
Identified (direct identifiers)	Expedited/Full Board	Usually Full Board

1.3 Gene Transfer

The convened IRB and the IBC shall review gene transfer studies independently. Such studies may also require review by external microbiology, virology, or molecular biology consultants to provide independent guidance to the IRB and IBC. If the study involves gene transfer to human participants for other than clinical purposes, the National Institutes of Health Recombinant DNA Advisory Committee (RAC) must review and approve the study 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 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 provisions for assuring the confidentiality of the data.

2. SCOPE

This policy and these procedures apply to all research involving banking of biologic specimens, genetic testing, and gene transfer.

3. RESPONSIBILITY

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

The IRB Chair or 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 designee cannot select primary and secondary reviewers with the relevant expertise, the IRB Chair or designee defers the review to another IRB with primary and secondary reviewers with the relevant expertise or obtains consultation for that expertise.

The IRB Reviewer is responsible for conducting appropriate review of research planned for this category, in consultation with any appropriate experts and resources.

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

Guidance on the Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards, March 24, 2009

5. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other policies.

6. ATTACHMENTS

203-A	New Study Reviewer Checklist – Full Board
203-B	New Study Reviewer Checklist – Expedited
203-BB	Categories of Expedited Review Criteria Checklist
203-C	New Study Reviewer Checklist – Exempt
203-CC	Categories of Exemption Checklist
203-E	Reviewer Checklist for Research Involving Pregnant Women, Fetuses & Neonates
203-F	Reviewer Checklist for Research Involving Prisoners
203-G	Reviewer Checklist for Research Involving Children
701-A	Informed Consent Template
701-C	Tissue Consent Template
701-D	Patient Information Sheet – Tissue Banking

7. PROCESS OVERVIEW

The IRB Staff makes sure all documents are reviewed for submission per SOP 301, Research Submission Requirements.

The IRB Administrator provides to the IRB Chair, designee, or the IRB the item to be reviewed and the tools to conduct the review.

- 7.1 The study is received in the IRB office and assigned to an appropriate IRB. The IRB Administrator reviews the submission for completeness and type of review. The IRB Administrator makes a new file and pre-reviews the submission to determine if additional institutional committee review or information is required. The IRB Administrator communicates with the Investigator what, if any, additional materials or reviews are required.
- 7.2 The study is assigned to an agenda or given to the IRB Chair or designee for review.
- 7.3 Modifications may be required before final approval. Once the modifications are received by the IRB, the IRB Administrator confirms all changes are made before putting the changes in the file and presenting the file to the IRB Chair for review/approval.
- 7.4 Final IRB approval will not be granted until all required institutional committees have completed their review and the research contract is signed, if applicable. Documentation of these reviews and ORA release are placed in the file.
- 7.5 Once the IRB review is completed, the IRB Administrator generates the appropriate letter to notify the Investigator of the results of the review.
- 7.6 All expedited studies follow the expedited process outlined in SOP 402, Expedited Review.

APPROVED BY: _____ **DATE:** 09/01/2009

NEXT ESTABLISHED REVIEW DATE: MAY 2012