

Policy and Procedures for Research Involving Human Blood, Fresh Human Tissue, or Body Fluids

I. Policy

All human blood, fresh tissue, or body fluids must be regarded as possibly infected with blood borne pathogens such as Human Immunodeficiency Virus (HIV) or Hepatitis B Virus (HBV). Therefore, the Upstate IBC will review research protocols which involve the use of human blood, fresh human tissue, or body fluids in a research lab or by Upstate research personnel to ensure maximum safety.

All persons working in laboratories that deal with these substances must be informed of the potential hazard and instructed in the procedures needed to avoid exposure and infection. It is the responsibility of the principal investigator to inform and instruct those persons under his/her supervision.

Specifically excluded from these requirements are hospital and patient-related service activities at University Hospital. These activities are governed separately under guidelines developed by the Department of Environmental Health & Safety and the Hospital Infections Committee.

The IBC is authorized to inspect research facilities, approve research practices and procedures, and to take actions, such as enforcement or cessation of research activities, in the event of an unsafe workplace situation.

The compliance office retains records for IBC approved projects for a minimum of three years following completion of a study.

II. Procedures for Reviewing Research Involving Human Blood, Fresh Human Tissue, or Body Fluids

Review of the project shall include: (i) assessment of the containment levels required; and (ii) assessment of the facilities (a site visit may be required), procedures, practices, and training of personnel involved in the research. Biosafety Level 2 is appropriate when work is done with any human-derived blood, body fluids, tissues, or primary human cell lines where the presence of an infectious agent may be unknown.

- A.** Submission of an IBC Application Form, BioSafety Manual and Study Personnel Form to the IBC is required for all experiments and research studies involving the use of human blood, fresh human tissue, or body fluids in a research lab or by Upstate research personnel.
- B.** The IBC Chair or his/her designee will review the materials for confirmation of investigator assessment, assessment of the facilities (a site visit may be required), procedures, practices, and training of personnel involved in the research. The investigator will be notified in writing if further information is required. Once the project is approved, an approval letter with an expiration date will be issued, so that tracking for annual renewal can be initiated. Approval will be granted for a maximum of one year. The IBC chair has the discretion to refer any project for review at a convened meeting of the IBC.

III. Continuing Review of IBC Approved Projects

Annual Review of all IBC approved projects is required. An Annual Protocol Review Form and any other required materials (e.g., Safety Engineered Medical Device Survey) will be made available to the Investigator prior to the expiration date. The completed Report Forms should be submitted to the IBC for review at least one week prior to the project's expiration date, to ensure a timely review.

The investigator will be required to submit a new application for review by the IBC Chair or Committee every five years to ensure compliance with the NIH and Institutional Guidelines.

Once the annual or 5-year renewal is approved, an approval letter with a new expiration date will be issued, so that tracking for annual renewal can be initiated. Approval will be granted for a maximum of one year.

IV. Amendments to Approved Projects

Prior to implementing any changes to an approved project, the Investigator will submit a memo outlining the proposed changes and applicable revised materials (e.g., IBC Application Form, BioSafety Manual, Personnel Form) with all changes highlighter or tracked to the IBC.

Amendments will be reviewed by the Chair; IBC member designated by the Chair or may be referred to the full committee for review if there is a change in risk to the public or employees or if required by the NIH guidelines. Once the amendment is approved, an approval letter will be issued.

V. Training Requirements

All employees must complete:

- Blackboard Training (*Required Annually*)
 - Laboratory Safety Course (#UH333)
 - Blood Borne Pathogens Course (#UH8794) (Required for BSL2 Labs)
- CITI Training (*Required every 4 years*)
 - Responsible Conduct of Research Course
- Training by their laboratory supervisor.

Questions concerning this policy or the IBC approval process may be directed to:

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