

# **Guidelines for collection, processing and storage of human samples by Clinical Researchers**

## **Purpose**

The purpose of this document is to inform investigators about the evaluation and approval process of the protocol application for collecting or handling human blood, tissue or fluids to protect themselves from bloodborne diseases.

## **Applicability**

OSHA's Bloodborne Pathogens standard (29 CFR 1910.1030) requires employers to protect workers who are occupationally exposed to blood and other potentially infectious materials (OPIM). Therefore, clinical trials or other research involving the processing, storage of, or research with the following human materials must be reviewed at Temple University by the Institutional Biosafety Committee (IBC): human blood, tissue, body fluids, nasal swabs, saliva or fecal matter.

## **Institutional Biosafety Committee**

This committee is appointed by Temple University's Institutional Official (Vice President for Research) to review the use of hazardous biological agents (including human material). The committee follows NIH Guidelines and University Policies to review proposed projects.

## **Personnel Protection**

The IBC is responsible for ensuring that University laboratory personnel are aware of the potential hazards of handling human blood and/or tissues and use the proper precautions to protect themselves from bloodborne diseases.

Hepatitis B vaccination is offered by Temple University free of charge to all employees who have potential for an occupational exposure to bloodborne pathogens (for details contact Employee Health Services at:

[employeehealth@temple.edu](mailto:employeehealth@temple.edu))

## **Safety Training**

Before starting to work with human material in research laboratory settings, every lab worker handling human material is required to complete: Bloodborne Pathogens (BBP) safety training. In addition, Airborne Pathogens (ABP), Biosafety and Hazard Communication safety trainings for Clinical Researchers (processing human material) provided by EHRS must be also completed. Individuals who

handle human materials intended for shipment or prepare/supervise shipping activities are required to complete Shipping of Dangerous Goods safety training.

To enroll safety training courses please use link:

<https://tuportal6.temple.edu/group/home/ehrs-course-finder>, and follow training matrix for *CLINICAL RESEARCHER (processing human material)*.

Initial BBP and Shipping of Dangerous Goods safety trainings must be completed virtually via the ZOOM video-conferencing platform (register at: <https://campusoperations.temple.edu/ehrs/training/virtual-training>), with the annual or biannual refresher available online, respectively.

For any specific questions related to the Shipping of Dangerous Goods safety training please contact Joan deVastey, EHRS Safety Officer, at [joan.devastey@temple.edu](mailto:joan.devastey@temple.edu)

For questions related to all other safety training courses please contact Kisha Grady, EHRS Senior Training Specialist at [kgrady@temple.edu](mailto:kgrady@temple.edu)

### **Before Conducting Research:**

- 1) Principal Investigators may need to submit an IBC Registration Form to the Institutional Biosafety Committee for expedited quality assurance review before starting a new project if:
  - Human material is utilized in further research at Temple University.
  - Human material is processed e.g., centrifuge, aliquoting.
  - Human material is stored for more than 24 hours.
  - Human material is shared with other researchers.
  
- 2) Documents needed (forms available at: <https://research.temple.edu/research-compliance/institutional-biosafety-committee-ibc/institutional-biosafety-forms-standard>):
  - Biosafety Registration Form (BRF) for select clinical trial protocols that do NOT involve the use of recombinant DNA (or regular BRF if recombinant DNA and other hazardous materials and procedures are involved)
  - Agent Summary for Bloodborne Pathogens and Other Potentially Infectious Materials
  - Standard Operating Procedure (SOP) 2.0
  - Exposure Control Plan (ECP)

Email documents to [ibc@temple.edu](mailto:ibc@temple.edu)

- 3) For initial protocols, Environmental Health and Radiation Safety (EHRS) will provide the risk assessment evaluation of the laboratory where human blood and/or tissues will be handled and stored, prior to approval.
- 4) For projects associated with human subject studies, Institutional Review Board (IRB) number and status should be listed in IBC submission documents. If an IRB application is not submitted yet, contact the IRB Office at: [irb@temple.edu](mailto:irb@temple.edu) for guidance.

### **Review Process**

- Principal Investigator should submit appropriate documents to the IBC Office.
- IBC Coordinator initiates administrative evaluation, confirms safety training status, assigns an IBC number in the eRA system, and sends the application to the BSO and EHRS Biosafety Group and Occupational/Employee Health IBC member for review.
- After review, the Principal Investigator is asked to address all comments and to resubmit the revised protocol to the IBC Office.
- If revised documents address all items cited in review, submission is sent to the IBC Chair for final assessment and approval.
- In a case of high volume of submissions, the IBC Chair can assign other committee member(s) to review protocols before final approval.

Protocols can be approved for maximum six-years, but an annual renewal form must be submitted every year to confirm active status and provide necessary information about procedural, funding, location(s) and personal changes. In a meanwhile all changes to these protocols must be reported via submission of the IBC amendments.