

Tissues and Body Fluids Rules Summary

Because fresh or frozen tissue, blood, and body fluids obtained from humans or vertebrate animals may host pathogenic microorganisms or blood-borne pathogens, they are treated as **Potentially Hazardous Biological Agents (PHBA)**. The primary goal is to ensure safe acquisition, handling, and disposal using appropriate Biosafety Level (BSL) protocols.

Prohibited Studies

- Student researchers are **strictly prohibited** from collecting or examining body fluids or tissues that contain biological agents rated above **BSL-2** (e.g., BSL-2+, BSL-3, or BSL-4).
- Euthanizing a vertebrate animal *solely* for the student's project. (If an animal was euthanized for a non-student purpose, it qualifies as a tissue study; if euthanized specifically for the student, it must follow full Vertebrate Animal rules).

Key Rules by Tissue & Fluid Type

- **Human Blood & Blood Products:** Must be handled under **BSL-2** containment supervised by a Qualified Scientist (QS) following OSHA and APHIS guidelines.
 - *Exception:* A student researcher collecting their own capillary blood (e.g., finger stick) is considered BSL-1 and exempt from QS supervision.
- **Animal Blood:** Wild animal blood requires **BSL-2** containment. Domestic animal blood may be classified as **BSL-1**.
- **Human Body Fluids & Privacy:** If body fluids can be identified with a specific individual, or if they serve as a measure of an experimental procedure on human subjects, the study **must** receive IRB review and informed consent. Unpasteurized domestic animal milk and human breast milk of unknown origin are rated **BSL-2**.
- **Cell Lines & Tissue Cultures:** Primary cell lines and established human/vertebrate cell lines (e.g., ATCC) are assigned a biosafety level (BSL-1 or BSL-2) based on manufacturer/source specifications and must be treated accordingly.
- **Disposal & Safety:** All blood-contaminated items or tissues releasing blood when compressed must be properly decontaminated (autoclaved or incinerated) prior to disposal.

Documentation & Pre-Approval Requirements

- **Prior Approval Required:** All research involving fresh/frozen tissues, primary cell lines, blood, or body fluids requires written pre-approval from an affiliated SRC, Institutional Biosafety Committee (IBC), or IACUC before work begins.
- **Required Forms:**
 - **Form 6A (PHBA Risk Assessment Form):** Required to document the BSL determination and safety protocols.
 - **Form 6B (Human and Vertebrate Animal Tissue Form):** Required to certify the source, catalog number, and handling procedure of the tissue or fluid.
 - **IACUC Documentation:** If non-commercial tissue is obtained from an ongoing research study at an RRI or mentor's lab, official IACUC approval documentation (or publication reference) from the original study must be provided.

Exempt Tissues & Fluids (No Form 6B or SRC Pre-Approval Required)

The following biological materials are exempt from PHBA rules:

- Plant tissues (unless known to be toxic/hazardous).
- Established vertebrate cell lines and tissue culture collections with catalog/source documentation (must still be noted on Form 3).
- Student researcher's own finger-stick capillary blood.
- Fresh or frozen meat, poultry, eggs, or pasteurized milk purchased from commercial food stores or packing houses, as long as they are **not cultured**.
- Hair, hooves, nails, feathers, and sterilized teeth (treated to kill blood-borne pathogens).