

Tissue, Body Fluid & Blood Guidelines

Studies involving fresh or frozen tissue, blood or body fluids obtained from humans and/or vertebrate animals may contain microorganisms and have the potential of causing disease. For this reason, a proper risk assessment (Form 6A) is required along with a tissue certification form (Form 6B).

Studies Exempt from Prior SRC Review/Approval

The following types of tissue do not need to be treated as potentially hazardous biological agents and are thus exempt from prior SRC review and approval, but **MUST** be included on the Risk Assessment Form 3.

- Plant tissue (except those known to be toxic or hazardous).
- Plant and non-primate established cell lines and tissue culture collections (for example those obtained from the American Type Culture Collection). The source and/or catalog number **MUST BE IDENTIFIED** in the Research Plan.
- Fresh or frozen meat, meat by-products, pasteurized milk or eggs obtained from food stores, restaurants or packing houses.
- Hair, hooves, nails and feathers.
- Teeth that have been sterilized to kill any blood-borne pathogen that may be present. The dentist who provided the teeth must provide a letter certifying the sterilization.
- Fossilized tissue or archeological specimens.
- Prepared fixed tissue.

ALL Tissue, Body Fluid, Blood & Blood Product Study Guidelines

The following items may or may not apply to a Student Researcher's project.

- If tissues are obtained from an animal that was euthanized for a purpose OTHER THAN the Student Researcher's project, it may be considered a tissue study and not a vertebrate animal study.
- Use of tissue from research conducted at a Regulated Research Institution required documentation of the IACUC approval for the original animal study.
- Use of tissues obtained from agricultural/aquacultural studies required prior SRC approval.
- If tissues are obtained from an animal that was euthanized solely for the Student Researcher's project, the study must be treated as a vertebrate animal project and is subject to the vertebrate animal rules found on pages 21-23 and Form 5B.
- Studies of human body fluids, where the sample can be identified with a specific person, must be considered a human subjects study and have IRB review and approval and informed consent.
- Studies involving embryonic human stem cells must be conducted in a Regulated Research Institution and be reviewed and approved by their Embryonic Stem Cell Research Oversight (ESCRO) Committee.
- All blood must be handled in accordance with standards and guidelines set forth in the OSHA, 29CFR, Subpart Z.
- Any tissue or instrument with the potential of containing blood-borne pathogens must be properly disposed of after experimentation.
- Any study involving the collection and examination of body fluids or blood that may contain biological agents belonging to BSL-3 or BSL-4 are prohibited.

Examples of BSL-1 Tissue Studies:

- Studies involving the collection and examination of fresh/frozen tissue and/or body fluids (not blood or blood products) from a non-infectious source with little likelihood of microorganisms present.
- Studies involving domestic animal blood.
- Studies involving a Student Researcher using their own body fluids (if not cultured). Will need IRB approval if the body fluid is serving as a measure of an effect of an experimental procedure on the Student Researcher.
- Studies involving human and/or non-human primate established cell lines and tissue culture collections indicated as BSL-1 by the source. The source and/or catalog number of the cultures MUST BE IDENTIFIED in the Research Plan and on Form 6B.

Examples of BSL-2 Tissue Studies:

- Studies involving the collection and examination of fresh/frozen tissues or body fluids or meat, meat by-products, pasteurized milk or eggs NOT obtained from food stores, restaurants or packing houses.
- Studies involving human breast milk of unknown origin, unless certified free of HIV and Hepatitis C and domestic unpasteurized animal milk.
- Studies involving human or wild animal blood or blood products.
- Studies involving human and/or non-human primate established cell lines and tissue culture collections indicated as BSL-2 by the source. The source and/or catalog number of the cultures MUST BE IDENTIFIED in the Research Plan and on Form 6B.

Human and Vertebrate Animal Tissue Form (6B) – Middle School

This form is required for ALL projects involving fresh/frozen tissue, blood, blood products and body fluids. Form 6A MUST also be completed. If the research also involves living organisms (human or vertebrate animals), please ensure that the proper forms are completed.

This form is to be completed by the Student Researcher(s) in collaboration with the Qualified Scientist/Mentor. All questions MUST be answered and additional pages may be attached.

1. Student's Name(s): _____
2. Project Title: _____
3. What type of tissue will be used in this study? Check ALL that apply.
 - Fresh or Frozen Tissue Sample
 - Fresh Organ or Other Body Part
 - Blood
 - Body Fluids
 - Primary Cell/Tissue Cultures
 - Human or Other Primate Established Cell Lines
 - Other: _____
4. From where will you obtain the above tissue(s)? Established cell lines must be identified by the source and catalog number.

If the tissue will be obtained from a vertebrate animal study conducted at a research institution, attach a copy of the IACUC certification with the name of the research institution, the title of the study, the IACUC approval number and the date of IACUC approval included.

Qualified Scientist/Mentor:

I verify that the student will work solely with organs, tissues, cultures or cells that will be supplied to him/her/them by myself or qualified personnel from the laboratory; and that if vertebrate animals were euthanized, they were euthanized for a purpose other than the Student Researcher(s)' project.

AND/OR

I certify that the blood, blood products, tissues, or body fluids in this project will be handled in accordance with the standards and guidance set forth in Occupational Safety and Health Act, 29CFR, Subpart Z, 1910.1030 – Blood Borne Pathogens.

Printed Name

Signature

Date of Review (mm/dd/yy)
(MUST be PRIOR to experimentation)

Title

Email

Institution