

Additional Rules for Projects with Tissues and Body Fluids, Including Blood and Blood Products

Studies involving fresh/frozen tissue, blood or body fluids obtained from humans and/or vertebrates may contain microorganisms and have the potential of causing disease. Therefore, a proper risk assessment is required.

1. The following types of tissue do not need to be treated as potentially hazardous biological agents:
 - a. Plant tissue
 - b. Plant and non-primate established cell lines and tissue culture collections (e.g., obtained from the American Type Culture Collection). The source and/or catalog number of the cultures must be identified in the Research Plan.
 - c. Fresh or frozen meat, meat by-products, pasteurized milk or eggs obtained from food stores, restaurants, or packing houses.
 - d. Hair.
 - e. Teeth that have been sterilized to kill any blood-borne pathogen that may be present. Chemical disinfection or autoclaving at 121 degrees Celsius for 20 minutes is recommended.
 - f. Fossilized tissue or archeological specimens.
 - g. Prepared fixed tissue.
2. Research involving human and/or non-human primate established cell lines and tissue culture collections (e.g., obtained from the American Type Culture Collection) must be considered a BSL-1 or BSL-2 level organism as indicated by source information and treated accordingly. The source and/or catalog number of the cultures must be identified in the Research Plan.
3. If tissues are obtained from an animal that was euthanized for a purpose other than the student's project, it may be considered a tissue study. Documentation of the IACUC approval for the original animal study from which tissues are obtained is required.
4. If the animal was euthanized solely for the student's project, the study must be considered a vertebrate animal project and is subject to the vertebrate animal rules for studies conducted at a Regulated Research Institution. (See vertebrate animal rules.)
5. Biosafety level 1 tissue studies involve the collection and examination of fresh/frozen tissue and/or body fluids, (not including blood or blood products; see rule 7) from a non-infectious source with little likelihood of microorganisms present. Biosafety level 1 studies must be conducted in a BSL-1 laboratory or higher and must be supervised by a Qualified Scientist or trained Designated Supervisor.

6. Biosafety level 2 tissue studies involve the collection and examination of fresh/frozen tissues or body fluids that may contain microorganisms belonging to BSL-1 or -2. These studies must be conducted in a Regulated Research Institution in a BSL-2 laboratory under the supervision of a Qualified Scientist.
7. All studies involving human or wild animal blood or blood products is considered a BSL-2 and is required to be conducted in a BSL-2 laboratory under the supervision of a Qualified Scientist. Studies involving domestic animal blood may be considered a BSL-1 level study. All blood must be handled in accordance with standards and guidelines set forth in the OSHA, 29CFR, Subpart Z. Any tissue or instruments with the potential of containing blood-borne pathogens (e.g. blood, blood products, tissues that release blood when compressed, blood contaminated instruments) must be properly disposed after experimentation.
8. Human breast milk of unknown origin, unless certified free of HIV and Hepatitis C and domestic unpasteurized animal milk, are considered BSL-2.
9. Any study involving the collection and examination of body fluids which may contain biological agents belonging to BSL-3 or -4 is prohibited.
10. Studies of human body fluids, where the sample can be identified with a specific person, must have IRB review and approval, and informed consent.
11. A project involving a student researcher using their own body fluids (if not cultured)
 - a. can be considered a BSL-1 study
 - b. may be conducted in a home setting
 - c. must receive prior SRC review and approval prior to experimentation.
 - d. is exempt from IRB review as long as the student is not the subject of the research
12. Studies involving embryonic human stem cells must be conducted in a Registered Research Institution and reviewed and approved by the ESCRO (Embryonic Stem Cell Research Oversight) Committee.