

101 Lewis Hall Bozeman, MT 59717 Phone: (406) 994-6733

IBC approval Date: 12/10/2025

MSU Collection of Human Biological Specimens Policy

Scope

This policy applies to human subject research in which biological specimens are collected from study participants/donors.

Responsibility

Research staff collecting human specimens are required to follow this policy and other plans/policies as outlined.

References

MSU Bloodborne Pathogens Exposure Control Plan

MSU IBC Manual

MSU IRB Website

Definitions

Donor: An individual from whom a human biological specimen is derived, with their consent.

Human Biological Specimens (specimens): Wide range of human specimen types and the data associated with them. These specimens include, but are not limited to:

- Blood and other bodily fluids (including saliva)
- Cells or tissues from any part of the human body
- Molecules derived from tissues (DNA, RNA, proteins, etc.)
- Gametes (ova and sperm)
- Stem cells
- Bodily products such as teeth, hair, urine, feces

IRB: Institutional Review Board

IBC: Institutional Biosafety Committee

Universal Precautions: All human blood, tissue, and certain human body fluids are treated as if known to be infectious for HIV, HBV, HCV, and other bloodborne pathogens.

Training

All researchers collecting, handling, or transporting specimens must complete OSHA Bloodborne Pathogens training. Training may be completed via <u>CITI</u> online training or <u>in-person training</u> provided by the Biosafety Officer.

Policy

Prior to collection of human biological specimens, an approved IRB protocol is required. Please refer to the <u>IRB website</u> for more information on the protocol process.

If the researcher is only collecting, storing, or shipping specimens, an IBC protocol is not required. Any laboratory that handles or manipulates, (e.g., by pipette, centrifuge, vortex, pouring) or performs



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analysis (excluding lancet-type, test strip analysis where no manipulation occurs) on potentially infectious specimens requires an IBC protocol. Review the <u>IBC Manual</u> or contact the Biosafety Officer with any questions regarding IBC requirements.

Collection of Specimens

Researchers must observe Universal Precautions when collecting and handling specimens. See sections below for specific scenarios and requirements.

Collection of Specimens on MSU Campus

Researchers must wear protective clothing (e.g., lab coat, gown, scrubs), and disposable gloves when actively collecting specimens. Gloves will be worn when handling any specimen container.

Gloves and other potentially contaminated materials will be disposed of in biohazardous waste bags inside of a biohazard waste bin. Sharps (including lancets) will be disposed of in sharps containers.

Collection of Specimens Off-Campus

Specimens are often collected off-campus (e.g., in donor's house). In these scenarios, researchers must wear disposable gloves when collecting specimens and handling specimen containers. Additional PPE may be required based on consultation with the Biosafety Officer.

If collecting specimens that require the use of sharps (e.g., lancet to collect blood), researchers will use a portable sharps container to dispose of used sharps. When full, sharps containers are collected and disposed of by MSU Safety and Risk Management.

Specimens are transported in hard-sided, leak-proof, shatter-proof secondary containers that are sturdy enough to remain closed if dropped. Secondary containers are labeled with the biohazard symbol.

Receiving Specimens from Donors

Donors often collect specimens at their home and then bring the specimens to researchers on campus. Researchers will identify a location on campus where they will meet the donor. Researchers will bring labeled, hard-sided, leak-proof, shatter-proof secondary containers that are sturdy enough to remain closed if dropped to the meeting point. Donor's will place their specimen into the secondary container and researchers will transport the specimen to the storage location.

If the researcher must handle the specimen at the meeting point, gloves will be worn to place the specimen into the secondary container.

Transporting Samples on Campus

Researchers transporting samples between spaces on campus must follow the <u>MSU Transporting</u> <u>Biological Agents</u> policy.