

GUIDANCE FOR COLLECTION AND STORAGE OF HUMAN SAMPLES

Purpose

The purpose of this document is to inform researchers of considerations related to collection and storage of samples collected from human subjects.

Introduction

Human samples can be divided into two groups: 1) those that are subject to the United States Occupational Safety and Health Administration's (OSHA) Standard for Bloodborne Pathogens (29 CFR 1910.1030) and 2) those that are **not** subject to the Bloodborne Pathogens standard.

Human samples subject to the Bloodborne Pathogens Standard include the following:

- Human blood
- Semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids
- Any unfixed tissue or organ (other than intact skin) from a human (living or dead);
- HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

Human samples that are NOT subject to the Bloodborne Pathogens Standard

Any sample that is not described as being subject to the standard, for example:

- Saliva – must not be visibly contaminated with blood
- Urine – must not be visibly contaminated with blood
- Hair samples
- Nail clippings
- Sweat or tears
- Breast Milk

If your sample is not listed above, please contact EHS for assistance in determining the exposure risk.

Compliance

Depending on the details of the proposed work, initiation of the work may be contingent upon review and approval by the UNL Institutional Biosafety Committee (IBC), Institutional Review Board (IRB), or both committees.

Institutional Biosafety Committee (IBC)

All clinical/diagnostic, research, and teaching activities involving human samples that are subject to the Bloodborne Pathogens Standard require submission of a protocol to and approval by the IBC. Information on submitting a protocol for review and approval by the IBC is provided in the UNL Biosafety Guidelines, available on the UNL Environmental Health and Safety (EHS) website (ehs.unl.edu).

Institutional Review Board (IRB)

The prospective collection of ALL biological specimens for research purposes by invasive and noninvasive means from human subjects requires submission of a protocol and approval of the UNL Institutional Review Board (IRB). If there are any questions regarding IRB Approval, please consult your IRB Coordinator. Contact information can be found via NUgrant or at the Office of Research website. Information to be described in the IRB application (via new project form or change request) is as follows:

- Type of biological sample
- Sample analysis procedures (including genetic analysis)
- Sample identification/Coding practices for confidentiality
- Where the sample will be stored
- Who will have access to the sample
- Length of storage of the sample
- Plans for the destruction of the sample, if any

Please refer to the following UNL Human Research Protections policies regarding requirements for submission to the IRB when obtaining or using biological specimens:

- #3.001 "Investigational Activities Requiring IRB Review and Approval;"
- #3.003 "Initial Application Submission;"
- #3.004 "Criteria for IRB Approval of Research;" and,
- #4.002 "Expedited Research" (this policy will specifically discuss the amount of blood allowed to be collected in specific populations eligible for Expedited review)

Collection of Samples

Sample collection kits often provide detailed instructions on the actual process of sample collection and should be followed at all times. Regardless of whether the sample is subject to the Bloodborne Pathogens Standard, "**Universal Precautions**"

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should be observed during collection and handling of the sample. In simple terms, this means using precautions during sample collection and handling that would be observed if the sample was known to contain a bloodborne pathogen. In the case of human samples subject to the Bloodborne Pathogens standard, precautions must be described in the protocol submitted to the IBC, and be consistent with the precautions described in the required Bloodborne Pathogens Standard training administered by EHS.

Following are typical Universal Precautions appropriate for any type of human sample:

- Use appropriate personal protection equipment (PPE) during collection and handling. This typically includes impervious gloves (such as surgical type gloves), eye protection, and outer garment (such as a lab coat).
- To the extent feasible, avoid the use of sharps when manipulating human samples. If sharps are unavoidable, use a labeled, rigid plastic container with closure to contain and dispose used sharps.
- Exercise good hygiene and wash hands after handling human derived samples.
- Label storage locations (described later in this document)
- Promptly clean-up spills.
- Regularly clean/disinfect work surfaces.
- Do not eat, drink, apply cosmetics, store food/drink for human consumption, or engage in similar activities in areas where human samples are collected, manipulated, or stored.

Storage of samples

Human samples must be stored in a safe and secure location, and in a manner that is consistent with the IBC and/or IRB approved protocol, as applicable. It is recommended to follow the storage instructions in the collection kit to ensure viability of the samples. If the samples will be transferred to another facility on or off campus for testing/analysis (e.g. UNL Salivary Bioscience Laboratory), the samples should be stored according to the submission requirements of that laboratory. However, minimum safe storage recommendations at UNL are listed below:

- Refrigerators and freezers should preferably be located in laboratory space, not office space.
- Floor coverings in storage locations should be hard surfaces that can be easily cleaned and disinfected.
- Signage is recommended.
 - For samples subject to the Bloodborne Pathogens Standard, EHS will assist with proper signage of the laboratory. In addition, storage locations must be placarded with the Universal Biohazard symbol.



- For samples not subject to the Bloodborne Pathogens Standard, the template in Appendix A of this document is recommended. The Universal Biohazard symbol should NOT be used for samples that are not subject to the Bloodborne Pathogens Standard.
- ❑ Generally, storage locations should be locked and have limited access to prevent unauthorized access to the samples. For samples subject to IRB approval, security precautions should be consistent with those required for sensitive human subject data.

Shipping of samples

Shipping of human samples off campus is subject to Department of Transportation (DOT) and/or International Air Transport Association (IATA) regulations. These regulations pertain to packaging and labeling requirements of dangerous goods packages sent through a commercial carrier. Training is required for persons that pack and ship dangerous goods such as human samples. For more information about this training contact EHS.

Definitions

Biohazard: a substance or material that contains an agent (e.g. microbe, virus, bacteria, etc.) that is capable of causing disease in humans.

Bloodborne Pathogens: means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV)

Contaminated: means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface or in a sample.

Universal Precautions: is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.

CAUTION: BIOLOGICAL SAMPLES

The samples stored in this refrigerator/freezer are not considered a biohazard. However, they should still be treated as if they are a biohazard. Do **NOT** access this piece of equipment or handle the samples contained within unless you are authorized to do so.

If a power failure occurs or there is a problem with this equipment, please contact the sample owner listed below.

Sample Owner	Department	Contact number

Alternate Contact	Department	Contact number