

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 (including human blood components and products made from 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);
- Primary and established human-derived cells, cell explants and cell lines that have not been tested and confirmed to be free of bloodborne pathogens (HIV, HBV, HCV, HTLV, EBV, HPV, or CMV);
- 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, initiation of the work may be contingent upon protocol review and approval by the UNL Institutional Biosafety Committee (IBC), Institutional Review Board (IRB), and/or Scientific Research Oversight Committee (SROC).

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 UNL [IRB Policies and Procedures](#) regarding requirements for submission to the IRB when obtaining or using biological specimens.

Scientific Research Oversight Committee (SROC)

The University of Nebraska-Lincoln's Scientific Research Oversight Committee (SROC) is responsible for the review and approval of research involving human embryonic stem cells (hESCs) and human fetal tissue (hFT). Contact the UNL Office of Research Compliance for additional information.

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 sample type or source, "**Universal Precautions**" should be observed during collection and handling of the sample. Simply, treat all human **blood** and body fluids as if they were known to be infectious bloodborne or other human pathogens. In the case of human samples subject to the Bloodborne Pathogens standard, precautions must be described in the submitted IBC protocol, and be consistent with the precautions described in the required Bloodborne Pathogens Standard training, as administered by EHS. Following are typical Universal Precautions appropriate for any type of human sample:

- In addition to standard lab attire, use appropriate personal protection equipment (PPE) during collection and handling. This typically includes impervious gloves (such as surgical gloves), eye and/or face protection, and outer garment (such as a lab coat).
 - When collecting samples of saliva and other samples from the mouth or nose, consider the use of face protection (e.g., face shield with a fluid-resistant mask) to protect researchers from a cough or sneeze response from the subject. Alternatively, instruct the subject to self-collect the sample.
- To the extent feasible, avoid 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 decontaminate and clean-up spills using approved EPA disinfectants.
- Clean/disinfect work surfaces after each work session and between research subjects.
- 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 in an 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 or room. In addition, storage locations must be placarded with the Universal Biohazard Symbol containing the word “Biohazard.”



- 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. For samples subject to IRB approval, additional security precautions may be required for sensitive human subject data.

Shipping and transportation of samples

Shipping certain human samples off campus, using a commercial vendor, is subject to Department of Transportation (DOT) and/or International Air Transport Association (IATA) regulations. Specific training is required for persons who pack and ship dangerous goods, including regulated human samples. Contact EHS for more information.

Transportation of samples using either UNL or personal vehicles (e.g., to UNMC) should follow the guidelines in the EHS SOP, ***Transport of Biohazardous Materials at UNL (Including Research and Clinical Specimens/Materials)***.



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 human blood or other potentially infectious materials on an item, 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.



Appendix A

CAUTION: HUMAN BIOLOGICAL SAMPLES

The samples stored in this refrigerator/freezer are not considered a bloodborne pathogen hazard. However, they should still be treated as if they are a biohazard. Do **NOT** access this equipment or handle the samples contained within unless you are authorized and trained 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