



I. SCOPE

This SOP applies to Loyola University Chicago (LUC) research personnel obtaining biological specimens, including but not limited to blood, urine, saliva, cerebral spinal fluid, and tissue, from Loyola University Medical Center (LUMC) facilities in support of a research project.

This SOP is intended to align with LUMC policies and procedures for the handling and transport of biological specimens. LUMC employees should follow LUMC policies and procedures.

II. Definitions

- A. Exposure incident: a mucous membrane (e.g. eye or mouth), non-intact skin, or parenteral contact with potentially infectious material that results from the performance of an employee's duties.
- B. Parenteral: Puncture of mucous membranes or the skin barrier through such events as needle sticks, human bites, cuts, and abrasions.
- C. Personal Protective Equipment (PPE): Specialized clothing or equipment worn by an employee for protection against a hazard. These include gloves, laboratory coats, cover gowns (fluid-resistant, fluid-proof), aprons, protective eyewear, masks, face shields, shoe covers. General work clothes (e.g., uniforms, pants, or blouses) are not intended to function as protection against a hazard and are not considered personal protective equipment.
- D. Potentially Infectious Materials:
 - 1. All blood/blood products, and other potentially infectious materials (OPIM) including semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, amniotic fluid and saliva.
 - 2. Any unfixated tissue or organ (other than intact skin) from a human being (living or dead).
 - 3. HIV-containing cell or tissue cultures and other infectious cultures, organ cultures, and blood, organs, or other tissues from experimental animals infected with the human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV) or other infectious agents.

III. PROCEDURES

1. SPECIMEN COLLECTION AND TRANSPORT

a. *Coordinating*

- (1) The Principal Investigator or designee ("Study Team") is responsible for coordinating specimen retrieval with the clinical area before study initiation.
- (2) The Study Team is to provide the supplies necessary for the collection of the specimen unless otherwise directed by the clinical area.

b. *Retrieving Specimen*

- (1) When the specimen is to be retrieved, the Study Team presents to the clinical area or pre-determined location with the required supplies for transporting the specimen.
 - (a) If the Study Team may touch potentially infectious materials, handle items or surfaces soiled with potentially infectious materials, or handle primary specimen containers, the appropriate PPE (disposable nitrile gloves and a laboratory coat) must be worn. The gloves are removed prior to entering a clean or noncontaminated area.
- (2) All specimens must be placed into a primary leak-proof container.
 - (a) Primary containers include blood tubes, urine cups, formalin containers, blood culture bottles or any other suitable labelled and sealed container which safely contains the specimen for testing.



- (b) If the specimen is to be de-identified, the Study Team should bring labels or accompanying paperwork (e.g. requisition form) that includes:
 - i. The word RESEARCH
 - ii. The LU number or Study Name
 - iii. date of collection
 - iv. Participant/specimen identifier (Smart-ID, tissue type, etc.), as applicable
- (3) A secondary container must be used for transport to contain the specimen if the primary container breaks or leaks in transit to the laboratory.
 - (a) Secondary containers include biohazard specimen bags, red hospital designated biohazard bags or other suitable leak-proof container which has a biohazard label on it.
 - (b) An additional transport container is recommended, i.e. a transport bag or cooler (or other insulated container filled with ice/ice packs if the specimens are to be kept at 4 degrees).
 - (c) The tertiary container for tissues should be a black bag so the contents are not visible during transport.
 - (d) Once the specimen has been sealed in the secondary or tertiary container it may be handled without gloves.
- c. **Transporting Specimen**
 - (1) The Study Team is to transport all specimens directly to the CTRE or other approved location for processing.
 - (a) Gloves should not be worn in public spaces such as the hospital hallway
 - (b) Gloves should not be used on any door handles or other clean area surfaces
 - (c) Specimens with any identifying labels/paperwork should not be readily visible
 - (2) If transporting between campuses:
 - (a) Study Teams are encouraged to coordinate with the off site clinic or department to utilize the LUMC courier service.
 - (b) If the specimen will be transported by the Study Team:
 - i. A hard walled- tertiary container should be used.
 - ii. Ensure protocol requirements for specimen temperature conditions and time to processing are met.
- d. **Specimen Handling in CTRE or other LUC property**
 - (1) Once delivered, specimens with personally identifiable information should not be left unattended.
 - (2) Personal identifiers should be removed as soon as possible and replaced with de-identified study IDs
 - (3) Specimens should be kept and stored in the Study Team's designated (i.e. appropriate biohazard signage) and secure laboratory space.

2. SPILL CLEAN-UP

a. **First response**

- (1) Attention to any injured party is the first priority. The severity of the injury will determine what course to take with respect to medical attention versus clean-up.
- (2) Restrict access to the area to minimize further contamination. [Confirm LUMC requirements]

b. **Clean up**



- (1) Individuals involved should first remove any contaminated clothing and either dispose of it in the biohazard trash or seal it in a plastic bag.
- (2) Any potentially exposed skin should be washed thoroughly with soap and water (see exposure below)
- (3) Those involved in the clean-up should wear gloves and gowns/lab coats. If splattering is likely, face protection must be worn.
- (4) Remove any visible blood/body fluids from the surface. Successful disinfection requires that any visible blood/body fluids be removed prior to disinfection.
 - (a) Clean-up should be done by containing/covering the spill with absorbent pads/paper towels (or sprinkling an absorbent agent such as Red-Z), and then adding 25% bleach beginning at the edges of the spill.
 - If possible, ideal to let bleach sit on spill 20 minutes to decontaminate fully before disposing
 - (b) Wipe up the soaked pads (or congealed matter) using additional absorbent paper and dispose of in a red biohazard bag.
 - (c) Allow the area to dry.
- (5) Disinfect the area.
 - (a) If the spill occurred in LUMC, disinfect with PDI Sani-Cloths, Clorox Healthcare Bleach Germicidal Cleaner (formerly known as Dispatch) or a 1:10 bleach solution. Each disinfectant has specific instructions for use which must be followed. Instructions for use are printed on the container.
 - (b) If the spill occurred in LUC, disinfect a second time with 10% bleach followed by water and 75% ethanol.

c. **Reporting**

Any large spills of potentially infectious material represents a potential exposure risk and must be reported.

- (1) If the spill occurred in the hospital or clinic, inform the Engineering Department (ext. 6-5555).
- (2) If the spill occurred in LUC laboratory or building, inform Matt Hejna (ext. 6-6738).

3. **POTENTIAL EXPOSURE INCIDENT**

In the event of a serious medical emergency, assist those exposed. This may involve directly helping them or containing a spill while they decontaminate themselves.

a. **Remove contaminated garments**

- (1) If a garment is contaminated by potentially infectious materials, the garment must be removed immediately or as soon as feasible.
- (2) If disposable, the garment shall be disposed of in an appropriate biohazard waste container.
- (3) If the garment is reusable, it must be treated with an appropriate disinfectant as soon as feasible and laundered.

b. **Wash exposed areas**

- (1) Wash hands immediately following removal of gloves
- (2) Wash all other potentially exposed areas
 - (a) For exposed skin, wash with soap and water
 - i. Be careful not to injure or abrade intact skin
 - ii. Wash any cuts/broken skin thoroughly and follow-up with an antiseptic
 - (b) For any potentially exposed mucous membranes flush with water.
 - i. If the eye is exposed, utilize the an eyewash (or sink if eye wash is not readily available) to flush the eye with water for at least 15 minutes.



- c. Contact the Needlestick/Sharps/Splash Exposure pager 11709. This will allow a rapid test of contaminating (source) patient to be initiated and ensure testing is obtained prior to source patient leaving. Source orders are placed in EPIC.
 - (1) Post-exposure prophylaxis will be started as soon as possible for employees exposed to HIV-positive sources.
- d. After the exposed area is washed, report immediately to the Employee and Student Health Service (ESHS) located at Loyola Outpatient Center, 3rd Floor; 888-584-7888 or 4-7888 from an internal phone).
 - (1) If ESHS is closed, report to the LUMC Emergency Room, and follow-up with ESHS the next day.
 - (2) ESHS will evaluate postexposure prophylaxis, vaccination, laboratory tests and subsequent follow-up. Since some prophylaxis is most effective if given immediately after exposure, it is critical that the evaluation occurs immediately.
- e. Report the incident
 - (1) Notify supervisor immediately
 - (2) Complete an LUC incident report form (Appendix A) and submit to Matt Hejna (mhejna@luc.edu)

IV. REFERENCES

- 1) National Institutes of Health and Centers for Disease Control guidelines (*Biosafety in Microbiological and Biomedical Laboratories*, 5th Edition).
- 2) LUMC Patient Care Policy IC-008 INFECTION CONTROL- Bloodborne Pathogens Exposure Control Plan

V. ASSOCIATED DOCUMENTS AND FORMS

- A. LUC incident report form

VI. APPROVALS


 _____ Date 8/29/18
 LUMC Director, Research Operations Office (or designee)
 EVP, Clinical Affairs


 _____ Date 8-27-18
 LUC Senior Director, Clinical Research Office (or designee)