Registration for Procurement of Human Specimens

POLICIES AND PROCEDURES

The University Biosafety Committee (UBSC) reviews registrations for procurement and analysis of human specimens, cells or tissue cultures, including commercially derived cells or cultures (e.g. the American Type Culture Collection, ATCC). Per the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030), this includes:

- (1) The following human body fluids: 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;
- (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and
- (3) 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.

Due to the possibility that the material can harbor HIV, HBV, HCV or other bloodborne pathogens and the seriousness of these diseases, Biosafety Level 2 (BSL-2) practices are required. Specimens that are known to harbor HIV, HBV, HCV or influenza viruses (H1N1, H5N1) require UBSC review and approval prior to commencing any research activities. Specimens known to harbor the influenza viruses H1N1 or H5N1 require Biosafety Level 3 (BSL-3) practices.

The Principal Investigator is ultimately responsible for the safe use of human tissue specimens and assuring that all training and registrations are complete. Registration for procurement and use of human specimens should occur in conjunction with the IRB application to collect human specimens. The Department of Environmental Health and Safety provides the required General Laboratory and Bloodborne Pathogen training. This training must be completed before the registration is submitted and annually thereafter.

For Risk Level 1 and 2 specimens, the registration will receive an expedited review. For these specimens, complete the Human Specimens Registration Form, which can be found on the Human Tissue & Specimen Procurement page.

For specimens at a Risk Level of 3 or 4, submit the General Biohazard Form, which can be found on the <u>Biosafety Guidelines and Forms webpage</u>. The registration will be reviewed at a meeting of the UBSC. The UBSC meets monthly, normally on the last Tuesday of every month. A calendar of submission deadlines and meeting dates is available on the <u>Biosafety Calendar</u> webpage.