CU Guidance Document on Working with Human Material and Other Potentially Infectious Material

This document has been prepared to assist those working with human bodily fluids, blood and blood components, human tissue, cells lines and other potentially infectious material.

Clemson University requires that research involving human blood/body fluids and tissues be reviewed by the IBC prior to the initiation of the work. Laboratory practices should be followed on the assumption that all human blood, body fluid and tissues are infectious. As such, Universal Precautions should be followed.

According to the CDC and NIH, Bloodborne pathogens refer to pathogenic microorganisms that are present in human blood etc. and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV), hepatitis C virus (HCV) [OSHA clarified that HCV was included in 2001], and human immunodeficiency virus (HIV). Additionally, “Other Potentially Infectious Materials” (OPIM) are including under this standard.

OPIM means

1) the following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, amniotic fluid, pericardial 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.

Universal precautions apply to blood, other body fluids containing visible blood, semen, and vaginal secretions. Universal precautions also apply to tissues and to the following fluids: cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids. Universal precautions do not apply to feces, nasal secretions, sputum, sweat, tears, urine, and vomitus unless they contain visible blood. Universal precautions do not apply to saliva except when visibly contaminated with blood or in the dental setting where blood contamination of saliva is predictable.

Clemson University has a policy which outlines that all handling of human bodily fluids, cells, organ cultures, including well established cell lines, shall be handled in accordance with the OSHA Bloodborne Pathogens Standard and under Biosafety Level 2 (BSL-2) containment. The Clemson University policy can be accessed at:

http://www.clemson.edu/research/orcSite/orcIBC_Reg_CellLines.htm
Even cell lines obtained from a vendor, commercial source, or other institution should be handled under BSL-2 containment. Sometimes such sources as ATCC may have the containment level listed in their product description as BSL-1. However, it must be handled under BSL-2 containment. ATCC has indicated that “it is not feasible to test every cell line for the presence of every possible adventitious agent. It is strongly recommended that human and other primate cell lines be handled at the same biosafety level as a cell line known to carry HIV or hepatitis virus.”

Fixed tissues and tissue sections from human and animal sources that are fixed by treatment with chemical agents should be handled under containment level 1 conditions. This would also exempt participants from the need to enroll in the Medical Surveillance Program. Generally, these chemical treatments inhibit all biological activity. A notable exception is the group of unconventional agents known as ‘prions’. A higher level of containment may be required depending on the source of the material, the nature of the agent, and whether or not it is inactivated.

Exceptions to this “fixed in formalin” rule would be human brain, spinal cord, spleen, thymus, lymph node, lymg, retinal or tonsillar tissue fixed in formalin. Work with these would still require OSHA BBP Standard compliance, BSL2 precautions, and enrollment in the Medical Surveillance Program because these are not responsive to sterilization by formalin.

Here are some tips on preparing your IBC application for research in this area:

- Taken online training initially and annually for the life-span of the protocol at: http://ehs.clemson.edu/training/BBP/index.htm

- Make reference in the IBC application that adherence will be to the OSHA Bloodborne Pathogens Standard

- Enroll in the Medical Surveillance Program and send the information to Sue Pedrick at spedric@clemson.edu or 865-656-5529.

- Have written proof of Hep B series immunizations. Employees can sign an OSHA decline form in lieu of either taking or providing documentation of Hep B series.

- Biosafety Cabinets must be inspected annually or when moved. Contact Environmental Health and Safety on campus at 864-656-1806.

- Local transport of Bloodborne Pathogens specimens. You may transport samples from one building on campus to another or within the local community without having to have had HM 181 training. They must be properly packaged (leak-proof container with a leak proof lid packaged with an absorbent materials (and ice if needed). This means double-bagged with a biohazard label attached. If samples are sent by other courier, e.g. UPS, FedEx, then HM 181 training needs to be completed by those who prepare the shipment and handle the material. EHS
on campus presents HM 181 training and also has a CD for training. Sometimes, there are individuals in one’s department that has already had the training and can be contacted.

☐ Be familiar with the sections of the BMBL 5th edition that relate to working with blood, human cells and tissues and BSL-2 containment and provide specific information as requested on the IBC application.
http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm

☐ For disinfection, make sure that the agent is effective against HIV-1, Hepatitis B and/or Hepatitis C virus. Registered effective agents with EPA can be found at:
http://www.epa.gov/oppad001/chemregindex.htm
Make sure that there is strict adherence to the instructions on the label regarding cleaning of the area and contact time with the surface to be disinfected.

☐ If Non-CU Personnel will be working on the IBC project, they should complete the following Assumption of Liability form.
http://www.clemson.edu/research/orcSite/orcIBC_Forms.htm