

Established Human Cell Cultures
&
Compliance with the OSHA Bloodborne Pathogen Standard

The University of Pennsylvania Exposure Control Plan (ECP) is required by the **OSHA Bloodborne Pathogen Standard**¹ for workplaces with occupational exposure to human tissues that may harbor bloodborne pathogens or other potentially infectious materials (OPIM). The ECP must be site-specific, updated as needed and must be reviewed annually by all faculty, staff & students at your site.

Human materials subject to the Standard include:

- Blood, blood components, and products made from human blood.
- 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.
- 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, HBV, or HCV.
- All unfixed tissue, organs, and cells.

Pursuant to OSHA interpretations of the Standard vis-à-vis established human cell lines, the Office of Environmental Health and Radiation Safety (EHRS) adopted the following policy in 2017:

All primary human cells, cell explants, and *in vitro* passages of human tissue explant cultures must be regarded as containing bloodborne pathogens and are subject to the OSHA BBP Standard requiring a laboratory-specific ECP. Human cell lines² are subject to the BBP Standard, unless they are documented to be free of contamination with bloodborne pathogens.³ Human cell lines obtained from commercial vendors or other sources that are documented as free of bloodborne pathogens⁴ and protected by the employer from contamination may be excluded from the Bloodborne Pathogen Standard. *“The final judgement for making the determination that human or other animal cell lines in culture are free of bloodborne pathogens must be made by a Bio-safety Professional or other qualified scientist with the background and experience to review such potential contamination and risk, in accordance with the requirements of the BBP Standard.”*⁵

When documentation is not available or is deemed incomplete, all human cell lines are subject to the Bloodborne Pathogen Standard and completion of an ECP is required. If you cannot provide recent test results that your cultures are free of BBP and/or an inventory-supported chain of custody documenting protection from contamination, your certification is considered incomplete.

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- 1: The Occupational Safety and Health Administration's (OSHA) standard **29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens."**
 - 2: Human cell lines are defined as *in vitro* or animal passaged (i.e., nude mouse) cultures that fulfill traditional requirements of a cell line designation. This includes immortalized cells, cultures transformed by spontaneous mutation, cultures transformed by natural or laboratory infection with an immortalizing agent.
 - 3: Characterization of human cell lines for exclusion from the Exposure Control Plan requirement must be documented and provided to EHRS. Documentation must include screening for viruses characterized as bloodborne pathogens (HIV, HBV, HCV, EBV). Acceptable testing may include antigenic screening for viral markers, co-cultivation with indicator cells that allow contaminants to grow, or molecular techniques such as PCR or nucleic acid hybridization.
 - 4: If you believe that you have adequate documentation of testing, please submit you test results and request for exemption from the BBP Standard to biohazreg@upenn.edu.
 - 5: OSHA Interpretation Letter regarding established human cell lines.