

Appendix D - Use of Human, non-human Primate, and other Mammalian Cells and Tissues

Background: In 1991, the Occupational Safety and Health Administration (OSHA) issued the Bloodborne

Pathogens (BBP) Standard to protect employees who have occupational exposure to human blood or

other potentially infectious materials. While human blood, most body fluids, unfixed human tissues and

organs were clearly included within the scope and application of the standard, the inclusion of human

cell lines was ambiguous.

In 1994, OSHA issued an interpretation of the applicability of the BBP Standard towards human cell lines.

According to the interpretation, human cell lines are considered to be potentially infectious and within

the scope of the BBP Standard unless the specific cell line has been characterized to be free of hepatitis

viruses, HIV, Epstein-Barr virus, papilloma viruses and other recognized bloodborne pathogens. In alignment with this interpretation, the American Type Culture Collections (ATCC) recommends that all

human cell lines be accorded the same level of biosafety consideration as a line known to carry HIV.

ATCC also states "However, in general, we do not test for animal viruses, therefore not all of our cell

lines have been tested for animal viruses and should be treated accordingly".

ATCC assigns biosafety level (BSL) designations for the purposes of safe shipment, according to whether

or not at the time of accessioning it is known that the cell lines is harboring any known virus or any portion of a virus which causes human disease. "While ATTC does provide the biosafety level for each

ATCC culture, we do not provide information on biosafety practices. Each researcher should determine

the appropriate BSL using a risk assessment based on the characteristics of the cell line and how the cell

line will be used." This includes, but is not limited to, laboratory manipulations employed during its handling.

Human, primate or mammalian cell lines, even in the absence of overt contamination, may contain adventitious viruses and/or other opportunistic pathogens or zoonotic agents. Since it is extremely

difficult to screen for every pathogen, all human, primate and mammalian cell lines must be handled with standard precautions i.e. treated as though they are contaminated with infectious agents and should utilize BSL2 practices.

In addition to viral and bacterial threats, the European Union – European Medicines Agency document “Viral Safety Evaluation of Biotechnical Products Derived from Cells lines of Human or Animal Origins” also indicates the potential for the introduction of bovine spongiform encephalopathy prions (BSE) contamination into established cell lines via use of contaminated animal-derived products (including animal serum products) and/or through the use of improper work methods. “However, in contrast to most of the infectious agents, prions are particularly difficult to inactivate. In fact, no method can guarantee total inactivation of these agents. So, one should bear these considerations in mind when using growth media of bovine origin”.

In consideration of the aforementioned regulatory interpretations, consensus guidelines, best practices, and other factors, the EHS has adopted the following guidance: All cell and organ cultures of human origin, including well established cell lines, human bodily fluids, non-human primate and mammalian cells and tissues should be handled in accordance with the OSHA Bloodborne Pathogens Standard and under Biosafety Level 2 (BSL2) containment.

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