### **IBC-43: UNMC IBC Policy on Use of Human and Nonhuman Primate Tissues, Cells, and Cell Lines**

**Introduction**

Human and nonhuman primate (NHP) cells, cell lines, and tissues are commonly used in biomedical research, yet appropriate biosafety requirements for handling these materials are often subject to debate within the scientific community. To clarify the University’s position on this matter, the UNMC Institutional Biosafety Committee (IBC) has created the following policy.

#### **Background**

In 1991, the Occupational Safety and Health Administration (OSHA) released the Bloodborne Pathogens (BBP) standard ([29 CFR 1910.1030](https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS)). The intention of the standard is to protect employees who may 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 a [letter of interpretation](https://www.osha.gov/laws-regs/standardinterpretations/1994-06-21) as to 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 Collection (ATCC) [recommends](https://www.atcc.org/support/faqs/26699/Biosafety%20level%20for%20ATCC%20cultures-9.aspx) handling all cell cultures under Biosafety Level 2 (BSL 2) conditions since cell lines cannot be tested for all viruses. Moreover, the CDC publication, Biosafety in Microbiological and Biomedical Laboratories, 5th Edition ([BMBL](http://www.cdc.gov/biosafety/publications/bmbl5/)), recommends that human and other primate cells should be handled using BSL-2 practices and containment.

**Policy**

In consideration of the aforementioned regulatory interpretation, consensus guidelines, and other factors, the UNMC IBC has adopted the following policy:

**All human and NHP derived materials (including tissues, cells, and cell lines) must be handled in accordance with the OSHA Bloodborne Pathogens Standard and under BSL-2 containment. Animal Biosafety Level 2 (ABSL-2) containment and practices may be required when these materials are used in animal experiments.**

Certain well-established human cell lines may be eligible for an exemption from this policy and therefore may be downgraded to BSL-1 containment and practices for cell culture experiments and ABSL-1 containment and practices when used in animals if the following criteria are met:

* Bloodborne pathogen screening documentation is submitted to the IBC.
* There is an extremely low possibility of the cells being exposed to other pathogens/biological materials that could result in contamination of the cell line (i.e., there may not be any other BSL2 or higher materials or cells handled in the same facility).

All requests for an exemption to this policy must be reviewed and approved by the IBC prior to downgrading work with human cell lines to BSL-1. Research involving NHP-derived materials and human-derived primary cells and tissue requires an IBC protocol. Experiments involving established human cell lines may require an IBC protocol-please contact the IBC administrator or UNMC Biosafety (biosafety@unmc.edu) for additional information.

*Adopted and approved by the UNMC Institutional Biosafety Committee (IBC) on July 12, 2019.*

**References**

1. [OSHA Bloodborne Pathogens standard (29 CFR 1910.1030)](https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS)
2. [OSHA Letter of Interpretation](http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=21519)
3. [ATCC (American Type Culture Collection) Frequently Asked Questions](https://www.atcc.org/support/faqs/26699/Biosafety%20level%20for%20ATCC%20cultures-9.aspx)
4. [BMBL (Biosafety in Microbiological and Biomedical Laboratories), 5th Edition](http://www.cdc.gov/biosafety/publications/bmbl5/)

**Questions?** Please contact **UNMC IBC** at402-559-6463 **or UNMC Biosafety** at biosafety@unmc.edu or unmcehs@unmc.edu

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