

<b>IBC Policy Number:</b> 2	<b>Version Number:</b> 1.0
<b>Effective Date:</b> January 19, 2018	
<b>Title:</b>	<b>Biosafety Containment for Animals Exposed to Human-Derived Materials</b>

### Purpose

This policy establishes the Institutional Biosafety Committee (IBC), acting upon recommendations made by the Biosafety Officer (BSO), as the Committee responsible for assigning biocontainment levels for research involving the deliberate administration of human-derived materials to animals.

### Regulatory Background

Human tissues and cells have the potential to harbor infectious agents. Testing may not identify all pathogens of concern.

Research with materials of human origin, including primary human tissue and human cell lines, must be conducted in accordance with the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Standard (29 CFR Part 1090.1030) and the CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*, 5<sup>th</sup> ed.

The OSHA Bloodborne Pathogen Standard mandates the use of Universal Precautions, not reliance on testing results, to protect workers from potential exposure to bloodborne pathogens. The Standard defines Universal Precautions as: "All human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, HCV and other bloodborne pathogens", and also outlines the required training and work practices that minimize the risk of exposures.

If human cell lines are tested and documented to be free of known bloodborne pathogens (BBP), the research may be exempt from the requirements of the Bloodborne Pathogen Standard, including participation in annual training, however the cell lines and animals involved in the research must be handled in accordance with this Policy and IBC recommendations. The exemption from requirements of the OSHA Bloodborne Pathogen Standard only applies to human cell lines that have been tested for and shown to be free of known BBP.

### Scope

This Policy applies to all personnel, including Principal Investigators (PIs), laboratory personnel, Laboratory Animal Resources (LAR) staff, and other animal users at Princeton University and Princeton University satellite facilities, who perform research on a Princeton University Institutional Animal Care and Use Committee (IACUC)-approved animal use protocol and an IBC registration.

### Responsibilities

Principal Investigator (PI) is responsible for:

- Obtaining IACUC and IBC approval for animal research involving materials of human origin.

- Ensuring that all staff and students, including the PI, who handle human cell lines or human tissues associated with the approved registration, participate in the University's Bloodborne Pathogen Program and Animal Worker Medical Surveillance Program.
- Providing BBP screening results if requested by the IBC or IACUC.
- Notifying LAR prior to implantation or injection of human cell lines/tissues into research animals.
- Following procedures and practices in IACUC Policy 202, Administration of Biohazards to Research Animals for all research approved by the IBC at Animal Biosafety Level (ABSL) 1 and 2.
- Complying with IACUC requirements for rodent pathogen screening of all human cells that have been previously passed through rodents.

Environmental Health and Safety/Biosafety Officer (BSO) is responsible for:

- Oversight of the University's Bloodborne Pathogen Program, including provision of initial and annual training to all persons who conduct research with human-derived materials.
- Performance of laboratory surveys to evaluate effectiveness of containment
- Assessment of risks and assignment of biocontainment levels

The IACUC is responsible for:

- Approving research with human cell lines or human tissues injected or implanted into laboratory animals.

The IBC is responsible for:

- Approving research with human cell lines or human tissues injected or implanted into laboratory animals
- Establishing biocontainment levels and special handling requirements based upon the risk assessment conducted by the BSO.

Laboratory Animal Resources (LAR) provides:

- Signs and labels for use by researchers to indicate that animals have been exposed to human-derived materials
- Personal protective equipment
- Husbandry services in accordance with this policy.

University Health Services is responsible for administering the:

- Animal worker medical surveillance program.
- Hepatitis B immunization program for employees, students and faculty included within the scope of the University's bloodborne pathogen program

### **Definitions/Terms**

Bloodborne Pathogens, as defined by the OSHA Bloodborne Pathogen Standards, refers to "pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV)."

## Policy

All research protocols involving the deliberate introduction of materials of human origin into animals must be reviewed by the BSO and the IBC. A biocontainment level will be assigned based upon the outcome of a risk assessment. A complete description of the animal biocontainment level requirements can be found on the [Environmental Health and Safety website and the IACUC Policy: Research with Biohazards in Princeton University Animal Facilities.](#)

Preparation and administration of primary human cells or tissues into animals and necropsy of unfixed animals will be conducted at ABSL 2. Research animals injected or engrafted with primary human cells or tissues must be housed at ABSL 2, unless the BSO and the IBC determine, through a risk assessment, that the containment can be lowered. Factors involved in the assessment include, but are not limited to:

- Availability of screening results showing that the specific sample to be used in animals is free of known bloodborne pathogens.
- Animal's immune status
- Presence of other infectious agents in the animal.

Biosafety containment levels for research animals exposed to human cell lines will be recommended by the BSO and the IBC. Preparation and administration of cell lines and necropsy of unfixed animals must be conducted using A/BSL 2 containment. Animal housing containment may be lowered to ABSL 1, depending upon:

- Availability of screening showing that the cell line to be used in animals is free of known BBP. Note: The LAR Attending Veterinarian and the BSO will provide recommendations for the frequency of human cell line testing on a case by case basis.
- Animal's immune status
- Presence of other infectious agents in the animal
- Nature of the cell line
- Nature of the transgene(s), if present

## References

IACUC Policy 202 Work with Biohazards in Princeton University Animal Facilities  
<https://www.princeton.edu/ria/animal-research-protectio/documents/IACUC-Policy-202-Work-with-Biohazards-in-Princeton-University-Laboratory-Animal-Research-Facilities.pdf>

Princeton University Bloodborne Pathogen Exposure Control Plan  
([https://ehs.princeton.edu/sites/ehs/files/media\\_files/Bloodborne%20Pathogen%20ECP%20Rev%2002-15.pdf](https://ehs.princeton.edu/sites/ehs/files/media_files/Bloodborne%20Pathogen%20ECP%20Rev%2002-15.pdf))

Princeton University Biosafety Manual (<https://ehs.princeton.edu/laboratory-research/biological-safety/biosafety-manual>)

LAR Standard Operating Procedures [2.42 Transportation of Animals](#)

IACUC Guideline 310 Induction and Monitoring of Tumors in Rodents  
<https://www.princeton.edu/ria/animal-research-protectio/documents/IACUC-Guideline-310->

[Induction-and-Monitoring-of-Tumors-in-Rodents.pdf](#)

**Version History**

<b>Version Number</b>	<b>Revision Date</b>	<b>Revisions</b>
1.0	January 19, 2018	Initiation