

 BROWN	Institutional Animal Care and Use Committee (IACUC): Biologics Testing Policy	POL 10.10.31
		Effective Date: Pending Approval

1.0 Policy Purpose

The purpose of this policy is to set forth the requirements for pathogen screening of biologic materials (*e.g.*, tumors, tissue, serum, cell lines) that may be introduced into experimental animals.

2.0 To Whom the Policy Applies

This policy applies to all research on live vertebrate animals using biological materials (*e.g.*, tumors, tissue, serum, cell lines) under an IACUC-approved animal use protocol at Brown University.

3.0 Policy Statement

Pathogen screening of biologic materials is required in order to minimize the potential introduction of infectious diseases into rodent colonies, and to protect the health of humans from zoonotic agents.

Research biologics of rodent or human origin are often introduced into research animals as part of a research procedure. Researchers must screen biologic materials intended for use in research animals to ensure they are free of adventitious infectious agents that may adversely impact the health of the animals or humans.

Biological materials of rodent origin, such as cell lines, tissues, and tumors, may be the cause for accidental introduction of pathogens, particularly viral infections, into animal colonies. In many cases, the infectious agents produce no clinical signs, but may produce physiologic changes that could alter or invalidate research results. This can have serious detrimental effects on experimental results, as well as jeopardize the health of animals and people. Many rodent pathogens cause either subclinical disease that alter rodent immune function and confound cancer, infectious disease, and immunologic research or, as in the case of Lymphocytic Choriomeningitis Virus, may be transmitted as a zoonotic disease to humans. In rare cases, severe, uncontrollable clinical disease may require depopulation of entire colonies.

3.1 Biological Materials

Biological materials that will be introduced into rodents housed at Brown University must be tested for and certified free of specified pathogens before they may be used in rodents. **Please note that many commercial vendors do not routinely test or certify their compounds.**

The following are examples of biologics that must be tested:

- Rodent derived cell lines OR cell lines of non-rodent origin that have been passaged through rodents
- Transplantable tumors
- Tissues
- Serum
- Embryonic stem cells (ES or ESC)
- Bodily fluids (*e.g.*, sperm, ascites fluid)
- Basement membrane matrix (*e.g.*, Matrigel)
- Hybridomas

- Antibody preparations that have been passaged through or that have been exposed to rodents outside of Brown University.

Human derived cell lines will be handled at the BSL-2 biohazard level using [Universal Precautions](#) for blood-borne pathogens, and therefore testing is NOT required. If the Brown laboratory is using fresh tissue directly harvested from in-house animals, no additional testing is needed.

The agents linked in the following lab panels (IDEXX and Charles River Labs) under “Testing” represent those pathogens that pose the greatest risk to rodent colonies.

3.2 Testing

Testing can be completed through IDEXX laboratories, Charles River Diagnostics laboratories or any equivalent laboratory that can provide screening for adventitious rodent pathogens. The following test panels are recommended by the CARE Veterinary Staff based on the potential to impact experimental results, the potential of transmission to other animals within the colony, and the prevalence of the agent. The research team should contact CARE directly to arrange for the testing of biologic materials. If the research team arranges for testing, the results should be provided to the Attending Veterinarian or their designee.

- Mouse Impact I panel (Idexx)
- Rat Impact V panel (Idexx)
- Mouse Essential Panel (Charles River Laboratories)
- Rat Essential Panel (Charles River Laboratories)

4.0 Definitions:

Universal Precautions: Measures taken when handling potentially infectious materials to reduce the risk of disease transmission in clinical and biomedical research settings. Measures may include the use of personal protective equipment and implementation of handwashing.

5.0 Responsibilities

All individuals to whom this policy applies are responsible for becoming familiar with and following this policy. University supervisors are responsible for promoting the understanding of this policy and for taking appropriate steps to help ensure compliance with it.

6.0 Consequences for Violating this Policy

Violation of this policy may be considered a serious event of noncompliance that is reportable to the IACUC, funding and accrediting agencies, as well as other regulatory agencies. Violations of this policy are a serious matter that may adversely affect both the ability to perform animal work and acquire funding sources.

Failure to comply with this and related policies is subject to disciplinary action, up to and including suspension without pay, or termination of employment or association with the University, in accordance with applicable (e.g., staff, faculty, student) disciplinary procedures.

7.0 Related Information

Brown University is a community in which employees are encouraged to share workplace concerns with University leadership. Additionally, **Brown's Anonymous Reporting Hotline** allows anonymous and confidential reporting on matters of concern online or by phone (877-318-9184).

The following information complements and supplements this document. The information is intended to help explain this policy and is not an all-inclusive list of policies, procedures, laws and requirements.

7.1 Related Policies: N/A

7.2 Related Procedures: N/A

7.3 Related Forms: N/A

7.4 Frequently Asked Questions (FAQs): N/A

7.5 Other Related Information:

References:

- Boston University Policy on Pathogen Screening of Biological Materials Introduced into Rodents.
- Charles River Laboratories
http://www.criver.com/flex_content_area/documents/rm_ld_c_research_animal_diagnostic_services.pdf
- Cornell University Policy on Tumor and Cell Line Testing
- Emory University Policy on Pathogen Screening of Biological Material
- IDexx BioResearch <http://www.idexxbioresearch.com/impact-pcr-0>

8.0 Policy Owner and Contact

8.1 Policy Owner: Vice President for Research

8.2 Policy Approved by: Vice President for Research

8.3 Subject Matter Contact: Brown University Animal Research Compliance (ARC)

- Telephone: 401-863-3050
- Email: IACUC@Brown.edu

9.0 Policy History

9.1 Policy Issue Date: April 5, 2019

9.2 Policy Effective Date: Pending Approval

9.3 Policy Update/Review Summary: This policy was reviewed by the IACUC at its convened meeting on October 1, 2021. Prior versions of this policy are listed below:

- Converted to University Compliance Policy Template - Reviewed by IACUC February 5, 2021
- IACUC Biologics Testing Policy, date of IACUC review and approval: April 5, 2021