IACUC Guidance:	**TAMU-G-043**	Title:	**Guidelines on Testing of Biologic Materials Administered to Rodents**

Location	Effective Date	Review By
College Station/Dallas/Galveston/Kingsville	9/01/2025	08/31/2028
Houston	XX/XX/XXXX	XX/XX/XXXX

1. PURPOSE

1.1. Establish IACUC guidelines outlining recommendations for pathogen or contaminant testing of cell lines and other biologic materials intended for administration to rodents.

2. SCOPE

2.1. Applies to vertebrate animals used for research, teaching, or other related purposes under the oversight of the Texas A&M University IACUC.

2.2. Applies to rodent administration of biologic materials obtained from an external source and not material originating from Texas A&M facilities.

3. RESPONSIBILITY & COMMON MISCONCEPTIONS

3.1. The **PI** is responsible for assuring biologic materials administered to rodents during the conduct of TAMU IACUC approved research are free of rodent pathogens that are known to impact rodents used at TAMU. As such:

3.1.1. The **PI** must outline in the AUP the biologic material and material's source. The PI should address strategies to mitigate inadvertent introduction of adventitious rodent pathogens that have the potential of contaminating biologic material of rodent origin.

3.1.2. The **PI** should consider testing of materials obtained from outside sources prior to implantation, and maintaining documentation of all testing.

3.1.3. The **PI** assumes all potential risks to their rodent colony as a result of contamination from biologic materials.

3.1.4. Depending on the biologic material, IBC approval may be required prior to initiation of animal work.

3.2. Common myths and misconceptions regarding biological materials.

3.2.1. Myth #1: Cell lines and other biologicals are free of all infectious agents.

3.2.1.1. This is **False**.

3.2.1.2. Repositories, such as the American Type Culture Collection (ATCC), receive cell lines and other biological materials "as is" from the scientist donor. The only "guarantee" made by the ATCC is that the cell line will be sterile. **The sterility guarantee encompasses ONLY bacteria**. Fungal agents and viruses are not included.

3.2.2. Myth #2: Cell lines and other biologicals are free of *Mycoplasma*.

3.2.2.1. This is **False.**

3.2.2.2. While the ATCC and other repositories give assurance that cell lines and other biologicals will be sterile and Mycoplasma-free, there have been documented cases where cell lines contained Mycoplasma and transmitted the infection to recipient animal models.

3.2.3. Myth #3: The repository tests for HIV, so the cell line must be free of all viruses, including rodent viruses.

3.2.3.1. This is **False**.

3.2.3.2. If the HIV-status of a human patient (from which the biological was harvested) is known, the donor scientist should report this when donating the sample to the repository. However, the repository itself does not do ANY testing for viral agents. Thus, no assumptions should be made that the biological material is free of (rodent) viruses.

3.3. The **IACUC,** in consultation with the **AV (or designee)**, is responsible for the review and approval of the PI's proposed use of a biologic material administered to rodents, material source, mitigation strategies, and determining if testing of the material is required prior to implantation.

4. DEFINITIONS AND/OR ACRONYMS

4.1. **AUP**: Animal Use Protocol. Document submitted by the PI indicating the housing and procedures involving animals.

4.2. **AV:** Attending Veterinarian. Individual designated by Texas A&M University to fulfil the regulatory role of AV. May also describe veterinary staff who report directly to, and have delegated authority from, the AV.

4.3. **Biologic Material:** For the purposes of this document, includes but is not limited to rodent derived cell lines, transplantable tumors, tissues, serum, embryonic stem cells, bodily fluids (sperm, ascites fluid, etc.), basement membrane matrix ("Matrigel"), and hybridomas, as well as cell lines of non-rodent origin and antibody preparation that have been passed through rodents.

4.4. **IACUC:** Institutional Animal Care and Use Committee. Institutional body responsible for ensuring adherence to federal regulation and institutional policy relating to the care and use of animals in teaching, testing and research. Appointed by the Institutional Official.

4.5. **IBC:** Institutional Biosafety Committee. Institutional body responsible for the review and oversight of research, teaching, and testing activities utilizing biohazardous materials and Dual Use Research of Concern. Appointed by the Institutional Official.

4.6. **Guidance:** Guidance documents are developed by the IACUC to provide procedural standards to the research community on the topics identified. Animal care and use program participants are expected to adhere to the standards described unless an exception has been requested and approved by the IACUC.

4.7. **PI:** Principal Investigator. The individual who has ultimate administrative and programmatic responsibility for the design, execution, and management of a project utilizing vertebrate animals.

4.8. **Rodent**: Of the order Rodentia

5. GUIDELINES OR PROCEDURE

5.1. Pathogen and/or contaminant testing of biologic materials is strongly encouraged prior to implantation into rodent models. In some cases, testing may be required by the IACUC or IBC prior to implantation procedures.

5.2. The PI should identify all biologic material(s) intended for implantation as part of an approved TAMU AUP.

5.2.1. These biologic materials should be evaluated in terms of their potential to be contaminated with known rodent pathogens. A *separate* risk evaluation should be performed for *each* biological material to be used in rodents. Rodent-origin biologic materials (e.g., rodent serum, rodent cell lines) are at particularly high risk for transmission of rodent viruses. Several viruses are known to be transmittable *across* rodent species (e.g., Sendai virus, Lymphocytic Choriomeningites virus, and Hantavirus, among others).

5.2.2. Testing of biologic material should be considered using commercial services such as:

5.2.2.1. IDEXX BioAnalytics IMPACT 2 Mouse Profile.

5.2.2.2. IDEXX BioAnalytics IMPACT 6 Pat Profile

5.2.2.3. VRL CytoClear testing

5.2.2.4. Charles River non-GLP cell line screening

5.2.3. Documentation of testing results should be maintained by the PI and made available for review upon request.

5.2.4. The following list of pathogens are recommended to be included in testing strategies:

5.2.4.1. Hantaan virus, LCMV, MAV 1 & 2, MHV/RCV/SDAV. MNV, Mouse Parvovirus (MPV/MVM), Mousepox (ectromelia), MRV (EDIM), POLY, PVM, Rat Parvovirus (RPV), Rat Polyomavirus 1, REO, RTV/TMEV, SEND, Seoul, Mycoplasma genus, and M pulmonis.

6. RECORDS

6.1. Research records, including records of biologic material testing, must be maintained consistent with Texas A&M University Standard Administrative Procedures (SAPS) 15.99.03.M1.03. and 29.01.03.M0.01

7. EXCEPTIONS

7.1. The PI may request an exception to the above standards by describing the departure in the AUP

7.2. For programmatic exceptions, the facility director or manager may submit a request for the exception using TAMU-F-013

8. REFERENCES, MATERIALS, AND/OR ADDITIONAL INFORMATION

8.1. **References**:

8.1.1. OLAW Website: http://grants.nih.gov/grants/olaw/

8.1.2. Guide for the Care and Use of Laboratory Animals

8.1.3. Idexx Bioanalytics: Cell Health Services

8.1.4. VRL Animal Health Diagnostics: Cell Line Pathogen Screening

8.1.5. Charles River: Research Animal Diagnostic Services

8.2. Resources:

8.2.1. For more information on testing of biologic materials, please contact:

8.2.1.1. CMP: at (979) 845-7433

8.2.1.2. ARU: at (214) 828-8149

8.2.1.3. PAR: at (713) 677-7471

8.2.1.4. PRF: at (361) 221-0770

8.3. Texas A&M University SAPs:

8.3.1. 15.99.03.M1.03 The Responsible Stewardship of Research Data

8.3.2. 29.01.03.M0.01 Security of Electronic Information Resources

8.4. **IACUC/AWO Referenced Documents:**

8.4.1. TAMU-F-013 Request for Programmatic Exception from Animal Welfare Standards

8.5. **Acknowledgement**

8.5.1. This document was partially prepared using materials obtained from Brown University.

9. HISTORY

Effective Date	Version #	Description
09/01/2025	000	College Station/Dallas/Galveston: New Document