Version: 1.1 **Effective Date:** **March 1, 2020**	**TESTING BIOLOGICALS USED IN LABORATORY RODENTS**	**Supercedes Document Dated: 8/24/2012**

I. Background

All rodent colonies housed in the University of California, Berkeley (UCB) animal facilities are screened for infectious diseases and are free of excluded viruses and other microbial agents capable of interfering with research. Biologicals are a potential source of contamination with excluded pathogens; practices outlined in this policy serve to lessen the risk of contamination to rodent colonies through appropriate screening.

II. Policy

Biological materials of unknown status as defined in this policy are to be tested prior to inoculation into rodents at UC Berkeley. Biologicals should be evaluated based on the preparation of the biological, or history of the cell line and/or the health status of the originating animal facility. Biologicals, as defined in this policy, which have not yet been tested, may be used in rodents only if the use is biocontained under ABSL2 or greater protocols.

III. Definitions

Biologicals – Materials that have the potential to carry excluded rodent pathogens, including externally sourced rodent tissues/blood products and all rodent-derived cell lines, transplantable tumors, hybridomas.

Not included: molecules, nanoparticles, cytokines or lipoproteins that are produced chemically or using recombinant technology, pharmaceutical grade products, sterile preparations of drugs vehicles and isotonic fluids, sterile preparations of biologicals that by the nature of the preparation cannot contain live pathogens, organisms used for infectious disease studies (and carried out in biocontainment conditions), primary cells or tissues of other species that have not come into contact with rodents or rodent tissues/blood products, and untested biologicals that are contained under ABSL2 or greater conditions.
Passaging – also known as subculturing of cells, is a common procedure wherein cells from a given culture are divided, or “split”, into new cultures and fed with fresh media to facilitate further expansion.

IV. Responsibilities

A. Animal Care and Use Committee (ACUC) and the Office for Animal Care and Use (OACU) – The ACUC informs investigators what is required in the Biological Material/Animal Product(s) section of eProtocol.
B. Animal user – Individuals administering biologicals to rodents must ensure that the biologicals have been prepared or tested in compliance with this policy.

C. Office for the Environment, Health & Safety (EH&S) – EH&S will oversee use of human cells/tissue in rodents through review of the AUP and the Biosafety Use Authorization (BUA).
D. Office for Laboratory Animal Care (OLAC) – OLAC veterinary staff will review AUPs for the use of biologicals in colony rodents and will evaluate preparation method or testing history and coordinate testing services with the investigator when necessary.
E. Principal Investigator (PI) – The PI must ensure that all biological agents are disclosed and described in their protocol. All laboratory members using biologicals in colony rodents must be informed of this policy.

V. Applicable Biologicals and their Testing Requirements

A. Biological materials originating from rodents within the UCB rodent colony, and only contacting rodent-pathogen free materials, need not be tested, as their health status is monitored via the UCB rodent health surveillance program.
B. Biological materials from institutions or commercial sources outside of the UCB rodent colony will need to be assessed by OLAC veterinary staff on a case by case basis to determine any required testing. It is the investigator's responsibility to provide documentation to OLAC for evaluation of any testing exemption.
    1. All tumors/tissues/cell lines originating from rodents outside the UC Berkeley colony must test negative for excluded rodent pathogens or the colony from which they originate must be of acceptable health status. New acquisitions of the same tumors/tissues/cell lines must be reevaluated by OLAC veterinarians or repeated for each shipment.
    2. Tumors/tissues/cell lines that have been passaged in rodents outside the colony since they were last tested must be re-evaluated by OLAC veterinary staff.
    3. Tumors/tissues/cell lines that have been in contact with rodent-derived biologicals (eg., rodent serum, rodent cell or tissue extract, rodent feeder cells), must be evaluated by OLAC staff.
C. Established human tissue/cells must be tested for human pathogens, including Lymphocytic Choriomeningitis Virus (LCMV) and Mycoplasma spp, if the animals are to be housed at ABSL1. Untested established human cell lines can only be used in animals at ABSL2.
D. Primary human sourced materials are not required to be tested for human pathogens as they must always be housed at ABSL2.

VI. Arranging for Testing and Evaluation

Testing of tumors/tissues/cell lines or evaluation for exemptions can be arranged through the OLAC veterinary staff at vetstaff@lists.berkeley.edu.

Exemptions are valid for as long as the rationale for the exemption remains valid, and must be re-evaluated if there are relevant changes in the biological (e.g., source of biological or rodent-derived products in contact with the biological, method of preparation), or changes in Policy.

VII. References

A. Boston University Research Support. Biological Materials in Rodents. https://www.bu.edu/researchsupport/compliance/animal-care/working-with-animals/procedures/biological-materials-in-rodents-iacuc/

B. Institute of Laboratory Animal Research (ILAR). National Research Council (2011). *Guide for the Care and Use of Laboratory Animals* (8th edition). Washington, D.C.: The National Academies Press.

C. University of California, San Diego Institutional Animal Care and Use Committee. *Policy and Guidelines for the Use of Biologicals in Rodents*. Retrieved on 22 June 2015.

D. University of South Carolina Institutional Animal Care and Use Committee. *IACUC Policy #15: Policy of Use of Cell Lines in Live Animals*. Retrieved on 22 June 2015 from https://uscm.med.sc.edu/ARF/images/celllines15.pdf

E. University of South Florida Division of Comparative Medicine. SOP 425 - Characterization of Biologics for Use in Rodents. https://www.usf.edu/research-innovation/comparative-medicine/documents/sops/s425-characterization-of-biologics-used-in-rodents.pdf