Albert Einstein College of Medicine

IACUC & IAS Recommendations for the Use of Human- and Animal-Derived Biologicals Policy

I. Purpose

Human and animal derived biological reagents should be tested prior to use in animals as these materials can present a number of scientific and safety concerns. Organs, tissues (including blood products), cells, and cell lines derived from humans or animals are potentially subject to contamination by a variety of adventitious infectious agents (e.g., viruses, bacteria [mycoplasmas], fungi, and prions). Contamination by these agents are among the factors that affect the authenticity and integrity of these key biological research resources, as well as affecting their performance characteristics in experiments*. Contamination of human or animal derived biologicals by human infectious agents (including zoonotic agents) presents a risk to human health and safety. Contamination of these biological reagents by agents infectious to the animal host presents a risk to the health of any animals that are exposed and potentially to the health quality of all investigators' animals in the vivarium.

**Guidelines for the use of cell lines in biomedical research*: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4453835/

*NIH requires authentication of key biological and/or chemical resources. "This includes, but is not limited to, cell lines, specialty chemicals, antibodies, and other biologics (see https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-068.html)

While it is not feasible to test tissues, cells, and tissue derived biological reagents for all possible microbial contaminants, which would include those that have yet to be discovered, it is important to screen them for any agents that are well recognized to be problems and for which practical diagnostic assays exist. This process allows these reagents to be authenticated as "specific pathogen-free" (SPF).

II. Scope

All human or animal cell lines and biologicals that will be injected into animals (typically rodents) should be tested before use to confirm their SPF status for as many human and animal infectious agents as feasible. Testing of human derived materials (especially clinical samples and early passage tissue cultures) should include human pathogens that may be prevalent in patient derived biopsies, such as human hepatitis viruses, human herpesviruses, and human retroviruses. All biological reagents derived from animals (rodents) and human cell lines passaged in rodents should be tested for specific host (rodent) infectious agents that may infect and propagate in the material or simply be carried as a contaminant. The specific agents to be tested must include known pathogens that are excluded from the SPF animal facility.

III. Policy

A. Responsibility

Investigators are responsible for ensuring that the biologic materials used in their study are assessed to evaluate the risks to human health and safety, the health of study animals or other animals housed in the facility.

Investigators should provide documentation (types of tests performed and the date tests were performed) that the material has been tested and verified free of human and/or animal pathogens before introducing these materials into animals.

Cell lines, tumors or other materials for which no documentation is provided from the source should be tested prior to use. However, if not tested, arrangement MUST be made to house the experimental animals in appropriate quarantine or isolation (Animal Biosafety Level 2 (BSL-2) or above).

B. Procedures

Arrangements for testing of cell lines and biologicals may be made by contacting IAS veterinary staff or the IAS Director.

The preferred method for testing material for most infectious agents is by polymerase chain reaction (PCR) procedures. There are several commercial labs that run testing panels for human and animal agents.

C. Commercial Laboratories Providing Testing

http://www.criver.com/products-services/basic-research/health-monitoring-diagnostic-services/cell-line-research-biologics-screening

IV. Definitions

None.

V. Effective Date

Effective as of: 21 February 2018.

VI. Policy Management and Responsibilities

Einstein's Institutional Animal Care and Use Committee (IACUC) is the Responsible Office under this Policy. The Institutional Official for the IACUC is the Responsible Executive for this policy. The IACUC Chairperson is the Responsible Officer for the management of this policy.

VII. Approved (or Revised)

Institutional Official — Date: 3/30/2018

Revised: 12/21/2017, 2/21/2018