# Testing Requirements for Biological Materials Proposed for Use in NCI-Frederick Animal Study Proposals

Protecting the health status of experimental animals from infectious disease is critical for obtaining valid and reliable *in vivo* data. An important potential source of viral infections that are introduced into an animal facility is contaminated biological materials that are injected into live animals. Biological materials include tumor cell lines, stem cells, matrigel, serum, antibodies, and other materials which may have been produced in the presence of serum or other biological products from infected mice or rats or those that become contaminated during processing in the laboratory. Contamination poses a risk to multiple populations in an animal facility, and in the case of zoonotic agents such as Lymphocytic Choriomeningitis Virus, there can be health risks for research staff.

As a result, the NCI-Frederick ACUC will only accept biological testing results [MAP, RAP, and MTBM] coordinated through the LASP Animal Health Diagnostic Laboratory [AHDL]. A copy of these results must be appended to your applicable Animal Study Proposal submission. Please refer to the AHDL website [http://web.ncifcrf.gov/rtp/lasp/intra/ahdl/] for additional information regarding the available testing modalities and guidance for requesting testing services in advance of proposing biological materials for use in NCI-Frederick animal facilities.

The NCI-Frederick ACUC has provided the following guidance in an effort to assist investigators with the requirements for completing Section K [Biological Material/Animal Products] of the NCI-Frederick Animal Study Proposal form. Please note that this list is not inclusive and investigators should contact the AHDL [301-846-1134] if there are questions or concerns regarding the requirements for biological testing.

## Requires AHDL Biological Testing

These materials require testing prior to use in NCI-Frederick animal facilities. Copies of the AHDL test results must be appended to the applicable ASP form and/or modification before ACUC approval will be granted. This includes but is not limited to the following:

- *Rodent Tumors*
- *Rodent Cell Lines*
- *Manipulated Rodent Tumor Cell Lines **
- *Rodent Derived Antibodies*
- *Human Cell Lines [unless proven that there is no risk of exposure to rodent products] ***
- *Matrigel [lot specific testing required]*
- *Naturally obtained Cytokines [purified not generated by recombinant technology]*
- *Rodent By-Products [e.g., sera]*
- *Natural Materials [e.g., virus stocks grown in or containing rodent products]*
- *Other biological materials containing murine derived products*

## Requires Vendor Specification Sheets

Copies of the vendor specification sheets must be provided to ensure that no rodent materials were used in the preparation of the material or that the purification process [by the vendor or in the laboratory] ensures complete destruction or elimination of any viral contaminants. Copies must be appended to the applicable ASP form and/or modification before ACUC approval will be granted.

- *Purified Antibodies*
- *Antigens*
- *Proteins*

- *Cell extracts*

## Do NOT Require AHDL Biological Testing

- *Spontaneous or induced rodent tumors and/or cell lines derived from rodents within NCI-Frederick animal facilities and used within the same animal facility*
- *Human Primary Tumors* **
- *Materials of non-rodent origin [i.e., rabbit]*
- *Synthetic materials*
- *Bacterial growth media not containing any rodent products*

NOTE: *There is no time limit on the validity of results. However, investigators are encouraged to update testing periodically, such as every ten years, as the sensitivity and agents screened are likely to increase over time. Please refer to the ACUC Notice Biological Material Risk Factors for additional information.*

* *If cell lines have been manipulated [i.e., transfected] outside of the NCI-Frederick campus [i.e., Bethesda], these lines must be re-tested by AHDL prior to reintroduction into an NCI-Frederick animal facility*

** *Please refer to the ACUC Guidelines Regarding Engraftment of Human Cells or Tissues into Immunodeficient Mice for guidance on human pathogen testing and housing requirements for using human materials*