

Guideline for Biological Material Risk Factors

Animal studies are an integral component of research at the Frederick National Lab. The overall health status of the animals utilized in research plays a crucial role in the validity of experimental results generated from *in vivo* studies. Health risks may come from a variety of sources, such as the introduction of infected rodents into the animal facility, the presence of feral animals, and experimental and genetic manipulations. The Laboratory Animal Sciences Program (LASP) makes great efforts in preventing the introduction of infectious agents through an exhaustive Receiving & Quarantine Program, extensive health monitoring and in cooperation with Facilities, Maintenance, and Engineering (FME), a pest control program. One important and potentially devastating source of adventitious viral infections is through the injection or implantation of various biological materials. Historically, many of these biological materials included tumor and cell lines, but now may include materials such as monoclonal antibodies, antigens, and non-cellular materials produced in the presence of rodent sera. Although an investigator may be diligent in having biological material tested for infectious agents through MTBM (Molecular Testing of Biological Materials) testing [viral screening], there exists a threat of cross contamination from other biological materials which are manipulated in the same laboratory space and/or containment devices.

Here are some important factors to consider:

- All biological materials pose a potential and significant health risk to animals. This includes material from humans, which may be contaminated with zoonotic agents such as Lymphocytic Choriomeningitis Virus (LCMV).
- Certain synthetic antigens and compounds may be exempted by the Animal Care and Use Committee on a case-by-case basis.
- Biological materials that are shared with investigators off the Frederick National Lab campus (including NCI-Bethesda) must be MTBM tested prior to *in vivo* applications, even if the material had been previously tested.
- There is no prohibition which would prevent investigators from receiving virally infected materials that are for *in vitro* uses only, however cross contamination can occur within biological safety cabinets or other approved engineering controls (i.e. vented hoods). Before working with material for *in vivo* use, the hood should be thoroughly decontaminated.
- Spontaneous tumors, which develop in animals at Frederick National Lab, are exempted from viral testing, providing they are not collected during a health outbreak and are used in a facility with equivalent health status.
- If a health outbreak is detected and confirmed within a Frederick National Lab animal facility, all biological materials passaged *in vivo* within a six-week period or longer depending on the agent must be viral screened.

- There is no time limit on the validity of MTBM results. However, investigators are strongly encouraged to update testing periodically, as the sensitivity and viral screen is often enhanced and/or expanded.

Please contact Mr. Pete Gorelick, LASP Animal Health and Diagnostic Laboratory, at 301-846-1134 if you have any questions or concerns. Thank you for your attention to this matter.