

# Biological Material Risk Factors

Animal studies are an integral component of research at the NCI-Frederick. 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, experimental and genetic manipulations. The Laboratory Animal Sciences Program (LASP) takes great efforts in preventing the introduction of infectious agents through an exhaustive Receiving & Quarantine Program, extensive health monitoring and in cooperation with 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 MAP/RAP (Mouse/Rat) testing, there exists a threat of cross contamination from other biological materials which are manipulated in the same laboratory space and/or hood lines.

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 maybe exempted by the Animal Care and Use Committee on a case-by-case basis.
- Biological materials that are shared with investigators off of the NCI-Frederick campus (including NCI-Bethesda) must be MAP/RAP tested prior to *in vivo* applications, even if the material had been previously MAP/RAP 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 hoods. Before working with material for *in vivo* use, the hood should be thoroughly decontaminated.
- Spontaneous tumors, which develop in animals at NCI-Frederick, are exempted from MAP/RAP testing, providing they are not collected during a health outbreak.
- If a health outbreak is detected and confirmed within a NCI-Frederick animal facility, all biological materials passaged *in vivo* within a six-week period must be MAP/RAP tested.
- There is no time limit on the validity of MAP/RAP test 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.

December 2002

Memorandum from ACUC to Principal Investigators

