Biological Agents and Materials that Require Oversight

Revised April, 2015

1) Select Agents and Toxins
These agents require substantial paperwork and federal involvement and must be registered with EH&S. Research or possession can only occur following compliance with all select agent registration requirements. They cannot be transferred to or from OSU without the prior approval of the Centers for Disease Control and Prevention and also from the OSU Responsible Official. In addition, many of these agents may also require a permit from USDA or CDC to receive the agents. More information is available by contacting the Biological Safety Officer at 541-737-4557.

A current list of regulated Select Agents and Toxins can be accessed from the National Select Agent Registry website and are listed below.

2) Shipping Infectious Agents and Toxins on the Commerce Control List
Many microorganisms, toxins and other biological materials require a license from the Department of Commerce to ship them to Canada or other destinations outside the U.S. Other requirements may apply. The shipping of these materials needs to be coordinated by the OSU Export Control and International Compliance office.

3) Recombinant and/or Synthetic Nucleic Acids
   A. Recombinant nucleic acid molecules containing Toxin Genes
   B. Recombinant nucleic acid molecules derived from or introduced into Risk Group-2, 3 or 4 Organisms
      For more information about risk groups and current listings, see the ABSA Risk Group Database.

      Note: Some common biological materials that will fall into this category are recombinant animal virus vectors (even those commercially available). This includes retrovirus, adenovirus, herpesvirus and poxvirus vectors, with or without insert nucleic acids.

   C. Transgenic Animals
      The breeding of many transgenic rodents is exempt from oversight. To be exempt, both parental lines must be able to be housed at ABSL-1 containment, and transgenes may not produce infectious agents or toxins. Contact the OSU Biosafety Officer for guidance on particular constructs.

      Transgenic animals other than rodents must be registered with the Institutional Biosafety Committee, which must establish the appropriate containment level for such research.

   D. Other Non-Exempt Recombinant or Synthetic Nucleic Acid Molecules
All other non-exempt recombinant DNA materials are required to be registered with the IBC. More information can be found in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

For guidance on whether a particular construct is exempt, please contact the OSU Biosafety Officer.

4) Infectious Agents of Humans, Plants or Animals
Any research of infectious agents must be reviewed and approved by the Institutional Biosafety Committee before the work may begin.

5) Human Source Materials
Work that involves contact with the following human source biological materials:
   A. Blood
   B. All body fluids except urine, sweat, sputum or saliva (urine, sweat, sputum or saliva will require oversight if visibly contaminated with blood)
   C. Unfixed tissues or cells, including established cell lines.
Work that involves possible exposure to any of the above requires participation in the university’s Bloodborne Pathogen Program.