Section 12 Biosafety

1. Principal Investigators must develop and implement a written biosafety plan which is commensurate with the risk or the agent or toxin. The plan must comply with:
   - The biosafety standards and requirements in the CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories," including all appendices;
   - The OSHA Lab Standard (29 CFR parts 1910.1200 and 1910.1450, "Occupational Exposure to Hazardous Chemicals in Laboratories"); and
   - The NIH Guidelines for Research Involving Recombinant DNA Molecules.

   Plans must incorporate all other compliance elements found on the UK research compliance checklist (http://ehs.uky.edu/checklist.html).

   Biosafety plans must contain sufficient information and documentation to describe the biosafety and containment procedures.

2. The Responsible Official or his or her designee must conduct regular inspections (at least annually) of the areas where select agents and toxins are stored or used to ensure compliance with all of the procedures and protocols of the safety plan.
   The results of these inspections must be documented, and any deficiencies identified during inspections must be corrected.
   Records of these inspections will be retained for a minimum of three years.

3. The Responsible Official will ensure that drills or exercises are conducted at least annually to test and evaluate the effectiveness of the plan. The plan will be reviewed and revised, as necessary, after any drill or exercise and after any incident.

4. Principal Investigators may not conduct the following experiments unless approved by the HHS Secretary after consultation with experts:

   - Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.

   - Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD50 < 100 ng/kg body weight.