revision date: 18 November 2005

Section 9 Responsible Official

- 1. The Responsible Official and Alternate Responsible Official must be approved by the HHS Secretary or Administrator following a security risk assessment by the Attorney General under §73.9, must be familiar with the requirements of 42 CFR 73, and must have authority and responsibility to ensure that the requirements of this part are met, on behalf of the University of Kentucky, and ensure compliance with the requirements of 42 CFR 73.
- 2. The Responsible Official is responsible for
 - Developing and implementing safety, security and emergency response plans,
 - Allowing only approved individuals to have access to select agents or toxins,
 - Providing appropriate training for safety, security and emergency response,
 - Transferring select agents or toxins to registered individuals or entities,
 - Providing timely notice of any theft, loss, or release of a select agent or toxins,
 - Maintaining detailed records of information necessary to give a complete
 accounting of all activities related to select agents or toxins, which will be
 retained for a minimum of three years,
 - Ensure annual inspections are conducted for each laboratory where select agents or toxins are stored or used in order to determine compliance with the requirements of 42CFR 73; the results of each inspection must be documented, and any deficiencies identified during an inspection must be corrected,
 - Reporting identification of a select agent or toxin as a result of diagnosis, verification or proficiency testing,
 - Ensuring all visitors are informed of and follow the entity's security requirements and procedures, and
 - Notifying CDC of changes in circumstances (amending or discontinuing registration)
 - Submitting the information necessary to conduct a security risk assessment to the Attorney General for individuals the Principal Investigator is seeking authorized access to a select agent or toxin for.

The Alternate Responsible Official must assume these responsibilities when the Responsible Official is unavailable.

3. Marcia Finucane is the appointed Responsible Official and David Hibbard is the appointed Alternate Responsible Official for the University of Kentucky.