

Transfer, Receipt, and Storage of Select Agents Duke University/Medical Center

Policy Statement

Revised: February 2004, February 2008

Background

The purpose of this policy is to ensure that "[Select Agents](#)" on Duke University campuses are handled safely, secured properly, and properly registered with the Department of Health and Human Services, [Centers for Disease Control and Prevention \(CDC\)](#) and/or the United States Department of Agriculture, [Animal Plant Health Inspection Service \(APHIS\)](#).

A full text version of the Select Agent Rule (42 CFR 73) is accessible at <http://www.cdc.gov/od/sap/>

All Select Agents and Toxins are ordered and obtained through the Biological Safety Office of the Occupational and Environmental Safety Office. Laboratories receiving, shipping, or possessing Select Agents or Toxins must be registered with the CDC Select Agent Program. Contact the Biological Safety Office to help with this registration.

Responsibilities and Procedures

"Responsible Official" (RO):

The rule requires that a RO be designated at each institution where select agents are shipped, received, and/or possessed. The Director of the Biological Safety Division of the Occupational and Environmental Safety Office shall serve as Duke's RO. An alternate may be designated by the RO if deemed necessary. The primary responsibility of the RO is to oversee the registration of the laboratory with the CDC and/or the APHIS, and assure that all requirements of compliance are met. The RO must give final approval of the facility registration application prior to it being submitted to the applicable federal department.

Researcher:

The principal investigator (PI) is held responsible for assuring that he registers all possession, transfer, and receipt of select agents through the Biological Safety Office. He is also responsible for assuring that his laboratory fully complies with all prescribed safety policies and procedures. Consequently, the PI must work closely with the RO to assure compliance with this standard.