

## **Section 1 Definitions**

Access means the freedom or ability to obtain or make use of.

Biological agent means any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment.

CDC means Centers for Disease Control and Prevention of the Department of Health and Human Services.

Diagnosis means the analysis of specimens for the purpose of identifying or confirming the presence of a listed select agent or toxin provided that such analysis is directly related to protecting the public health or safety.

HHS means the Department of Health and Human Services.

HHS select agent or toxin means a biological agent or toxin included in §73.3.

Overlap select agent or toxin means a biological agent or toxin included in §73.4 and 9 CFR part 121.4.

Package means a wrapped or boxed object, parcel, or container in which something is packed.

Proficiency testing means a sponsored, time-limited analytical trial whereby one or more analytes, previously confirmed by the sponsor, are submitted to the testing laboratory for analysis and where final results are graded, scores are recorded and provided to participants, and scores for participants are evaluated.

Principal Investigator means the one individual designated by the entity to direct a project, program or laboratory (including research, clinical, diagnostic or other lab) and who is responsible to the entity for the scientific and technical direction of that project, program or laboratory.

Responsible Official means the individual designated by the University with the authority and control to ensure compliance with the regulations in this part.

Select agent or toxin or select agent and toxin means all of those biological agents or toxins included in 42 CFR 73, 7 CFR 331, and 9 CFR 121

Specimen means samples of material from humans, animals, plants, or the environment or isolates or cultures from such samples for the diagnosis, verification, or proficiency testing.

Toxin means the toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes any poisonous substance or biological product that may be engineered as a result of biotechnology, produced by a living organism; or any poisonous isomer or biological product, homolog, or derivative of such a substance.

University means the University of Kentucky

USDA means the United States Department of Agriculture.