APPENDIX A: POLICY DEFINITIONS

The definitions provided below are from Section 3 of the Policy:

A. "*Biological agents*" are any microorganism (including, but not limited to, bacteria, viruses, fungi, or protozoa), infectious material, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious material, 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.

B. "*Biosafety*" is the application of practices, controls, and containment infrastructure that reduces the risk of unintentional exposure to, contamination with, release of, or harm from pathogens, toxins, and other associated biological materials.

C. "*Biosecurity*" is the application of security measures designed to prevent the loss, theft, misuse, diversion, unauthorized possession or material introduction, or intentional release of pathogens, toxins, biological materials, and related information and/or technology.

D. "*Dual use research*" is research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that can be utilized for benevolent or harmful purposes.

E. "*Dual use research of concern (DURC)*" is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be misapplied to do harm with no, or only minor, modification to pose a significant threat with potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

F. *"Federal funding agency*" is a federal department, agency, institute, center, or office that funds or sponsors intramural or extramural research at research institutions in the United States or internationally, with pathogens or toxins where the research is within Category 1 or Category 2 under the Policy, as described in Section 4.

G. "*Institutional Contact for Dual Use Research (ICDUR)*" is the official designated by the research institution to serve as an internal resource for application of the Policy as well as the liaison (as necessary) between the institution and the relevant federal funding agency.

H. "*Institutional review entity (IRE)*" is the entity established by the research institution to execute the institutional oversight responsibilities described in Section 5.2, with the attributes described in Section 5.2.B.

I. "*Life sciences*" is the study or use of living organisms, viruses, or their products, including all disciplines, methodologies, and applications of biology (including biotechnology, genomics, proteomics, bioinformatics, and pharmaceutical and biomedical research and techniques).

J. "*Pathogen with enhanced pandemic potential (PEPP)*" is a type of pathogen with pandemic potential (PPP) resulting from experiments that enhance a pathogen's transmissibility[26] or virulence, or disrupt the effectiveness of pre-existing immunity, regardless of its progenitor agent, such that it may pose a significant threat to public health, the capacity of health systems to function, or national security. Wild-type pathogens that are circulating in or have been recovered from nature are not PEPPs, but may be considered PPPs because of their pandemic potential.

K. "*Pathogen with pandemic potential (PPP)*" is a pathogen that is likely capable of wide and uncontrollable spread in a human population and would likely cause moderate to severe disease and/or mortality in humans.[27]

L. "*Principal investigator*" (PI) is the senior/key person seeking or receiving federal research and development funding (i.e., extramural funding). This includes researchers at federal agency laboratories and facilities, as well as researchers at government-owned, contractor-operated laboratories and facilities (i.e., intramural researchers, whether or not federally employed). There may be more than one PI on a research grant or project within a single or multiple institution(s).

M. "*Reasonably anticipated*" describes an assessment of an outcome such that, generally, individuals with scientific expertise relevant to the research in question would expect this outcome to occur with a non-trivial likelihood. It does not require high confidence that the outcome will definitely occur, but excludes experiments in which experts would anticipate the outcome to be technically possible, but highly unlikely.

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[26] Experiments that enhance a pathogen's transmissibility (as listed in Section 4.2.2.i of the Policy) include those that enhance environmental stability of the pathogen or toxin or change the tropism or host range of the pathogen or toxin in a way that enables an increased ability to infect and transmit between humans, among others.

[27] Pathogens with pandemic potential are often those with little to no pre-existing immunity in the human population.

N. "*Research institution*" is any academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, government agency, or other legal entity that conducts life sciences research.