APPENDIX C: CATEGORY 1 LIST OF BIOLOGICAL AGENTS AND TOXINS

Section 4.1 of the Policy provides for Category 1 review for research on any biological agent or toxin in the following list (from Section 4.1.1 of the Policy), where the research is reasonably anticipated to result in one of the experimental outcomes outlined in Section 4.1.2 of the Policy and where the research constitutes DURC as specified in Section 4.1.3 of the Policy:

- All Select Agents and Toxins listed in 9 CFR 121.3–121.4, 42 CFR 73.3–73.4, and 7 CFR 331.3 and regulated by USDA and/or HHS.
- All Risk Group 4 pathogens listed in Appendix B of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) - Classification of Human Etiologic Agents on the Basis of Hazard.
- A subset of Risk Group 3 pathogens listed in Appendix B of the NIH Guidelines - Classification of Human Etiologic Agents on the Basis of Hazard.
- For biological agents affecting humans that have not been assigned a Risk Group in the NIH Guidelines, refer to the current edition of Biosafety in Microbiological and Biomedical Laboratories (BMBL). In such cases, agents affecting humans that are recommended to be handled at Biosafety Level 3 (BSL-3) or Biosafety Level 4 (BSL-4) per the BMBL guidance are subject to this Policy.
- Biological agents added during future updates to the Implementation Guidance as specified in Sections 7 and 8.

The checklist below is a list of the particular biological agents and toxins that are generally described above and under Section 4.1.1 of the Policy, as of the date of this *Implementation Guidance*. This checklist is provided as an implementation tool for identifying research that may require Category 1 review. It is important to note that this checklist is subject to change depending upon amendments to the source documents listed above, including the BSAT list managed by HHS and USDA, and the Risk Group 3 and Risk Group 4 designations managed by NIH. Thus, it is always prudent to consult the original sources to confirm that your biological agent or toxin of interest is or is not subject to Category 1 review. It is encouraged, on a voluntary basis, to apply this *Implementation Guidance* and assess DURC risks even if the biological agent of interest is not one from the source documents. When questions arise regarding particular strains of pathogens, please refer to the BSAT list, the *NIH Guidelines*, or the BMBL, as appropriate.[28]

[28] For the purposes of the Policy, where a pathogen is both a Select Agent and a Risk Group 3 or Risk Group 4 biological agent, the strain exclusions under the FSAP supersede those specified in the *NIH Guidelines*.

As described further in Section 6 of the Policy, there may be additional types of life sciences research that do not involve these biological agents or toxins described in Section 4.1.1 of the Policy or experiments in Section 4.1.2 of the Policy, yet pose DURC risks as described in Section 4.1.3 of the Policy. PIs and research institutions are encouraged to remain vigilant to such research, including work involving any other pathogen or toxin regardless of its Risk Group, and develop and apply appropriate risk mitigation measures.

HHS Select Agents and Toxins[29]	
☐	Abrin
☐	*Bacillus cereus* Biovar *anthracis*
☐	Botulinum neurotoxins
☐	*Clostridium botulinum* and neurotoxin-producing species of *Clostridia*
☐	Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$)
☐	*Coxiella burnetii*
☐	Crimean-Congo hemorrhagic fever virus
☐	Diacetoxyscirpenol
☐	Eastern equine encephalitis virus
☐	Ebola virus
☐	*Francisella tularensis*
☐	Lassa fever virus
☐	Lujo virus
☐	Marburg virus
☐	Mpox virus Clade I
☐	1918-1919 H1N1 including reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
☐	Ricin
☐	*Rickettsia prowazekii*
☐	Severe acute respiratory coronavirus (SARS-CoV)
☐	SARS-CoV/SARS-CoV-2 chimeric viruses resulting from any deliberate manipulation of SARS-CoV-2 to incorporate nucleic acids coding for SARS-CoV virulence factors
☐	Saxitoxin
☐	Chapare virus

[29] Biological agents and toxins listed in this part of the list are controlled by Select Agent Regulations, please refer to the Select Agents and Toxins list for any relevant strain exclusions.

☐	Guanarito virus
☐	Junín virus
☐	Machupo virus
☐	Sabía virus
☐	Staphylococcal enterotoxins (subtypes A, B, C, D, E)
☐	T-2 toxin
☐	Tetrodotoxin
☐	Tick-borne encephalitis complex virus: Far Eastern subtype
☐	Tick-borne encephalitis complex virus: Siberian subtype
☐	Kyasanur Forest disease virus
☐	Omsk hemorrhagic fever virus
☐	Variola major virus (Smallpox virus)
☐	Variola minor virus (Alastrim)
☐	*Yersinia pestis*
Overlap Select Agents and Toxins	
☐	*Bacillus anthracis*
☐	*Bacillus anthracis* Pasteur strain
☐	*Brucella abortus*
☐	*Brucella melitensis*
☐	*Brucella suis*
☐	*Burkholderia mallei*
☐	*Burkholderia pseudomallei*
☐	Hendra virus
☐	Nipah virus
☐	Rift Valley fever virus
☐	Venezuelan equine encephalitis virus
USDA Veterinary Services (VS) Select Agents and Toxins	
☐	African horse sickness virus
☐	African swine fever virus
☐	Avian influenza virus [this is included here as a veterinary select agent in 9 CFR 121.3. Low pathogenicity strains are excluded.]
☐	Classical swine fever virus
☐	Foot-and-mouth disease virus
☐	Goat pox virus
☐	Lumpy skin disease virus
☐	*Mycoplasma capricolum*
☐	*Mycoplasma mycoides*
☐	Newcastle disease virus
☐	Peste des petits ruminants virus
☐	Rinderpest virus

☐	Sheep pox virus
☐	Swine vesicular disease virus
USDA Plant Protection and Quarantine (PPQ) Select Agents and Toxins	
☐	*Coniothyrium glycines*
☐	*Peronosclerospora philippinensis (Peronosclerospora sacchari)*
☐	*Ralstonia solanacearum*
☐	*Rathayibacter toxicus*
☐	*Sclerophthora rayssiae*
☐	*Synchytrium endobioticum*
☐	*Xanthomonas oryzae*
Other Risk Group 4 Pathogens[30]	
☐	Tick-borne encephalitis virus complex including Absetterov, Central European encephalitis, Hanzalova, Hypr, and Kumlinge
☐	Herpesvirus simiae (herpes B or monkey B virus)
☐	Hemorrhagic fever agents and viruses as yet undefined
Other Risk Group 3 Pathogens[31]	
☐	*Bartonella*
☐	Brucella
☐	*Orientia tsutsugamushi*
☐	*Pasteurella multocida* type B -"buffalo" and other virulent strains
☐	*Rickettsia akari*, *R. australis*, *R. canada*, *R. conorii*, *R. rickettsii*, *R, siberica*, *R. typhi* (*R. mooseri*)
☐	Chikungunya virus except the vaccine strain 181/25
☐	Semliki Forest virus
☐	St. Louis encephalitis virus
☐	Flexal virus
☐	Lymphocytic choriomeningitis virus (LCM) (neurotropic strains)
☐	Hantaviruses, including Hantaan virus
☐	Middle East respiratory syndrome coronavirus (MERS-CoV)
☐	Severe acute respiratory coronavirus 2 (SARS-CoV-2)
☐	Japanese encephalitis virus except strain SA 14-14-2
☐	West Nile virus

[30] Pathogens listed in this part of the list are Risk Group 4 but not controlled by the Select Agent Regulations, please refer to the *NIH Guidelines* for any relevant strain exclusions.
[31] Pathogens listed in this part of the list are Risk Group 3 but not controlled by the Select Agent Regulations, please refer to the *NIH Guidelines* for any relevant strain exclusions.

☐	Yellow fever virus
☐	Human influenza A virus H2N2 (1957-1968)
☐	Highly pathogenic avian influenza A virus H5Nx strains within the Goose/Guangdong/96-like H5 lineage (e.g., H5N1, H5N6, H5N8 etc.)
☐	Transmissible spongiform encephalopathy (TSE) agents (e.g., Creutzfeldt-Jacob disease and kuru agents)
Other	
☐	Any attenuated pathogen or vaccine strain that is currently excluded from the Select Agent Regulations that exhibits the recovery of virulence at or near the wild-type
☐	Mpox virus clade I/II chimeric viruses resulting from any deliberate manipulation of clade II to incorporate nucleic acids coding for clade I virulence factors