

Dual Use Research of Concern, Pathogens with Pandemic Potential, and Dangerous Gain of Function Research Information Sheet



Background: A new government policy, [Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential](#), entered effect on May 6th, 2025, and [Executive Order 14292](#) entered effect on May 5th, 2025.

Policy definitions:

Category 1 research: Involves one or more of the biological agents or toxins listed in Section 4.1.1 of the policy, which includes over 80 specific agents and toxins and is reasonably anticipated to result, or does result, in one or more of the nine experimental outcomes listed in Section 4.1.2 of the policy.

Category 2 research: Involves or is reasonably anticipated to result in a Pandemic Potential Pathogen (PPP) as specified in Section 4.2.1 of the policy and is reasonably anticipated to result, or does result, in one or more of the experimental outcomes or actions specified in Section 4.2.2 of the policy. Any research that meets the definition of both Category 1 and Category 2 research is designated as Category 2 research.

Executive order definition:

Dangerous Gain of Function research: Involves research on an infectious agent or toxin with the potential to cause disease by enhancing its pathogenicity or increasing its transmissibility. Covered research activities are those that could result in significant societal consequences and that seek or achieve one or more of the outcomes (a) to (g) listed in the chart below.

	Type of Pathogen in Scope	Experimental Outcome or Action
Category 1 Research	<ul style="list-style-type: none"> • Select Agents and Toxins regulated by USDA and/or HHS; • Risk Group 3 Pathogens listed in Appendix B of the NIH Guidelines; • Risk Group 4 pathogens listed in Appendix B of the NIH Guidelines; OR • Biological agents affecting humans that have not been assigned a Risk Group in the NIH Guidelines which are recommended to be handled at BSL-3 or BSL-4 by the Biosafety in Microbiological and Biomedical Laboratories (BMBL). 	<ol style="list-style-type: none"> 1. Increase transmissibility of a pathogen within or between host species; 2. Increase the virulence of a pathogen or convey virulence to a non-pathogen; 3. Increase the toxicity of a known toxin or produce a novel toxin; 4. Increase the stability of a pathogen or toxin in the environment, or increase the ability to disseminate a pathogen or toxin; 5. Alter the host range or tropism of a pathogen or toxin; 6. Decrease the ability for a human or veterinary pathogen or toxin to be detected using standard diagnostic or analytical methods; 7. Increase resistance of a pathogen or toxin to clinical and/or veterinary prophylactic or therapeutic interventions 8. Alter a human or veterinary pathogen or toxin to disrupt the effectiveness of preexisting immunity, via immunization or natural infection, against the pathogen or toxin; 9. Enhance the susceptibility of a host population to a pathogen or toxin.
Category 2 Research	<ul style="list-style-type: none"> • Pandemic Potential Pathogens (PPPs)¹ (pathogens with a high case fatality rate or a high case hospitalization rate capable of causing moderate to severe disease in humans and capable of sustained human-human transmission); OR • Pathogens with enhanced pandemic potential (PEPP), resulting in experiments that enhanced transmissibility or virulence, or disrupted the effectiveness of pre-existing immunity. 	<ol style="list-style-type: none"> 1. Enhance transmissibility of the pathogen in humans; 2. Enhance the virulence of the pathogen in humans; 3. Enhance the immune evasion of the pathogen in humans such as by modifying the pathogen to disrupt the effectiveness of pre-existing immunity via immunization or natural infection; OR 4. Generate, use, reconstitute, or transfer an eradicated or extinct PPP, or a previously identified PEPP.
Dangerous Gain of Function Research	<ul style="list-style-type: none"> • Any infectious agent or toxin that could result in significant societal consequences. 	<ol style="list-style-type: none"> a. Enhancing the harmful consequences of the agent or toxin; b. Disrupting beneficial immunological response or the effectiveness of an immunization against the agent or toxin; c. Conferring to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against the agent or toxin or facilitating their ability to evade detection methodologies; d. Increasing stability, transmissibility, or the ability to disseminate the agent or toxin; e. Altering the host range or tropism of the agent or toxin; f. Enhancing the susceptibility of a human host population to the agent or toxin; g. Generating or reconstituting an eradicated or extinct agent or toxin.

¹Factors that may impact the assessment for determining whether a pathogen is a PPP include pre-existing population immunity, environmental stability of the pathogen, ability of the pathogen to spread via the respiratory route, ability of the pathogen to exhibit sustained human-human transmission, pathogen reproductive number (Rt) greater than one, availability of or access to measures to contain the pathogen, case hospitalization rates, case fatality rates, types and persistence of symptoms, and duration of disease.