United States Government Policy for Stopping High-Risk Life Sciences Research

July 20, 2026

1. PURPOSE

Life sciences research is necessary to ensure the United States maintains global leadership in biotechnology, biosecurity, and health and agricultural research, as well as readiness against biological threats. However, there are clear cases in which the potential benefits of life sciences research do not outweigh the potential risks, and such research should not be undertaken domestically or abroad in any circumstance. This United States Government Policy for Stopping High-Risk Life Sciences Research (hereafter referred to as the Policy) defines areas of life sciences research posing the greatest risk to our Nation's security, implements federal funding prohibitions, and establishes a robust framework for addressing risk and ensuring compliance.

This Policy defines two broad categories of life sciences research posing the highest risk, as directed by *Executive Order 14292 Improving the Safety and Security of Biological Research:*[1]

- *Dangerous gain-of-function (DGOF) research.* DGOF research enhances a property or properties of a biological agent in ways that make it more dangerous (see definitions section for full policy definition). DGOF research has the potential to significantly endanger Americans and should not be supported domestically or internationally.
- *International research of concern (IROC).* Global scientific collaboration is key to discovery. However, it is essential that research undertaken abroad does not pose a threat to public health, public safety, economic security or national security. Any federally funded life sciences research that is conducted outside of the United States must be carried out in compliance with U.S. oversight standards and policies and should not be conducted in foreign countries of concern or by foreign entities of concern (see Table 1 for further information).

This Policy establishes a robust, transparent, and accountable framework to protect against the negative consequences of life sciences research posing the highest risk. Importantly, all participants in the research enterprise are required to maintain robust vigilance and actively address risks of their research. Key to success are requirements for researchers and research institutions to provide faithful and reliable certification of materials provided to the United States Government, under penalty of law, including research applications, research disclosures, and other support. Funders of research are required to implement strong oversight mechanisms to protect our Nation's health and security as well as ensure taxpayer funded research provides benefits.

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[1] Additional statutory action is required to ensure all DGOF research and funding of DGOF from all U.S. entities are stopped. Pursuant to section 5 of Executive Order 14292, additional regulatory, legislative or other actions to broadly manage the risks associated with research that has DGOF potential, including research that is privately funded, will be explored by an interagency working group.

This Policy does not prohibit development of essential medical products and medical countermeasures to protect against bioterrorism and biological weapons, nor does it prohibit international collaboration. This Policy maintains compliance with legislation and international treaties, obligations, and frameworks, as appropriate, and encourages global cessation of DGOF research regardless of funding source. The United States continues to emphasize the importance of sharing the knowledge, products, and results of life sciences research while striving to improve the laboratory biosafety and biosecurity of life sciences research performed worldwide.

Within 180 days of the issuance of this Policy, the heads of relevant executive branch departments and agencies supporting life sciences research will promulgate implementation guidance consistent with this Policy and specific to each department and agency's mission and authorities. Implementation guidance should incorporate other United States Government efforts to safeguard the Nation's investment in research, and include modifications to review processes, funding mechanisms, and terms and conditions necessary for compliance. All provisions of Executive Order 14292 remain in effect, including the suspension of federally funded potential DGOF research required by section 3(b), until departments and agencies have promulgated implementation guidance and the review mechanisms defined within this Policy have been established.

The definitions used in this policy are found below, in Section 6.

2. SCOPE AND COVERED ENTITIES

Table 1. Federally Funded Life Sciences Research within Policy Scope.

Category*	Research	Definition	Federal Funding Status
DGOF	DGOF Research	Research with a biological agent that seeks, achieves, or has a substantial risk of achieving one or more of the outcomes listed below and could result in significant negative societal consequences:[2] 1. enhancing the harmful consequences of the biological agent;[3] 2. disrupting beneficial immunological response or the effectiveness of an immunization against the biological agent; 3. conferring to the biological agent resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that biological agent or facilitating its ability to evade detection methodologies; 4. increasing the stability, transmissibility, or ability to disseminate the biological agent; 5. altering the host range or tropism of the biological agent; 6. enhancing the susceptibility of a human, animal, or plant host population to the biological agent; or 7. generating or reconstituting an eradicated or extinct biological agent.	Prohibited
	Potential DGOF Research	Research with a biological agent that could potentially result in one or more of the outcomes listed above and could result in significant negative societal consequences.	Permissible following review and recommendation by independent third-party review body (ITPRB) to ensure research does not meet the definition of DGOF research.
IROC	Research Involving Countries or Entities of Concern	Life sciences research involving entities of concern, *i.e.*, research conducted in a country of concern; or research conducted outside the United States by an institution of concern or an individual of concern.[4]	Prohibited
	Other Risky International Research	Life sciences research that could reasonably pose a threat to public health, public safety, and economic or national security, conducted in a country with inadequate oversight to ensure that the country is compliant with United States oversight standards and policies.[5]	Permissible only following risk-based assessment of the potential threat and the institution's ability to provide adequate oversight.

* DGOF = Dangerous Gain-of-Function; IROC = International Life Sciences Research of Concern

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[2] Some research will contribute to the development and approval of medical countermeasures; this potential positive benefit should be weighed against the potential negative societal consequences.

[3] This includes creation of mirror organisms.

[4] In accordance with 42 U.S.C. 6627 and existing policies for research integrity, the Director of National Intelligence, Secretary of State, Secretary of Agriculture, and the Secretary of Health and Human Services, shall establish, maintain, and publish, as appropriate, a list of entities of concern for the purposes of this policy. These lists will be reviewed and updated, as appropriate, at least annually.

[5] As determined by the head of the funding department or agency, with support from relevant agency(ies).

The following entities will comply with this Policy:

1. All principal investigators (PIs) who receive or apply for federal funds for life sciences research.
2. All research institutions that receive federal funds for life sciences research.
3. All federal funding agencies that conduct, fund, or support life sciences research.

When a proposal includes plans to create or modify a biological agent that would meet the definition of DGOF research or potential DGOF research and is the result of *in silico* research, this policy applies. However, purely computational (*i.e.*, *in silico*) research that may include development of computational models and software, or may use such means to design novel forms of biological agents, is not prohibited by this policy unless it involves an entity of concern. The White House Office of Science and Technology Policy (OSTP) will convene an interagency group to monitor advancements at the intersection of biological sciences and artificial intelligence, including *in silico* life sciences research.

All proposed or ongoing life sciences research at research institutions that receive federal funds for life sciences research must be evaluated against the definitions in Table 1, and all proposed or ongoing federally funded life sciences research described in Table 1 is subject to the oversight listed. Research institutions that do not receive federal funding but conduct research described in Table 1 are strongly encouraged to implement equivalent oversight procedures to those described here. Failure to do so may affect future eligibility for federal funding and contracting.

3. ROLES, RESPONSIBILITIES, AND OVERSIGHT

The following section describes the organizational oversight and articulates the roles and responsibilities of entities that conduct research (*e.g.*, PIs and research institutions) and entities that fund or sponsor life sciences research.

Principal Investigators

Preparing Proposals. All proposed or ongoing life sciences research must be continuously evaluated for DGOF and IROC. Prior to submitting a proposal for federal funding, PIs must determine whether their proposed research meets the definition for DGOF or potential DGOF and will be required to attest in writing, their confirmation of this determination. In identifying life sciences research that meets the definition of DGOF or potential DGOF research, PIs must consider various types of risks: biological, physical, technological, informational, epistemic, etc.

If a PI assesses their proposed research may meet the definition of DGOF or potential DGOF research, the PI, in conjunction with their institutional review entity (IRE),[6] must complete an initial risk-benefit analysis before submitting the proposal to a funding agency. If the proposal is being considered for funding by a federal department or agency, before ITPRB review, the PI, in conjunction with their institution's IRE, must complete a full risk-benefit assessment and risk mitigation plan. This plan must include any experimental modifications to ensure no DGOF research will be conducted and any specific safeguards to ensure such an outcome. These safeguards include but are not limited to: stringent cybersecurity practices, restrictions on physical access to labs and research materials, transfers of technology and intellectual property,

[6] IREs must be established by research institutions that propose or support federally funded life science research that has the potential for DGOF, as defined in this Policy.

and disclosure to journal publishers ahead of manuscript submission and other information sharing management. PIs must also ensure proper training and oversight for all relevant laboratory personnel working on the life sciences research, including collaborating partners.

PIs must also include the names and institutional affiliations of key personnel who will participate in the proposed research, including proposed foreign collaborators and any research proposed to be conducted abroad. Should the research aims or key personnel or research institutions change during the course of the research, the PI must update the federal funding agency. Consistent with Federal law, regulation, and policy, all key personnel must disclose information related to support of professional R&D efforts from all non-Federal sources.[7]

Federally funded, not ITPRB-reviewed. PIs will continuously evaluate their federally funded life sciences research to ensure it does not meet the definition of potential DGOF research. If at any time their research meets or has the potential to meet the definition of potential DGOF research, the research should be halted and the PI, in conjunction with the IRE, will complete an initial risk-benefit analysis and inform the federal funding agency.

Federally funded, ITPRB-reviewed. When a PI's potential DGOF research has been reviewed by the ITPRB and subsequently funded by a federal agency, the PI must agree to conduct their research in accordance with the approved risk mitigation plan. The PI's research will be evaluated by the IRE at least annually, to ensure that the PI is following the risk mitigation plan and any ITPRB-informed experimental changes, as described in the funding terms and conditions, and that risk mitigation measures remain appropriate. If at any time the research or context changes to increase the potential DGOF risk, the research should be halted and the PI will notify the IRE, Institutional Contact for Dangerous Gain-of-Function (ICDGOF), and the federal funding agency to determine if adjustments need to be made to the risk mitigation plan or if additional review is needed. Regardless of whether it was reviewed by the ITPRB, if at any time the research may meet the definition of DGOF research, the PI will halt the research immediately and notify the ICDGOF, IRE, and federal funding agency within 24 hours. Failure to recognize and report unanticipated DGOF research may result in revocation of ongoing federal funding, and a maximum five-year period of ineligibility for federal life sciences funds, and additional penalties consistent with Federal law and regulations for research institutions as well as principal investigators.

Research Publication. Should a publication outlet advise authors to identify covered research details in their cover letters, the PI and coauthors will describe the precautionary measures taken, any information-related risk mitigation actions required as a condition of funding, and the IRE review status of the research. To facilitate the responsible communication of research findings, publication outlets should consider establishing review procedures for potential DGOF research. When journals receive manuscripts describing potential DGOF, editors could consider subjecting the manuscript to more stringent review and oversight than ordinary peer review.

Research Institutions

Research institutions that propose or support federally funded life sciences research that has the potential for DGOF will designate an ICDGOF. All applications submitted for federal funding will be certified by the ICDGOF to ensure that proposals are accurate and truthful, and compliance will be monitored under penalty of law. Research institutions will also attest that

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[7] This includes resources provided directly or indirectly to the individual, including material and in-kind support.

each life sciences research proposal for federal funding has been evaluated for DGOF and IROC concerns and has been correctly attested by the PI. Research institutions will report potential DGOF and DGOF research supported by non-federal funding to their primary federal life sciences funding agency annually. This information will be treated as proprietary business information, as appropriate, and funding agencies will protect legitimate intellectual property interests.

Research institutions that receive federal life sciences funding will implement oversight mechanisms to identify non-federally funded potential DGOF and DGOF research, as well as monitor for IROC concerns. Such institutions are strongly encouraged to develop risk-benefit assessment and plans and procedures to prevent and stop DGOF research. Research institutions will avoid public release of information compromising national security, the safety and security of life sciences research, confidential business information, or sensitive information of relevant individuals or legitimate intellectual property interests.

Institutional Review Entity (IRE). Research institutions that propose or support federally funded life science research that has the potential for DGOF will establish an IRE consisting of at least five members who have life science subject matter expertise with sufficient knowledge to review potential DGOF research. These institutions are encouraged to include members of the local community and Institutional Biosafety Committee. Research institutions will ensure members have no conflicts of interest with research under their review and will implement appropriate protections for providing access to potentially sensitive information, such as non-disclosure agreements. The IRE, in conjunction with the PI, will perform an initial risk-benefit analysis, to include examination of potential negative societal consequences, for any potential DGOF research, and communicate their findings to the federal funding agency. If a potential DGOF research proposal is being considered for funding, the IRE, in conjunction with the PI, will provide a full risk-benefit assessment and risk mitigation plan to the federal funding agency, which will provide it to the ITPRB. When an ITPRB-reviewed life sciences project is awarded federal funding, the IRE will oversee implementation of the risk mitigation plan and ITPRB-informed experimental modifications, as described in the funding terms and conditions of the award. IREs will evaluate risk mitigation plans at least annually, and make modifications as needed. Modifications will be reported to the federal funding agency for review and approval. IREs will maintain all records necessary to demonstrate compliance with this policy.

Federal Funding Agencies

Federal funding agencies will evaluate each life sciences research proposal being considered for funding for compliance with this policy. Federal funding agencies will review all PI attestations for proposals being considered for funding; identify any DGOF research, potential DGOF research, or IROC not identified as such by PIs and institutions; and provide the Office of Management and Budget (OMB) and the ITPRB all negative and positive PI attestations on all potential DGOF research or IROC proposals being considered for funding.

Independent third-party review body (ITPRB). Federal funding agencies will establish a single United States Government ITPRB to review potential DGOF research being considered for funding. The ITPRB will make a final recommendation to the funding agency based on the full risk-benefit assessment, as well as the research project's plans and procedures for preventing DGOF research, and other relevant information. To the extent practicable, the ITPRB should complete the review process and provide their recommendation to the federal funding agency within 90 calendar days of receipt of review materials to inform the funding agency's decisions.

The ITPRB will publicly report annually on recommendations made to federal funding agencies, avoiding the release of information that might compromise national security, the safety and security of research activities, confidential business information, any identifiable sensitive information of relevant individuals or legitimate intellectual property interests.

Expedited Reviews. Heads of research departments and agencies, or their representatives, in consultation with the Director of OSTP and the Assistant to the President for National Security Affairs (APNSA), may request an expedited ITPRB review if the potential benefits of the research exceed the potential risks, and the research is:

1. A direct result of a declared public health or agricultural emergency, and is necessary to facilitate an effective response measure; or
2. Critical to national security.

Projects approved through expedited review do not supersede existing statutes, regulations, or policies that may apply to the research.

Potential DGOF research. Federal funding agencies will notify the research institution and the ITPRB regarding potential DGOF research being considered for funding. The funding agency will request that the IRE, in conjunction with the PI, complete a full risk-benefit assessment and risk mitigation plan, and provide them to the ITPRB. Should the ITPRB request additional information, the IRE, in conjunction with the PI, should provide the information in a timely manner. When federal funding is awarded for a project that was reviewed by the ITPRB, the federal agency must confirm that the IRE and PI accept the funding terms and conditions enumerated in the following sections. Funding agencies will submit annual reports of ITPRB-reviewed research to the Director of OSTP, the APNSA, and the Director of OMB. The reports will include any recommendations for changes to the oversight process established by this policy, including approaches to assessing risks and benefits and mitigating risks. The report will also include any information regarding non-federally funded potential DGOF or DGOF research that has been reported by research institutions. Federal funding agencies will maintain records from the attestation process and make them available for audit by OSTP and OMB. OSTP and the interagency may periodically review a subset of studies to assess consistency in implementation of the policy across funding agencies. The ITPRB may randomly review and audit up to 25% of all negative attestations annually for compliance.

International Research of Concern (IROC). Federal funding agencies will not fund life sciences research involving entities of concern (*i.e.*, research conducted in a country of concern; or research conducted outside the United States by an institution of concern or an individual of concern).[8] Federal funding agencies will review the names and institutional affiliations of key personnel who will participate in the proposed research, including any updates provided during the course of the research, to ensure that no research is proposed or is being conducted outside the United States by a foreign individual of concern or foreign institution of concern. This will

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[8] In accordance with 42 U.S.C. 6627 and existing research integrity policies, the Director of National Intelligence, Secretary of State, Secretary of Agriculture, and the Secretary of Health and Human Services, shall establish, maintain, and publish, as appropriate, a list of entities of concern for the purposes of this policy. These lists will be reviewed and updated, as appropriate, at least annually.

be done in coordination with existing policies and processes established for research security, with input from relevant United States Government agencies.

For other international life sciences research proposals being considered for funding, department or agency heads, in consultation with the Secretary of State, as appropriate, will ensure that the institution performing the research meets, exceeds, or complies with U.S. biosafety and biosecurity oversight standards and policies. Departments or agencies will use a risk-based method to determine the adequacy of the oversight.

4. IMPLEMENTATION GUIDANCE

Within 120 days of this policy issuance, the Director of National Intelligence, the Secretary of Agriculture, Secretary of State, and the Secretary of Health and Human Services, shall establish, maintain, and publish, as appropriate, a list of entities of concern for the purposes of this policy, in alignment with 42 U.S.C. 6627. This list will be reviewed and updated, as appropriate, at least annually.

Within 120 days of this policy issuance, federal funding agencies will develop resources and issue DGOF and IROC oversight implementation guidance to research institutions. This guidance will define roles, responsibilities, and review standards to ensure consistent compliance. Federal funding agencies will address all implementation questions and concerns from these institutions. To ensure consistent policy implementation, the Executive Office of the President (EOP) will lead an interagency coordination group to align plans across all funding agencies and relevant departments. EOP will have final clearance of all implementation plans. Agencies will coordinate with relevant stakeholders to support this effort.

Within 180 days of this policy issuance, research institutions that receive any federal life sciences funding will establish an IRE, as defined by this policy, and designate an ICDGOF. Institutions will develop and implement educational training for researchers on DGOF research in accordance with this policy. The research institutions will mandate this as an annual training and maintain a record of all individuals who accept and comply with this policy. Research institutions will establish implementation policies for identifying and addressing DGOF research and potential DGOF research, applicable to all life sciences research conducted at their institution. These policies and procedures will be in place before any research proposals categorized as potential DGOF can proceed to the federal funding agency.

Verification, Compliance, and Transparency

Within 180 days of this policy issuance, the heads of relevant departments and agencies, consistent with existing laws and regulations and pursuant to Executive Order 14292, should ensure every life sciences research contract, Other Transaction, cooperative agreement, or grant award includes the following elements:

1. Contractual counterparty or award recipients must confirm compliance with this policy and any applicable regulations promulgated by the procuring, contracting, or award-offering agency is material to the United States Government's payment decisions for purposes of 31 U.S.C. 3729(b)(4);
2. The violation of this policy or any applicable regulations promulgated by the procuring, contracting, or award-offering agency by any recipient of financial assistance may be considered a violation by the recipient's employer or institution; and

3. Any recipient of financial assistance, employer, or institution found to be in violation of oversight, tracking, and reporting obligations imposed by this policy, or any applicable regulations promulgated by the procuring, contracting, or award-making agency, may be subject to immediate revocation of ongoing federal funding, up to a 5-year period of ineligibility for federal life sciences funds offered by relevant funding agencies, and additional penalties consistent with existing Federal law and regulations.

Within 90 days of this policy issuance, federal funding agencies and relevant departments will establish a single ITPRB. The ITPRB will develop a charter, procedures, and criteria by which to review proposals that require ITPRB review, consistent with applicable law. The ITPRB will:

1. Consist of officials and subject matter experts in the field(s) of: molecular biology, microbiology, clinical medicine, biosafety, biosecurity, cybersecurity, medical countermeasure development and availability (human and veterinary), law enforcement and national security, ethics, public health and agricultural preparedness and response, biodefense, Select Agent Regulations, public health policy, as well as other relevant areas, as determined by the body.
2. Provide the names of member officials and subject-matter experts, confirming that they have no conflicts of interest.
3. Ensure that relevant agencies, including federal law enforcement agencies, intelligence community components, defense agencies, and the Department of State have an opportunity to share information and leverage national security biological review processes that might inform the assessments.
4. Establish procedures for expedited review to be completed within 30 days, if not sooner for time-sensitive national security objectives.

5. POLICY ADHERENCE, REVIEW, AND REVISION

Pursuant to subsection 4(a) of Executive Order 14292 and Section 2315 of the Consolidated Appropriations Act, 2023 (42 U.S.C. 6627), this policy replaces the 2024 "United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential," including the oversight described in the 2012 "United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern," the 2014 "United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern," and the 2017 "Recommended Policy Guidance for Potential Pandemic Pathogen Care and Oversight."

This policy does not supersede or modify federal statutory authorities applicable to relevant departments and agencies, including regulatory authorities managed by the Federal Select Agent Program (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331) and export control regulations (15 CFR Parts 730-774 and 22 CFR Parts 120-130). Except as expressly stated herein, this policy acts in conjunction with existing federal statutes, regulations, and guidance documents.

Per policy guidance, departments and agencies are expected to take enforcement actions within their authorities for any failure to adhere to this policy. All funding agencies are to incorporate these requirements as terms and conditions of funding. If a funding recipient fails to comply with these terms and conditions, enforcement actions such as suspension, termination, and withholding of support may be pursued. Failure to adhere to this policy and relevant implementation guidance issued by federal funding agencies, including the deliberate issuance of false negative attestation, may result in revocation of federal research funding and up to a 5-year

period of ineligibility for federal life sciences financial assistance, to the extent consistent with existing laws and regulations.

OSTP, in consultation with relevant federal departments and agencies, will review this policy and update it as necessary, at least every 4 years. Reviews of this policy or its implementation guidance should be consistent with 42 U.S.C. 6627 (a)(1)(B) and consider new risks arising from emerging scientific and technological advances, as well as any implementation challenges.

6. DEFINITIONS

This policy represents a shift from the previous list-based approach to a risk-based approach. The definitions provided in this section are consistent with the goals of this new policy. For the purposes of this policy, terms are defined as follows.

a. "Award" is defined as the provision of funds by a federal funding agency, based on an approved application and budget or progress report, to an organizational entity or an individual to carry out a project or activity.

b. "Biological agents" are as defined in 18 U.S.C. 178, as well as biologically derived toxins: any microorganism (including bacteria, viruses, fungi, or protozoa), as well as infectious material (including prions, self-transmissible or conjugative plasmids, and other transmissible compositions of biological matter), or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious material, capable of causing:

   i. Death, disease, or other harm in a human, animal, plant, or other living organism; or

   ii. Deterioration of food, water, air, equipment, supplies, or material of any kind; or

   iii. Deleterious alteration of natural resources.

c. "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.

d. "Biosecurity" is the protection, control of, and accountability for high-consequence biological agents and toxins, and critical relevant biological materials and information to prevent unauthorized access, possession, loss, theft, misuse, diversion, and intentional release.

e. "Dangerous gain-of-function research" is research with a biological agent that seeks, achieves, or has a substantial risk of achieving one or more of the outcomes listed below and could result in significant negative societal consequences:[9]

   i. Enhancing the harmful consequences of the biological agent;[10]

   ii. Disrupting beneficial immunological response or the effectiveness of an immunization against the biological agent;

   iii. Conferring to the biological agent resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that biological agent or facilitating its ability to evade detection methodologies;

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[9] Some research will contribute to the development and approval of medical countermeasures; this potential positive benefit should be weighed against the negative societal consequences.

[10] This includes creation of mirror organisms.

iv. Increasing the stability, transmissibility, or ability to disseminate the biological agent;

v. Altering the host range or tropism of the biological agent;

vi. Enhancing the susceptibility of a human, animal, or plant host population to the biological agent; or

vii. Generating or reconstituting an eradicated or extinct biological agent.

f. "Federal funding agency" is a federal department, agency, institute, center, or office that funds or sponsors intramural or extramural research with biological agents at research institutions in the United States or internationally.

g. "Has/have the potential" 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.

h. "Institutional Contact for Dangerous Gain-of-Function Research (ICDGOF)" is the official designated by the research institution to serve as an internal resource for the application of this policy as well as the liaison (as necessary) between the institution and the relevant federal funding agency.

i. "Key personnel" are individuals who contribute in a substantive, measurable way to the scientific development or execution of a project, regardless of whether they receive compensation.

j. "Life sciences research" means research pertaining to 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). This includes funding for building research capacity and infrastructure, including but not limited to, construction or renovation of biosafety level 3 or 4 laboratory space (BSL-3 or BSL-4).

k. "Principal investigator" is the senior or 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 institution or within multiple institutions. Some agencies refer to this individual as a Project Director.

l. "Potential DGOF" is research with a biological agent that could potentially result in one or more of the outcomes listed in the DGOF definition above and could result in significant negative societal consequences.

m. "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.

n. "Risk mitigation plan" is a plan that includes experimental modifications to ensure no DGOF research will be conducted and any specific safeguards to ensure such an outcome. These safeguards include but are not limited to: stringent cybersecurity practices, restrictions on physical access to labs and research materials, transfers of technology and intellectual property, disclosure to journal publishers ahead of manuscript

submission, and other information sharing management. It is not a plan on how to allow for the performance of DGOF or potential DGOF research.

o. "Significant negative societal consequences" means an event that results in a substantially negative outcome or produces substantially negative effects, which could include an information hazard, to one or more critical areas or systems, including public health, agriculture, the economy, national security, or the environment. For the public health system, this could include the uncontrolled spread of a biological agent with detrimental public health or environmental impacts, such as a surge in hospital admissions that impairs the function of the health system. For the economy, this could involve asset or trade losses or restrictions associated with a commodity of importance to the agriculture system. Such substantial negative effects can apply across multiple sectors. For example, combinations of effects to agriculture, energy, recreation (tourism, hunting, fishing, etc.), health care, etc. can together constitute significant negative societal consequences.