

Biosecurity Seal of Approval Proposed Biosecurity Norms/Requirements¹

In order to be eligible for a “Seal of Approval”², this chart proposes a set of potential standards for an institution, laboratory, facility, or other entity conducting research that includes one of the seven experiments of concern³, experiments enabled by tools and technologies developed since 2004, which may result in additional risk, and/or research that involves especially dangerous pathogens, toxins, or biological materials with pandemic potential.⁴

For the purposes of the chart on the following page, the seven experiments of concern include those that:

1. Demonstrate how to render a vaccine ineffective.
2. Confer resistance to therapeutically useful antibiotics or antiviral agents.
3. Enhance the virulence of a pathogen or render a non-pathogen virulent.
4. Increase transmissibility of a pathogen.
5. Alter the host range of a pathogen.
6. Enable the evasion of diagnostic/detection modalities.
7. Enable the weaponization of a biological agent or toxin.

For purposes of the chart on the following page, experiments that may result in new classes of risk could include:

1. Genome editing constructs targeted to human DNA sequences, combined with vectors with potential transmissibility.
2. Reconstitution of highly pathogenic viruses or closely related species, such as smallpox or horsepox.
3. Microbes or constructs that can target specific human subpopulations.
4. Microbes or constructs engineered to disrupt or damage the human microbiome.
5. Use of the synthetic biology “design, build, test” cycle to select for pathogen phenotypes associated with increased transmissibility, virulence, and ability to circumvent medical countermeasures or evade detection.
6. Organisms with intended or likely persistence in the environment, including those with fitness advantages over wild type.
7. Microbes engineered to metabolize critical infrastructure materials, such as concrete or metals, which have the potential to cause large-scale disruption.
8. Microbes or other engineered organisms with the potential to severely impair production of agricultural staples.



¹ For use by the working group and in the pilot project network(s) to help guide discussions about incentives.

² A “Seal of Approval” can be built around several key ideas: (1) Careful risk assessment before conducting potentially dangerous dual-use research that would be problematic if materials were accidentally released into the surrounding community or the environment, (2) careful consideration of information hazard risks before publishing sensitive scientific research, and (3) careful risk assessment when providing potentially dual-use goods and services to a public customer base.

³ From: “Biotechnology Research in an Age of Terrorism.” U.S. National Academy of Sciences. (2004).

⁴ Note that these would be in addition to national requirements.

Working Group to Establish a Seal of Approval that Incentivizes Adherence to Biosecurity Norms

<p>Risk Assessment and Oversight</p>	<p>Material Control, Information Hazard Management, and Physical Protection</p>	<p>Biosecurity & Biosafety Risk Mitigation, Training, and Personnel Requirements</p>
<p>Established a designated entity, such as an Institutional Biosafety & Biosecurity Committee, for oversight of research that involves dangerous pathogens, toxins, pathogens with pandemic potential, and/or dual use research. <i>This entity should perform a risk assessment, which informs a decision about whether the experiments should proceed.</i></p>	<p>Have specific policy in place for material control of especially dangerous pathogens, including an established entity within the institutions responsible for the enforcement of biosecurity requirements, including compliance with national legislation and regulations.</p>	<p>Require specific regular education on: bioethics, experimental design, and dual use research, including annual training on updates and new developments regarding biosafety and biosecurity.</p>
<p>Conducted an assessment to identify ongoing research involving especially dangerous pathogens, toxins, pathogens with pandemic potential, and/or dual use research involving the types of experiments outlined above. <i>All research involving these experiments requires a risk mitigation plan.</i></p>	<p>Have specific biosafety requirements in place, including an established entity within the institution that is responsible for the enforcement of biosafety requirements, including compliance with national legislation and regulations.</p>	<p>Require <u>biosecurity</u> training, using a standardized approach, such as through a common curriculum or a train-the-trainer program, for personnel working in facilities housing or working with especially dangerous pathogens, toxins, or biological materials with pandemic potential.</p>
<p>Review and assess risks associated with proposed research using an established specific institutional review entity, such as an Institutional Biosafety & Biosecurity Committee, if:</p> <ul style="list-style-type: none">  The research involves one or more of the seven classes of experiments of concern, initially defined in 2004; or  The research includes experiments enabled by tools and technologies developed since 2004, which may result in new classes of risk that were not previously considered. 	<p>Maintain an up-to-date record of its facilities in which especially dangerous pathogens and toxins are stored or processed, including details on inventories and inventory management systems of those facilities.</p>	<p>Require <u>biosafety</u> training, using a standardized approach, such as through a common curriculum or a train-the-trainer program, for personnel working in facilities housing or working with especially dangerous pathogens, toxins, or biological materials with pandemic potential.</p>

Risk Assessment and Oversight	Material Control, Information Hazard Management, and Physical Protection	Biosecurity & Biosafety Risk Mitigation, Training, and Personnel Requirements
<p>Conduct a thorough risk assessment, including an analysis of potential unintended consequences <u>before</u> initiating work on dangerous pathogens or other potentially harmful microorganisms.</p>	<p>Screening orders and customers:</p> <ul style="list-style-type: none"> ✚ Synthetic nucleic acid providers screen for pathogenic sequences and end-users.⁵ ✚ Foundries and companies that provide synthetic biology tools and services beyond nucleic acid synthesis screen their orders and customers. ✚ All commercial providers and institutional review entities (e.g., Institutional Biosafety & Biosecurity Committee) conduct end-user screening for orders of especially dangerous pathogens, toxins, and pathogens with pandemic potential. ✚ Researchers should only order synthetic nucleic acids and other synthetic biology tools and services from companies that conduct screening. 	<p>Develop specific countermeasures, antidotes, or intrinsic biocontainment* in parallel to research where there is a risk of population-wide damage, multi-generational effects, or severe ecosystem disruption.</p> <p><i>*Note intrinsic biocontainment means containment that is part of the microorganism itself.</i></p>
<p>Consider whether there are specific types of experiments that should never be conducted. Examples could include:</p> <ul style="list-style-type: none"> ✚ Engineering a microorganism that is designed to cause severe, large-scale damage to human or animal life. ✚ Engineering a microorganism that is designed to cause severe, long-term damage to the environment on a scale that would undermine its ability to support human and animal life. ✚ Engineering a microorganism that is designed to severely impair production of agricultural staple products. 	<p>Pre-publication review:</p> <ul style="list-style-type: none"> ✚ Evaluate potential biosecurity risks posed by publication of their research. ✚ Have a review entity conduct a formal pre-publication review for all proposed research involving any of the seven experiments of concern or experiments enabled by tools and technologies developed since 2004, which may result in new classes of risk that were not previously considered. Publication of this research requires a transparent public communication plan. ✚ Apply a “no undercut” principle, in which research rejected by one organization for risk-related reasons would not be published by a second organization without specific consultation. 	

⁵ This could include a requirement to purchase synthesized nucleic acids from a company that screens for end-users and pathogenic sequences.

Risk Assessment and Oversight	Material Control, Information Hazard Management, and Physical Protection	Biosecurity & Biosafety Risk Mitigation, Training, and Personnel Requirements
	<p>Annually review and update documentation of:</p> <ul style="list-style-type: none"> ✚ Procedures for physical containment, operation practices, failure reporting systems, and/or cyber-security of facilities in which especially dangerous pathogens and toxins are stored or processed. ✚ Institutional actions to consolidate inventories of especially dangerous pathogens and toxins into a minimum number of locations. ✚ Institutional actions to destroy un-needed collections. ✚ Institutional actions to maximize research that would preclude culturing live pathogens. ✚ Policies, records and/or protocols pertaining to the use of international standards for the safe and secure transport of infectious substances (Categories A and B) and their destruction. 	<p>Conduct annual personnel reliability screening⁶ that includes the following elements:</p> <ul style="list-style-type: none"> ✚ Requirements for personnel with access to especially dangerous pathogens, toxins, or biological materials with pandemic potential to undergo: drug testing, background checks, and psychological/mental fitness checks. ✚ Annual evaluation through a structured interview to identify potential signs and symptoms of behavioral risks resulting from medical, psychological, or social changes which may have occurred since the initial pre-access assessment, and which may otherwise threaten an employee's ability to safely carry out assigned duties. ✚ Self- and peer-recognition and reporting of behavioral changes or issues of concern. <p>Utilization of a Personnel Suitability Team (PST) to receive and evaluate concerns of safety and security brought forth by the various mechanisms including outcomes of the annual evaluation, self-reporting by employees, or peer-reporting, as described below, and to render a decision as appropriate.</p>
	<p>Do not use pathogen DNA when not working on pathogens. For example, researchers refrain from using housekeeping genes from pathogens and should instead use DNA sequences from organisms known to be non-pathogenic. <i>This will help maintain a clear distinction between work that requires additional oversight and scrutiny, and work that does not.</i></p>	

⁶ <https://www.bu.edu/researchsupport/forms-policies/personnel-suitability-and-reliability-policy-national-emerging-infectious-diseases-laboratories/>