Biosecurity Policy

Context and objective

CEPI's mission is to accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats so that they can be accessible to all people in need. To support this mission, CEPI supports a range of vaccine research, development and manufacturing (R&D&M) activities. As a steward of global public and private funds, CEPI has a critical responsibility to ensure its vaccine R&D&M investments do not inadvertently increase epidemic or pandemic risk due to accidental or deliberate misuse of CEPI-sponsored research.

CEPI is committed to ensuring that the vaccine R&D&M activities CEPI funds, and the project management processes CEPI uses, are conducted in accordance with internationally recognised Biosecurity and Biosafety norms, principles, standards and practices. By considering Biosecurity and Biosafety risks (biorisks) during pre- and post-award processes and defining requirements before an outbreak, CEPI can ensure risks are considered across the R&D&M continuum and help reduce delays at moments when speed is essential for achieving the 100 Days Mission.

This policy sets out CEPI's expectations for its funding oversight and awards to Third Parties to uphold appropriate and robust Biosecurity and Biosafety measures that effectively manage the risks associated with CEPI-sponsored research. To give Third Parties more detail about the requirements set out below, resources are provided at https://cepi-tr.tghn.org/biosecurity/ which describe how CEPI assesses the inherent level of biorisk of a project and the information and/or supporting documentation Third Parties can provide to explain how they mitigate the biorisks and demonstrate compliance with this Policy.

While the emphasis of this policy is on epidemic and pandemic viral pathogens reflecting CEPI's current scope of work, CEPI envisions that these same principles apply to other types of pathogens, and CEPI reserves the right to adapt and apply this policy, as appropriate.

Definitions

Biosafety: Containment principles, technologies, and practices that are implemented to prevent unintentional exposure to Biological agents or their inadvertent release (WHO, 2020).

Biosecurity: Principles, technologies, and practices that are implemented for the protection, control, and accountability of Biological materials and/or the equipment, skills and data related to their handling. Biosecurity aims to prevent their unauthorized access, loss, theft, misuse, diversion, or release (WHO, 2020).

Biological agent: A microorganism, virus, biological toxin, particle or otherwise infectious material, either naturally occurring or genetically modified, which may have the potential to cause infection, allergy, toxicity or otherwise create a hazard to humans, animals or plants (WHO, 2020). Biological agents can be high consequence Biological agents if they have the potential for widespread public health impact, to overwhelm health system capacity, or to threaten regional or global security. This category includes naturally occurring, emerging, re-emerging, and potentially engineered Biological agents—especially those with known or projected epidemic or pandemic potential.

Biological materials: Materials derived from a biological source, including genetic material or sequence data, derived from Biological agents.

Biorisk management: Principles, technologies and practices that are implemented to prevent unintentional exposure to Biological agents and their inadvertent release (i.e., laboratory Biosafety) as well as unauthorized access, loss, theft, misuse, diversion or release (i.e. laboratory biosecurity), including protection, control and accountability of Biological materials and/or the equipment, skills and data related to their handling (WHO Resolution 77.7, 2024).

Emerging and converging technologies: Innovative and rapidly developing technologies within the biotechnology field that are not yet widely adopted but have the potential to significantly impact the industry, society and the economy. These technologies often involve new biological applications or innovative approaches to existing ones and are characterized by their potential to disrupt traditional methods and create new opportunities and risks.

Incident: An occurrence that has the potential to, or results in, the exposure of personnel to high-consequence Biological agents and/or their deliberate or accidental release (that may or may not lead to actual harm); or an Incident occurrence that has the potential to reduce the security of high-consequence Biological agents or information pertaining to them.

Third Party: Contracting parties of CEPI, including (i) suppliers, comprising of individuals, organisations and companies that provide or are intending to provide goods or services, (ii) awardees receiving funding and (iii) other partners.

Virus with enhanced epidemic or pandemic potential (VEEPP): These are viruses which have been modified resulting in increased risk to the human population of causing an epidemic or pandemic. They are designed or created by a subset of *in-vitro*, *in-vivo* and *in-silico* research, whereby the research results in, or could be reasonably anticipated to result in, modification of a virus so it has enhanced epidemic or pandemic potential in the human population compared to the wild-type virus. For example, this includes modifications that increase the transmissibility or virulence of the virus, or that enable it to evade or reduce the effectiveness of pre-existing immunity, therapeutics or vaccines. Viruses with such enhancements may have increased potential to cause widespread public health impact, overwhelm health system capacity, or threaten regional or global security.

Applicability

This policy applies to CEPI funding oversight and all CEPI Third Parties who are engaged in activities that involve the handling of Biological materials regardless of geographic location. CEPI expects CEPI staff to consistently apply the policy to pre- and post- award process and all awardees and sub-awardees to purchase supplies and services from reputable sources and undertake proportionate due diligence.

Policy statement

At the heart of CEPI's approach to Biosecurity and Biosafety is a commitment to responsible science and global equity. As we fund and advance critical research to prepare for future epidemics and pandemics in support of the 100 Days Mission, it is essential that all CEPI-funded research is conducted safely, securely, and in ways that maximise societal benefit.
CEPI also recognises that effectively mitigating Biosecurity and Biosafety risks is a shared responsibility across the R&D&M continuum, including research funders like CEPI, the researchers CEPI supports, the facilities where the work is conducted, the governments of the countries in which it takes place, and scientific publishers that communicate research findings.

CEPI is committed to ensuring that the scientific and public health benefits of CEPI-funded activities contribute to the 100 Days Mission and that any identified Biosecurity and Biosafety risks are effectively mitigated. To support this, CEPI takes a systematic, risk-based approach to:

- Identify and assess Biosecurity and Biosafety risks across CEPI-funded vaccine R&D&M activities both prior to funding and throughout the research life cycle.
- Require clear and appropriate Biosecurity and Biosafety risk mitigation measures to protect personnel, surrounding communities, and the broader public.

- Ensure consistent application of these requirements across CEPI's vaccine R&D&M portfolio, while recognizing the diverse regulatory and operational contexts of our partners.

Policy requirements of Third Parties

CEPI has established nine core Biosecurity and Biosafety requirements that all awardees must adhere to as a condition of funding:

1. Adhere to applicable Biosecurity and Biosafety legislation, regulation, and policies:

All CEPI-funded work must be conducted in adherence with applicable Biosecurity and Biosafety legislation, whether local, national or regional, or combination thereof, including UN Security Council Resolution 1540, as a baseline requirement.

If comprehensive Biosecurity and Biosafety regulations are not in place in the location where the work is conducted, then adherence with international Biosecurity and Biosafety guidance such as WHO Laboratory Biosafety Manual 4 (2020), WHO Laboratory Biosecurity Guidance (2024), or equivalent is required.

Consistent with CEPI's approach in other areas, if CEPI requirements conflict with applicable national laws or regulations, CEPI partners are expected to apply the highest standards consistent with such national laws and regulations and promptly inform CEPI of the conflicts and planned approaches to address them.

2. Conduct Biosecurity and Biosafety risk assessments:

Biorisk assessments are mandatory for all projects involving Biological material. Each assessment must identify potential Biosecurity and Biosafety risks throughout the entire research workflow, including sample collection, transport, processing, storage, research, analytics, and safe disposal of waste. The assessment must also specify the controls in place to protect laboratory staff, facility staff and the environment from the identified risks.

3. Deliver effective organisational management and oversight:

All CEPI Third Parties must designate responsible individual(s) within their institutions who are accountable for adherence to Biosecurity and Biosafety requirements as outlined below. Recipients of CEPI funding maintain appropriate Biorisk management oversight to ensure that:

- A risk-benefit justification demonstrating how the anticipated research benefits outweigh the identified risks and proposed mitigations.
- The work complies with applicable legislation and regulations.
- The identified risks can be managed with available resources (e.g., facilities and trained laboratory staff).
- Risks are reassessed throughout the lifetime of the project.

Awardees must conduct regular internal audits and adherence assessments for projects based on the Biosecurity and Biosafety risks they present. Any Incidents or non-conformances that could lead to a breach in Biosecurity and Biosafety must be promptly reported to the relevant authority, in line with their local and national regulations, as well as the relevant CEPI project team and the CEPI Biosecurity department. (contact.cepibiosecurity@cepi.net).

4. Collect, manage and store samples in accordance with best practice:

All biological samples collected in CEPI-sponsored research must be obtained ethically, with appropriate informed consent and/or assent, and in conformity with international guidelines such as the ICH E6(R3) Good Clinical Practice Guideline and the ISBER Best Practices (Fifth edition sections C1.4 and F41.1), as well as applicable national legislation. Samples must be processed and stored in accordance with appropriate laboratory Biosecurity and Biosafety standards to protect personnel, preserve sample integrity maintain accurate inventories of samples and ensure data security.

5. Define and manage emergency response plans:

Third Parties must have written emergency response plans and ensure personnel are trained to respond appropriately to foreseeable Incidents. These plans should cover scenarios such as:

- Release of pathogens within or outside the laboratory.
- Equipment failure affecting containment or safety systems.
- Human error leading to exposure or contamination.
- A physical or data security threat to facilities.
- Natural disasters (e.g., earthquakes, extreme weather events).

6. Ensure appropriate protection and information security for Biosecurity sensitive data:

CEPI is committed to safeguarding data generated through its programmes against unauthorized access, misuse, or diversion. Accordingly, all Third Parties must comply with the data protection, security, and cybersecurity standards outlined in CEPI's Third-Party Code.

Partners must assess and manage Biosecurity risks associated with their data, to ensure appropriate measures for secure management and controlled accessibility of sensitive data to enable vaccine development in line with CEPI's mission. This applies to datasets involving:

- High-consequence Biological agents.
- Biosecurity risks, or emerging/converging technologies.
- Derivatives of these data, including AI tools.

Where necessary, CEPI will apply risk-based managed access approaches to mitigate Biosecurity risks while ensuring fair access and collaboration for all responsible actors.

7. Assess activities for the potential to generate viruses with enhanced epidemic or pandemic potential (VEEPP):

CEPI does not support research that could reasonably be anticipated to increase the transmissibility or pathogenicity of viruses, which CEPI refers to as VEEPP research. Such activities are defined as those that could result in significant societal harm and that seek or achieve one or more of the following outcomes:

a) Increase the ability to interfere with, bypass, or reduce the effectiveness of therapeutic or prophylactic treatments or vaccines.
b) Enhance virulence, communicability, transmissibility or potential to cause death.
c) Alter host range or tropism of the agent.
d) Modify the agent to evade detection methods and diagnostics.
e) Increase environmental stability, transmissibility, or the ability to disseminate the agent.
f) Enhance the susceptibility of a human host population to the agent.
g) Generate or reconstitute an eradicated or extinct virus.
h) Increase the ease by which an infectious agent might be weaponised.

8. Ensure responsible procurement of nucleic acid synthesis services and equipment:

CEPI funding may only be used to procure nucleic acid synthesis services and equipment from providers that implement comprehensive and verifiable screening mechanisms for synthetic nucleic acid orders. Providers should preferably be members of the International Gene Synthesis Consortium (IGSC) (see Informing Documents below).

9. Promote responsible emerging and converging technologies development and applications:

All Third Parties must adhere to CEPI's Third Party Code, which sets clear standards for responsible technology adoption and use, including the FAIRAI principles (Fairness, Accountability, Integrity, Responsibility, and Innovation).

Special attention should be given to emerging technologies deployed in CEPI-funded projects that could pose Biosecurity or Biosafety risks, such as AI-enabled biological design tools for vaccine design and development. For projects involving AI-enabled biological design tools, CEPI awardees are expected to comply with Community Values, Guiding Principles, and Commitments for the Responsible Development of AI for Protein Design (see Informing Documents below).

Policy Ownership, Implementation and Training

The Director of Biosecurity is the owner of this policy. CEPI management and the Executive Investment Committee of the CEPI Board are responsible for endorsing this policy, dedicating the appropriate resources for its implementation, and fostering a Biosecurity and Biosafety culture that upholds its principles and provisions.

The CEPI Biosecurity department, within the Governance, Policy, Strategy and Biosecurity (GPSB) division, is responsible for implementing this policy by developing and promulgating associated Biosecurity and Biosafety procedures and tools to support policy implementation and ensuring adequate communication to relevant stakeholders.

It is the responsibility of the policy owner to ensure that appropriate levels of information, awareness and training are provided to Third Parties and relevant employees to ensure compliance with this policy.

Monitoring and reporting

CEPI will review the implementation of this policy in accordance with the Annual Internal Audit and Assurance Plan, as agreed with CEPI Management and the Audit and Risk Committee. Compliance by CEPI partners will be monitored through CEPI's risk-based partner assurance programme.

CEPI expects its staff to report any suspicion of non-compliance immediately, to their usual CEPI contact and the policy owner as soon as possible. If appropriate, concerns may also be raised in accordance with the CEPI Whistleblowing Policy, and/or through CEPI's external Whistleblowing channel.

Violations and exceptions

Compliance with the Biosecurity Policy is the responsibility of the Third Party. Any breach must be appropriately investigated, its impact assessed and corrective actions implemented to prevent reoccurrence. These events will be managed via appropriate dialogue between CEPI and the impacted parties and documented via the CEPI risk management process.

Any exceptions to this policy or related procedures must be escalated to CEPI for approval. Exceptions must be clearly justified, assessed on a risk basis and formally documented.

While this policy aims to be as clear and direct as possible, CEPI recognises that it cannot address every potential risk or situation that may arise. In such cases, individuals and Third Parties are encouraged to bring questions, suggestions and concerns to CEPI.

Where required, violations of the CEPI Biosecurity Policy may result in immediate revocation of CEPI funding, project termination, and/or legal action.

Informing Documents

Laboratory Biosafety Manual, 4th edition (2020)
https://www.who.int/publications/i/item/9789240011311

Laboratory Biosafety Manual, 4th edition: Risk Assessment (2020)
https://www.who.int/publications/i/item/9789240011458

WHO Laboratory Biosecurity Guidance (2024)
https://www.who.int/publications/i/item/9789240095113

WHO Resolution on Strengthening laboratory biological risk management
https://apps.who.int/gb/ebwha/pdf_files/WHA77/A77_R7-en.pdf

International Gene Synthesis Consortium
https://genesynthesisconsortium.org/

Community Values, Guiding Principles, and Commitments for the Responsible Development of AI for Protein Design
https://responsiblebiodesign.ai/

Implementation Guidance for the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential
https://aspr.hhs.gov/S3/Documents/USG-DURC-PEPP-Implementation-Guidance-May2024-508.pdf

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Contact person	Senior Lead for Biosecurity and Biosafety Oversight
Linked documents and resources	*Biosecurity Strategy, Biosecurity Strategy Implementation Plan (2025-2026)* *CEPI Third Party Code.* https://cepi-tr.tghn.org/biosecurity/
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