Biosecurity Policy
Frequently Asked Questions (FAQ)

Published 5 February 2026

This FAQ accompanies the publication of CEPI's first Biosecurity Policy and is intended to support awardees, partners, and other stakeholders in understanding CEPI's expectations related to biosecurity and biosafety. The questions and answers below provide additional context on the policy's scope, objectives, and application across CEPI-funded research, development, and manufacturing activities. They are designed to clarify how the policy should be interpreted and implemented in practice by Third Parties. This FAQ is a living document and will be updated over time as CEPI receives and responds to questions from the awardee community and other stakeholders. It is not a substitute for the Biosecurity Policy itself but serves as a practical reference to promote consistent understanding, responsible conduct, and effective risk management across CEPI's international portfolio.

1. What is the aim of the Biosecurity Policy?

CEPI is committed to ensuring that the scientific and public health benefits of CEPI-funded activities contribute to the 100 Day Mission, and that the identified biosecurity and biosafety risks are effectively mitigated. To support this, CEPI sets out in its first Biosecurity Policy a systematic, risk-based approach to:

- Identify and assess biosecurity and biosafety risks across CEPI-funded vaccine research, development and manufacturing (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; and,
- 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.

2. What does the Biosecurity Policy cover?

The Policy sets out nine requirements that CEPI expects all Third Parties who are working with biological materials to comply with, in order to conduct their work with biological material to international levels of biosecurity and biosafety. In brief these are:

1. Adhere to appliable biosecurity and biosafety legislation, regulation, and policies
2. Conduct biosecurity and biosafety risk assessments
3. Deliver effective organisational management and oversight
4. Collect, manage and store samples in accordance with best practice
5. Define and manage emergency response plans
6. Ensure appropriate protection and information security for biosecurity sensitive data
7. Assess activities for the potential to generate viruses with enhanced epidemic or pandemic potential (VEEPP)
8. Ensure responsible procurement of nucleic acid synthesis services and equipment
9. Promote responsible emerging and converging technologies development and applications.

3. Who was consulted during the design phase of the Biosecurity Policy?

The Biosecurity Policy was developed through extensive collaboration across CEPI and its global network of partners. It draws on detailed external review by international experts, feedback from CEPI awardees and biosafety stakeholders, and close internal alignment across CEPIs governance, legal, compliance, and technical teams. The development process was further informed by lessons learned from CEPI's diverse research settings and global partnerships. Together, this collaborative approach has ensured that the Policy is robust, forward-looking, and practical to implement across more than 47 national jurisdictions in which CEPI-funded work has taken place.

4. Who does the Biosecurity Policy apply to?

The Biosecurity Policy applies to all CEPI Third Parties (i.e., recipients of grants, contractors, sub-contractors, sub-awardees) who are engaged in activities that involve the handling of biological pathogens and data regardless of geographic location. CEPI will apply and integrate the Policy and associated requirements to its awarding and project management processes. Biological materials are defined in the Policy as: materials derived from a biological source, including genetic material or sequence data, derived from biological agents. This Policy does not apply to CEPI funded projects that do not involve biological materials or which only use non-pathogenic microbes.

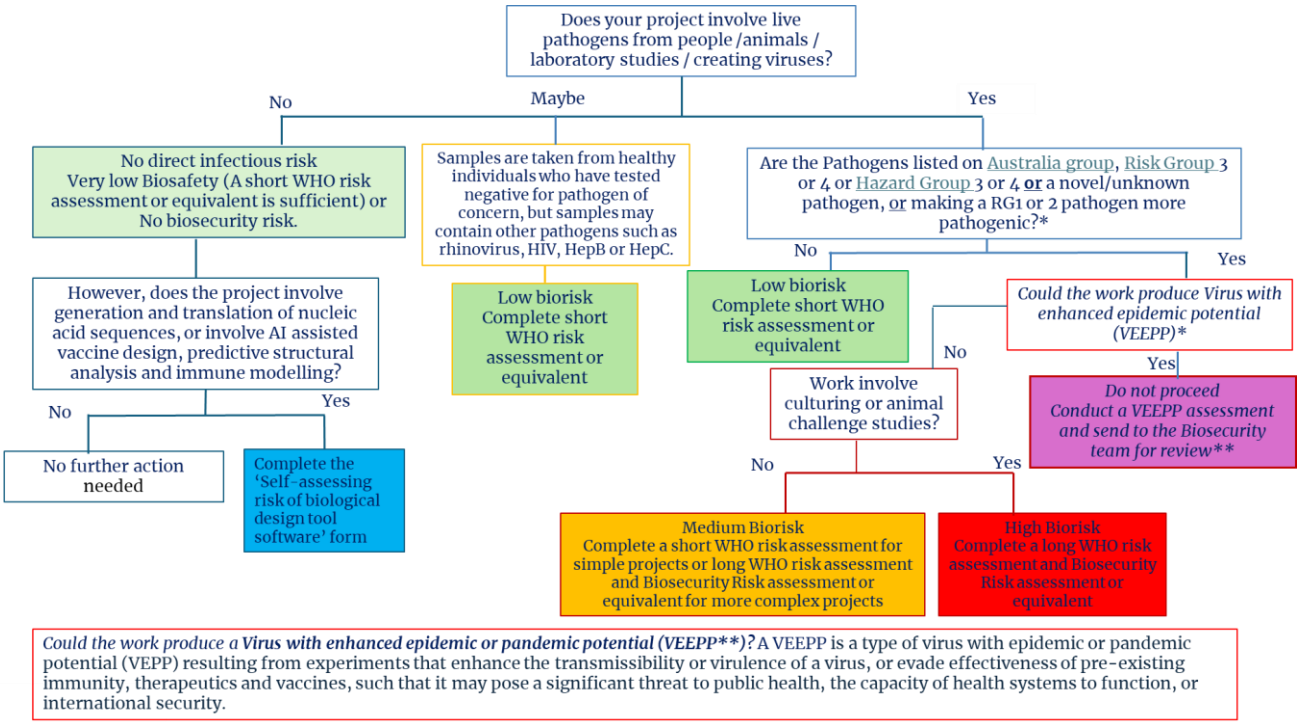
5. How will the Biosecurity Policy be implemented?

The Policy will be published on CEPI's website. For new Third Party awards involving biological materials, the policy will be incorporated into solicitations, funding agreements and guidance. For existing Third Party awards, the Policy will be incorporated into projects through the upcoming 2026 update to CEPI's Third Party Code.

6. How does CEPI assess the level of biorisk within a project?

CEPI supports work involving a range of pathogens and study types and so will use a biorisk identification flowchart (Figure 1) to categorise work as low, medium or high biorisk, in order appropriate levels of oversight can be given to projects. In addition, risk identification assessments will also be introduced for projects involving artificial intelligence (AI) or AI biological design tools applied to sequence data or similar, and for projects that could potentially generate viruses with enhanced epidemic or pandemic potential. Further information on this will be made available on the technical resources webpage https://cepi-tr.tghn.org/biosecurity/.

Figure 1. *Biorisk identification flowchart*



7. How do I demonstrate compliance to the Policy?

Following Policy publication, CEPI will begin contacting Third Parties involved with higher biorisk projects to request completion of a biosecurity self-assessment form (https://cepi-tr.tghn.org/biosecurity/) for submission to their designated project leader or manager and the Biosecurity Department. Primary awardees are responsible for sharing the Policy and biosecurity self-assessment with sub-awardees, and the biosecurity self-assessment is intended to document existing practices and demonstrate alignment with the Policy. Where institutions identify opportunities to further strengthen their biosecurity and biosafety systems, CEPI will work with those partners to review the findings and determine appropriate next steps. CEPI has resources that may be available to support continual improvement and capacity strengthening, particularly in low- and middle-income settings, consistent with the high standards already required for CEPI-supported research.

8. Does CEPI support gain of function research?

No, CEPI does not support gain of function research. CEPI is one of the leading global research funders calling on other funders to commit to ensure that studies involving potentially dangerous pathogens are conducted safely, securely and responsibly. While the term gain of function is widely used in policy discussions, it has varied meanings in different international scientific settings, and so CEPI employs the concept of Viruses with Enhanced Epidemic or Pandemic Potential (VEEPP) to provide greater precision about the research outcomes of concern. VEEP studies are defined as research that could result in significant societal harm and that seeks or achieves one or more outcomes listed below:

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.

Importantly, CEPI does not support research that could result in VEEPP. While VEEPP emphasis is on viral pathogens and reflects CEPI's current scope of work, these same principles apply to research involving other types of pathogens. Through this approach, CEPI supports innovation that accelerates preparedness while steering clear of work that could be expected to increase a virus's ability to spark an epidemic or pandemic and cause significant societal harm.

9. What happens in circumstances where Policy provisions conflict with national requirements?

CEPI Third Parties are required to comply with the national/regional laws that apply to them. 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. If there are circumstances where the Biosecurity Policy conflicts with national laws, please inform the CEPI Biosecurity team for CEPIs information.

10. How does the Policy enable and not restrict research in support of the 100 Days Mission?

CEPI's Biosecurity Policy is explicitly designed to enable speed, confidence, and continuity in research, development, and manufacturing activities required to achieve the 100 Days Mission. By setting clear, proportionate, and risk-based expectations up front, the Policy provides predictability for Third Parties and project teams, allowing biosecurity and biosafety risks to be identified early, in ways that are commensurate with the actual level of risk. This front-loaded clarity reduces the likelihood of late-stage disruption such as ad hoc risk reviews, regulatory uncertainty or reactive mitigation measures that can delay critical milestones. In practice, the Policy functions as a risk management enabler which supports faster decision-making by clarifying when advanced safeguards are required and when they are not, thereby avoiding unnecessary procedural burden on low-risk activities. The Policy is deliberately practical and flexible, recognising the diverse regulatory and operational contexts in which CEPI-funded research takes place. Safeguards are designed to scale with risk, rather than impose uniform constraints, ensuring that essential research can proceed rapidly while higher risk work receives appropriate scrutiny. In doing so, the Policy supports safe collaboration, responsible innovation and efficient governance, enabling researchers move quickly and confidently while protecting public health and trust.

11. Who should I contact if I have questions about the Biosecurity Policy?

If your question or comment is specific to your CEPI project, then please contact your designated project leader or project manager, copying the CEPI biosecurity department (contact.cepibiosecurity@cepi.net).

If your question is not specific to a CEPI-funded project, but relates more broadly to biosecurity or biosafety practices within the wider biosecurity community, you are warmly encouraged to contact the CEPI biosecurity department at contact.cepibiosecurity@cepi.net. We welcome inquiries from researchers, technical experts, implementing partners, and other stakeholders across the global health security ecosystem, and we are committed to supporting responsible, safe, and secure conduct in biological research and innovation.

Please note extra information to guide awardees to comply with the Biosecurity Policy can be found on our site https://cepi-tr.tghn.org/biosecurity/. This page is currently under development, and further resources will be added over time. We welcome suggestions from awardees and the wider biosecurity community on the types of content that would be most useful.