

Dangerous Gain of Function (DGOF) Readiness Checklist

Investigator preparation for high-risk life sciences research oversight

JANUARY 2027 READINESS

Use before proposal submission or changes

CHECK ANY ITEM THAT APPLIES. A checked item is a referral signal, not a final determination. Contact Research Compliance for review.

1 MATERIALS AND AGENTS

- ☐ Human, animal, or plant pathogen
- ☐ Biological toxin or Select Agent/toxin
- ☐ Recombinant or synthetic nucleic acid
- ☐ Genetically modified organism or viral vector
- ☐ Risk Group 3 or Risk Group 4 organism

2 ANTICIPATED OUTCOMES

- ☐ Enhance harmful consequences, virulence, or toxicity
- ☐ Disrupt immunity or immunization effectiveness
- ☐ Increase resistance to prophylaxis or treatment, or reduce detectability
- ☐ Increase stability, transmissibility, or dissemination
- ☐ Alter host range or tropism
- ☐ Increase susceptibility of a human, animal, or plant population
- ☐ Generate or reconstitute an eradicated or extinct biological agent

3 METHODS FOR CLOSER REVIEW

- ☐ Serial passage, adaptation, or directed evolution
- ☐ Pathogen genome editing or synthetic genome assembly
- ☐ Reconstitution of historical or extinct agents
- ☐ Novel pathogen-host combinations
- ☐ Engineering of biologically active toxins
- ☐ In silico work proposing creation or modification of a biological agent

4 PANDEMIC OR MISUSE POTENTIAL

- ☐ Pathogen with pandemic potential or enhanced pandemic potential
- ☐ Knowledge, material, product, or technology could be misapplied with little or no modification
- ☐ Potential significant effects on public health, agriculture, animals, plants, the environment, economic security, or national security

5 INTERNATIONAL ACTIVITIES

- ☐ Research conducted outside the United States
- ☐ Foreign institution, laboratory, collaborator, subaward, or key person
- ☐ International transfer of biological materials, technology, data, or intellectual property
- ☐ Possible country, institution, or individual of concern

6 DOCUMENTS TO PREPARE

- ☐ Accurate aims, methods, anticipated outcomes, agents, host systems, and protocol references
- ☐ Names and affiliations of key personnel and foreign collaborators
- ☐ Current IBC and other required approvals
- ☐ Training, occupational health, access, inventory, transfer, and destruction records
- ☐ Biosafety, biosecurity, cybersecurity, incident-response, and communication controls
- ☐ Plan to report changes in aims, methods, personnel, institutions, or anticipated outcomes

IF ANY ITEM IS CHECKED

PAUSE. DOCUMENT. REFER.

- Do not make the final scope determination alone. Contact Research Compliance before proposal submission or before initiating or changing relevant work.
- Prepare a research-specific explanation and, if requested, risk-benefit and risk-mitigation information.
- Reassess whenever aims, methods, agents, collaborators, institutions, or anticipated outcomes change.