



Executive Briefing: High-Risk Life Sciences & Biosafety Regulatory Overhaul

Joint Analysis of Draft NIH Biosafety Policy and Federal DGOF/IROC Policy

Executive Summary & Institutional Risk Profile

The federal regulatory landscape governing life sciences, biological research, and biosafety is undergoing a fundamental transformation. Two sweeping federal directives will significantly expand institutional compliance obligations, increase legal liability, and require structural administrative updates:

1. **US Government Policy for Stopping High-Risk Life Sciences Research** (Federal DGOF/IROC Policy) - Replacing 2024 DURC/PEPP rules per EO 14292:
 - a. Prohibits federal funding for Dangerous Gain-of-Function (DGOF) research; and
 - b. Requires pre-award screening measures and PI and IRE evaluations for Potential DGOF research; and
 - c. Restricts International Research of Concern (IROC); impacting foreign life-sciences collaborations.
2. **Draft NIH Biosafety Policy for Research Involving Biohazards** - Replacing the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules:
Expands oversight beyond recombinant/synthetic nucleic acids to encompass *all* laboratory biohazards (wild-type pathogens, toxins, prions, etc.) across the entire institution.

Key Takeaway for Senior Leadership:

Institutional risk exposure is moving from protocol-level oversight to institution-wide financial and legal liability. Non-compliance with either framework puts all federal funding at risk, with the federal government tying DGOF compliance certifications directly to False Claims Act (FCA) liability. Violations can result in immediate loss of current federal funding, a 5-year ban on federal life sciences grants, and additional legal penalties for the entire institution.

Implementation deadline for the Federal DGOF/IROC Policy is January 19, 2026.

Policy Comparison Matrix

Core Dimension	Federal DGOF/IROC Policy (EO 14292)	Draft NIH Biosafety Policy
Primary Focus	High-risk/DGOF and IROC life sciences research	General laboratory biosafety and biohazard oversight
Predecessor Framework	2024 DURC and PEPP Policies	NIH Guidelines for Recombinant/Synthetic Nucleic Acids
Scope & Reach	All life sciences research at institutions receiving federal funding, Principal Investigators (PIs), and foreign collaborations	All research conducted/sponsored by an institution receiving NIH funds, regardless of source
Funding Impact	Prohibits federal funding for DGOF; non-compliance causes 5-year funding bans	Failure impacts institutional NIH award eligibility
Legal/Liability Shift	FCA liability tied to payment certifications	Award terms and conditions compliance
New Oversight Bodies	New Institutional Review Entity (IRE) and Institutional Contact (ICDGOF)	New NIH-approved Biosafety Assurance signature by an Authorized Organizational Representative (AOR), Expanded Institutional Biosafety Committee (IBC) duties

Major Changes & Institutional Impact

1. Governance & Oversight Restructuring

- **Institutional Biosafety Assurance:** The institution must maintain an NIH-approved Biosafety Assurance (valid up to 4 years) signed by the AOR to receive funding.
- **Creation of an IRE:** The institution must establish a standalone IRE with at least 5 members to review potential DGOF projects. The current practice of integrating this within the IBC will no longer suffice.
- **Appointment of ICDGOF:** Requires appointing an ICDGOF to liaise with federal agencies. This contact must certify that all life sciences applications are accurate and truthful.
- **Change in Scope of IBC Review:** The draft NIH Biosafety Policy expands the scope of the IBC review beyond recombinant and synthetic nucleic acid molecules, which was the focus of the previous policy, and will require the establishment of an entirely new IBC at some institutions. Membership of existing IBCs may need to change to accommodate requirements for inclusion of committee members with subject matter expertise.

2. Workflow & Researcher Compliance Obligations

- **Continuous PI Attestations:** All life sciences PIs must submit initial (pre-proposal) and ongoing attestations regarding potential DGOF research.
- **Risk Mitigation Plans:** PIs must complete a risk-benefit assessment and risk mitigation plan for IRE review and subsequent approval by an external Independent Third Party Review Body for all identified potential DGOF research.
- **Mandatory Annual Training:** Required annual training for all life sciences researchers, PIs, IBC/IRE members, and research administration staff.
- **24-Hour Stop Work & Incident Escalation:**
 - **Draft NIH Biosafety Policy:** 24-hour mandatory notice to NIH for confirmed/potential lab-acquired infections, containment loss, incidents involving biohazardous exposure, or protocol non-compliance.
 - **Federal DGOF/IROC Policy:** Mandatory 24-hour stop-work order and federal notification if a project meets the DGOF threshold at *any stage*.

3. International Research & Transparency Standards

- **IROC Screening:** Expands compliance beyond export controls. Requires verifying that foreign collaborators and subawardees meet US biosafety and biosecurity standards and do not appear on upcoming federal "Entity of Concern" lists (including countries, institutions and individuals). The full impact of this element of the Federal DGOF/IROC Policy is unclear. It is expected that by November 17th, government agencies will publish additional information

regarding entities of concern and enhanced guidance on institutional screening expectations.

- **Public Transparency Mandates:** Draft NIH Biosafety Policy requires public posting of limitedly redacted IBC minutes and final incident reports on an institutional website using **mandatory** NIH templates, maintained for 5 years. Information that must be posted publicly includes PI name and award number.

Key Action Items for Senior Leadership

1. **Form a Cross-Functional Implementation Task Force:** Immediately assemble leadership from stakeholder departments, which may include environmental health and safety, research integrity, research administration, export control, and general counsel to lead policy rollout and determine institutional governance framework.
 2. **Execute Institutional Comment Strategy (By Oct 19, 2026):** Determine whether to submit independent feedback or align with higher education association responses (e.g., CSHEMA) regarding draft NIH Biosafety Policy scope, resource burdens, and public posting rules.
 3. **Conduct Portfolio Gap Assessment:** Inventory all current life sciences research including work with wild-type risk group 2 agents, toxins, primary cell cultures, and foreign subawards to identify projects falling under the new policies. For DGOE/IROC, devise a strategy for reaching life science researchers that typically do not fall under the purview of IBCs (i.e., computational research and field research).
 4. **Prepare to Allocate Resources:** In consultation with the implementation task force, identify internal funding pathways for implementation needs including staffing, training, and software solutions.
 5. **Appoint Leadership & Draft IRE Infrastructure (By Jan 16, 2027):** Officially designate the ICDGOE and begin recruiting members for the standalone IRE to meet the January deadline.
 6. **Upgrade IT & Compliance Systems:** Implement new software systems to capture continuous PI attestations and manage IROC foreign collaboration workflows. Update existing e-research software systems to meet IBC registration requirement changes and host public-facing documentation.
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Strategic Implementation Timeline

Federal DGOFF/IROC Policy

- **November 17, 2026:** Federal agencies publish "Entity of Concern" lists for international collaboration screening.
- **January 16, 2027:** Deadline to have the IRE established, ICDGOFF appointed, annual training active, and DGOFF compliance records fully operational. Federal grant enforcement begins.

NIH Biosafety Policy

- **October 19, 2026:** Deadline to submit institutional comments on the draft NIH Biosafety Policy.
- **TBD (Approx. Mid-2027):** Draft NIH Biosafety Policy becomes effective 6 months following final publication.