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Response to NOT-OD-26-112: Draft NIH Biosafety Policy for Research Involving Biohazards

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1. **Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed**

We support NIH's proposed expansion of biosafety oversight beyond recombinant and synthetic nucleic acid research to encompass a broader range of biological hazards. The expanded scope appropriately recognizes that biosafety risks are not limited to genetically modified agents and can arise from wild-type pathogens and other biological materials. The draft policy specifically notes that oversight would include wild-type agents and other biohazards, which is an important modernization of the current framework.

However, the draft creates a significant gap in oversight for zoonotic pathogens carried by animals used in experiments, particularly imported nonhuman primates. Imported nonhuman primates may harbor zoonotic pathogens unrelated to the approved research project, including pathogens that are not readily identified through routine screening. For example, the CDC has reported multiple cases of melioidosis caused by *Burkholderia pseudomallei* in imported macaques from [1]. *B. pseudomallei* is a Tier 1 Select Agent and can cause severe disease in humans. Tuberculosis has also been documented in imported macaques, including *Mycobacterium orygis,* which was identified[2] in macaques from Southeast Asia and had not previously been documented in nonhuman primates imported into the United States. Cases of tuberculosis have also been identified after mandatory [3] quarantine, highlighting the limitations of routine screening and the potential for infections to go undetected. Antimicrobial-resistant bacteria are another concern, as they can cause serious infections that are difficult to treat. In 2023, vancomycin-resistant Staphylococcus aureus, a rare and highly drug-resistant bacterium, was [4] in macaques imported from Mauritius and housed at the Oregon National Primate Research Center. Herpes B virus is also widespread among adult macaques, and infected animals can shed the virus without showing symptoms, posing a potentially fatal risk to humans. Routine screening for the virus is not required during import quarantine. CDC has also noted that imported nonhuman primates may develop disease months or years

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after importation, and that human exposure can occur through contact with infectious animal materials and bodily fluids.

The policy excludes many exposures to adventitious agents from federal reporting unless they result in a laboratory-acquired infection. While these agents may not be the focus of the experimental protocol, they present substantial occupational and public health risks. This oversight is at odds with the draft policy's broader recognition of zoonotic hazards. NIH defines a zoonotic agent as one reasonably suspected of transmission from animals to humans with the potential to cause human disease and establishes federal involvement in determining appropriate containment for certain emerging, novel, or zoonotic biological agents.

Whether a pathogen was deliberately introduced as part of an experiment or was carried by an animal does not determine the potential consequences of an exposure. The final policy should ensure that exposures to zoonotic pathogens associated with animals used in experiments are treated as biosafety events even when the pathogen is not part of the experimental protocol and no infection is ultimately confirmed. These exposures warrant federal attention and analysis.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local)

The proposed delineation between local and federal oversight may understate risks associated with zoonotic exposures involving nonhuman primates.

The draft policy identifies events such as animal bites, scratches, escapes, improper disposition, and other incidents involving animals housed in BSL-1/ABSL-1 or BSL-2/ABSL-2 facilities to local IBC review, without required reporting to NIH. It also specifically exempts treatment following potential exposure to adventitious agents such as nonhuman primate Herpes B or *B. pseudomallei* from NIH reporting unless a laboratory-acquired infection occurs. These provisions risk hiding information that could reveal recurring hazards associated with the use of particular animals or animal sources, even those used by facilities in different local jurisdictions, which could create risks beyond a single institution.

Federal oversight should be required for:

- Any bites, scratches, and mucosal exposures involving imported nonhuman primates.
- Incidents requiring post-exposure prophylaxis or precautionary medical treatment following exposure to imported nonhuman primates.
- Detection of significant zoonotic pathogens in imported nonhuman primates used in NIH-funded research.

These incidents should not be treated solely as local occupational health matters because they provide important information about broader biosafety risks across the research enterprise. Federal reporting would enable NIH to determine whether patterns exist across institutions, species, animal sources, or types of experiments that cannot be identified through isolated institutional review.

NIH should also resist treating administrative burden as a reason to exclude genuine hazards from meaningful oversight. The draft policy is explicitly intended to calibrate oversight to risk. Where an activity presents a significant occupational or public health hazard, additional review, documentation, and reporting are appropriate consequences of that risk.

3. Continued utility of Risk Groups (RGs) as a baseline for risk assessment, particularly when agents are being genetically modified, versus use of Biosafety Levels (BSL)

No comment

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy

For institutions and other entities not subject to the policy, NIH should encourage adoption of the same core principles for research involving biohazards, including meaningful incident reporting, public transparency, and oversight of zoonotic hazards associated with animals used in experiments. An institution's biosafety accountability should not be stronger or weaker based on its funding sources.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates

There must be meaningful public transparency regarding biosafety incidents. We urge NIH to retain its requirements for public posting of IBC meeting minutes and incident reports. The public has a legitimate interest in knowing where federally supported research involving biological hazards is conducted, the nature of biosafety incidents associated with that research, and what actions institutions take in response. Aggregate reporting alone would make it substantially more difficult for the public to identify recurring problems associated with particular institutions, projects, or research practices. NIH should therefore preserve disclosure of information necessary for meaningful accountability while allowing appropriate redaction of personally identifiable and medical information concerning individual workers.

The Draft Incident Reporting Template should be revised to capture exposure incidents involving zoonotic pathogens carried by animals in laboratories, even when no laboratory-acquired infection is ultimately confirmed.

Specifically, the reporting template should include fields for:

- Animal species involved in the incident
- Whether the animal was imported and country of origin
- Whether post-exposure prophylaxis or precautionary treatment was administered
- Whether the exposure involved a known or suspected zoonotic pathogen
- Whether pathogen testing was conducted following the incident and the results of that testing

For the Draft Meeting Minutes Template, NIH should encourage IBCs to document discussions involving zoonotic disease risks associated with animals used in experimentation, particularly imported nonhuman primates, and how the committee evaluated relevant zoonotic hazards and what corrective or preventive measures were considered. This information would improve NIH's ability to identify recurring risks, evaluate trends across institutions, and determine whether additional safeguards are warranted, as well as improve transparency and institutional decision making.

6. Feedback on implementation resources and areas in which additional guidance would be beneficial

NIH should issue additional guidance regarding zoonotic hazards associated with animals used in experiments, particularly imported nonhuman primates, when those hazards exist independently of the experiment's intended biological agent.

NIH should also ensure that its proposed National Biosafety Data and Safety Analysis Center can identify patterns involving animals used in experimentation. The draft establishes the Center to aggregate, de-identify, and analyze incident data, near misses, and anomalies. For incidents involving animals, standardized data should therefore identify the species involved and the animals' origin, as well as whether a known or suspected zoonotic agent and subsequent medical treatment were involved. This information would allow NIH to determine whether particular species, sources, or research practices are repeatedly associated with biosafety incidents.

Overall, the draft policy is a significant step toward modernizing biosafety oversight by expanding its scope beyond recombinant and synthetic nucleic acid research. But a modernized policy should evaluate a biological hazard based on the risk it actually presents, not on whether that hazard was deliberately introduced as part of an experiment. The final policy should close the adventitious-agent reporting gap, require federal reporting

of consequential zoonotic exposures involving these animals, collect animal-specific information necessary to identify patterns across institutions, and preserve meaningful public access to incident and oversight information. Doing so would better align the policy with NIH's goals of accountability, transparency, and protection of public health.

More information is available on the following webpages and in the following documents:
https://www.peta.org/misc/peta-reports-and-factsheets-regarding-monkeys-imported-for-experimentation/
https://www.peta.org/wp-content/uploads/2023/02/Melioidosis_NASPHV_Notification-2.22.22.pdf
https://www.peta.org/wp-content/uploads/2026/10/2024-05-29-PETA-letter-FBI-Burkholderia-pseudomallei-introduction-via-primate-importers.pdf