

NIH Institutional Biosafety Committee Meeting Minutes Draft Template and Points to Consider

Comments on this document can be made through the NIH comment portal found at: <https://osp.od.nih.gov/comment-form-draft-nih-biosafety-policy-for-research-involving-biohazards>

Comments will be accepted until **October 19, 2026**.

Background

The system of oversight described in the National Institutes of Health (NIH) Biosafety Policy for Research Involving Biohazards (the Policy) is built on principles of transparency and public access to information. A key component in this system is the review of research subject to the Policy at the institutional level by the Institutional Biosafety Committee (IBC). Institutions must prepare IBC meeting minutes that not only serve as the institution's record of the IBC's proceedings but also document for NIH and the public that the IBC is fulfilling its biosafety review and oversight responsibilities.

Purpose

NIH is committed to ensuring all institutions are complying with the transparency aims of the Policy and IBC minutes are accessible to the public. **As stated in Section III-B of the Policy, IBCs are required to use this template to prepare their IBC meeting minutes.**

For IBC meetings taking place on or after June 1, 2025, meeting minutes must be posted on a public-facing webpage on the website of the institution conducting the research (not hosted on the website of an externally administered IBC or another site).

Minutes from IBC meetings taking place before June 1, 2025, are not required to be posted to the institution's public-facing website but must be made available to the public upon request.

Points to Consider when Generating IBC Meeting Minutes for Public Posting

IBCs must adequately document fulfillment of their review and oversight responsibilities described in Section III-B of the Policy.

- The minutes should contain a summary of the proposed research. As part of the required risk assessment, minutes should include (as appropriate):

- Any risks identified and details of the risk mitigation measures to be employed
 - The biosafety level under which the research is approved plus any additional stipulations, if necessary
- In general, the minutes should offer sufficient detail to serve as a record of all major points of discussion and the committee's rationale for decisions. Key points made in discussion, motions of the committee, and whether those motions were approved should be documented. Minutes do not need to be transcripts or kept at a level of detail that attributes remarks to a specific individual.
- All official business conducted at the IBC meeting should be documented using this template. This would include not only the review and approval of registrations but also business such as the approval of previous minutes, review of incidents, laboratory inspection reports, reports from safety personnel related to the safe conduct of research at the institution, personnel training, review of policies, etc. Insofar as the IBC is discussing matters related to any research subject to the Policy, those discussions should be captured in the IBC meeting minutes.
- Meeting minutes should provide a transparent assurance to the public that the institution is conducting research in a safe and responsible manner in keeping with the requirements of the Policy.
- NIH acknowledges that the protection of private or proprietary information is a legitimate concern for what information to post publicly. Institutions may, therefore, redact proprietary or private information, but must do so judiciously. To promote consistency and proper redaction practices, institutions should articulate criteria for redaction in IBC operating procedures. Some examples of information that may be redacted include trade secret information and other confidential commercial information, home telephone numbers and home addresses of IBC members, and specific information where disclosure would directly compromise institutional or national security. Most institutions should be able to adequately document their biosafety reviews without the need to include this kind of information in their minutes.
- Information that is widely available from other public sources such as institutional webpages, publications describing a principal investigator's (PI's) research, or public grants databases (e.g., names of IBC members and PIs, biological agents used in research, including Select Agents, grant numbers) is not generally considered private or proprietary and may **not** be redacted from the IBC minutes.
- Institutions may choose to use the IBC to discuss other matters not subject to the Policy and document these issues in their IBC minutes at their discretion.

Draft IBC Meeting Minutes Template

The level of detail captured regarding the IBC's review of registrations will vary based on the complexity and potential risks associated with a specific protocol. These examples are provided for illustrative purposes only; actual content will depend on the topics discussed.

Element	Examples	Notes
Institution	List institution name, city, and state.	General location of the institution should be indicated. Specific facility addresses may be security sensitive and do not need to be included.
Meeting Date	Day/Month/Year	
Meeting Time	1:00 PM – 3:30 PM	Include start and end time.
Meeting Type	In-person meeting.	In-person and/or Virtual Platform (e.g., Webex, Teams, Zoom).
IBC Members Present	1. Name (IBC Chair) 2. Name (BSO) 3. Name (IBC Member/ Expertise) 4. Name (Local Non-affiliated Member) 5. Add additional members as needed Other expertise may include virology, ecology, occupational health, etc.	Indicate name, affiliation (if different from the institution) and role/expertise on the IBC. Specific roles of members may include: • Biological safety officer • Animal containment expert • Gene drive modified organism expert Note - The names of IBC members may not be redacted from the minutes.
Quorum	Present/Not Present The IBC has (number) voting members, and (number) members are required to conduct business.	Note late arrival/early departure of voting members and any impact on the quorum. All formal business at IBC meetings should only be conducted with a quorum present. A quorum is the minimum number of members who must be present to conduct an IBC meeting. IBCs should clearly stipulate what constitutes a quorum in their policies and procedures and adhere to this policy. IBC policies should also consider the necessary expertise that must be present to allow for adequate review of the protocols under

		consideration. NIH recommends the IBC quorum should require at least one non-affiliated member.
Other Individuals in Attendance	None or Name, Affiliation, and Title 1. Name, Chair, Department of Virology 2. Name, member of the public 3. Add additional names as applicable	
Call to Order	<i>The IBC Chair called the meeting to order at 1:05 PM.</i>	
Conflicts of Interest	<i>The IBC Chair reminded all members present to identify any conflicts of interest as each registration is reviewed.</i>	See Section III-B of the Policy.
Review and approval of previous IBC minutes	Date of the meeting minutes to be approved and motion: (e.g., to approve the minutes as written) Votes: For/Against/Abstain (number of votes)	Include summary of discussion of the minutes as applicable and document any changes to be made. If none, indicate no discussion.
Review of Prior Business	<i>The BSO received approval from NIH to lower containment for research involving <an attenuated agent - description>. NIH set the minimum biocontainment for research activities with this agent as BSL-2.</i>	Add summary of prior business if applicable, e.g.: • Actions taken on behalf of the IBC between meetings such as verifying conditions have been met for approval • Updates on actions taken regarding incidents or follow up on an injury, discussion of remediation/retraining efforts • Details of building maintenance • Activities pertaining to prior safety discussions • Follow-up on correspondence between IBC and NIH
New IBC Registrations and Amendments for Review (repeat for each registration)		
PI Name(s)	Name (s)	Note - The names of the PIs may <u>not</u> be redacted from minutes.
Title/Registration Number	New Registration 2025-123 Amendment to Registration 2024-456	Use institutional tracking number or other unique identifier.

Project Overview	<i>The PI is proposing to inject mice with a replication-defective, cre-dependent AAV vector expressing the tetanus toxin light chain. The AAV vector will be obtained from an outside vendor. Expression of the light chain is cre-dependent which will limit expression to cells constitutively expressing cre recombinase. This should block expression of the light chain in any personnel who are accidentally exposed.</i> <i>The protocol involves the use of canine adenovirus type 2 (CAV-2) with the deletion of E1 regions to render the virus replication deficient. The modified virus will carry recombinant transgenes of interest under the control of tissue-specific promoters. Reporter genes (GFP, RFP, and LacZ) and recombinases (Cre, Flp) will be overexpressed for neuronal tracing purposes. Intranasal and Intracranial delivery of recombinant adenovirus in rodents will be performed for preclinical evaluation of gene delivery efficiency, immune response, and transgene expression. Administration of virus to mice occur under BSL-2 conditions and animals will be housed at BSL-2 in an approved animal facility with strict adherence to protocols for handling viral vectors and animal waste disposal.</i>	Include information including, but not limited to: • Agent name (e.g., organism, host vector system, etc.). • Agent characteristics of note (e.g., virulence, pathogenicity, antibiotic susceptibility, environmental stability) • Sources and nature of the nucleic acid sequence(s) (e.g., species, structural transgene, oncogene, toxin) • Summary host(s) and type(s) of vector(s) if used • Modifications (e.g., deletions, insertions, mutations to attenuate or render replication incompetent) and note of any supporting documentation (published or unpublished data) • Types of experimental manipulations that will be employed (e.g., tissue culture, animal work). • Proposed biosafety containment level(s) at which research will occur • Any other pertinent information
Readout of Any Projects Approved by Delegated Review	Document all approvals granted by delegated review (may be attached to the minutes as a list). Note any specific issues discussed by the IBC as applicable.	
Risk Assessment and Discussion	Detail high risk or complex manipulations of the materials (e.g., vortexing, sonicating, centrifuging, using sharps, cell-sorting). Note relevant safety strategies used to prevent accidental occupational exposure (e.g., PPE, separation of genetic materials to prevent accidental integration, etc.).	

Training	Document completion of required institutional level training as well as detailed laboratory or protocol specific training: • Basic laboratory biosafety • Safe sharps handling Detail any additional IBC recommended training including, but not limited to: • Use of specialized equipment or higher hazard work • Protocol/agent specific biosafety training • Animal handling (restraint, injections, primate safety etc.) • High containment laboratory proficiency training • Specialized staff training on laboratory safety practices, including sharps safety precautions, prior to performing injections in mice	See Sections III-A and III-C of the Policy.
Occupational Health Representative Review (if applicable):	Document any required occupational health requirements including, but not limited to: • Vaccination requirements • Respiratory protection • Periodic review of any medical surveillance • Post-exposure response procedures	See Section III-A of the Policy. It may be helpful to have an Occupational Health representative serve on the IBC or attend IBC meetings when pertinent registrations are being discussed.
Biosafety Level Assignment	Document biosafety level assignment and special conditions for the proposed research. Example: • <i>BSL-2 for vector administration and for the first 72 hours post administration</i> • <i>Extra attention to sharps precautions and animal restraint techniques</i> • <i>BSL-1 for subsequent housing of animals</i>	Detail approved Biosafety level and any additional biosafety provisions, and document any enhanced work practices (e.g., double gloves, surgical mask, respiratory protection). Detail any specific requirements that differ from standard institutional policies (e.g., waste handling).

IBC Vote	<u>Votes:</u> • <i>A motion was made to approve the registration “as is”</i> • <i>A motion was made to approve the registration pending the following changes or conditions to be met (list changes or conditions)</i> • <i>A motion was made to defer the registration pending additional information from the PI (list details)</i> • <i>For/Against/Abstain (number of votes)</i> • <i>Conflict(s) of Interest: Committee Member Name(s); or “None”</i>	If the IBC grants approvals based on specific conditions being met, there should be a formal mechanism for verifying the conditions are fulfilled (e.g., the BSO will conduct an inspection to verify all Biological Safety Cabinets are up to date on certification before lab staff may begin work, etc.).
New Business/ Additional Topics	<i>Topic: Development of New IBC Application Management System</i> <i>Discussion: IBC leadership has been working with IT staff to help develop an IT tool to manage the IBC Application Portfolio.</i> <i>Topic: Institutional Policy Review/Updates</i> • <i>Document IBC vote as above as applicable</i>	
Review of Incidents	Document any incidents (e.g., safety incidents, non-compliance issues); If none – state, “nothing to report” <i>Example:</i> <i>An incident involving a parenteral exposure from a needle used on a mouse exposed to <a RG3 agent> was reported to NIH. NIH responded that no further information was required.</i>	See Section III-B of the Policy.
Inspections/ Ongoing Oversight	Describe the results of laboratory inspections conducted since the prior meeting. Discuss the results of laboratory inspections previously granted conditional approval based on correction of deficiencies discussed at a prior meeting.	See Section III-B of the Policy.
IBC Training	<i>The BSO presented an overview of the incident reporting requirements as a refresher training for the IBC members.</i>	

Public Comments	<i>There were no public comments.</i>	
Adjournment	<i>The IBC Chair moved to adjourn the meeting at 3:30 PM.</i> <i>The next meeting scheduled is for <Date/Time via (Insert Platform).</i>	