National Institutes of Health

NIH Guidance: Institutional Biosafety Committee Meeting Minutes
Template and Points to Consider

Purpose

Institutions and their Institutional Biosafety Committees (IBCs) are responsible for producing meeting minutes that sufficiently document their biosafety review and oversight responsibilities. Institutions should prepare IBC meeting minutes that not only serve the institution's need for a record of the IBC's proceedings, but that also demonstrate to NIH and the public that the IBC is fulfilling its responsibilities under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) to assess and implement the necessary safety practices and containment procedures for basic and clinical research involving recombinant or synthetic nucleic acid molecules. This guidance is intended to assist the research community in fulfilling this mandate.

Points To Consider When Generating IBC Meeting Minutes for Public Posting

- IBCs must adequately document fulfillment of their review and oversight responsibilities described in the NIH Guidelines including:
  - Conducting a robust risk assessment to determine the appropriate biocontainment levels for the conduct of proposed research subject to the NIH Guidelines (Section II-A-3 and Section III).
  - Assessing the facilities, procedures, practices, training, and expertise of personnel.
  - Periodically reviewing recombinant or synthetic nucleic acid molecule research to ensure ongoing compliance with the NIH Guidelines.

- 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 particular 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.

- The minutes should contain a brief summary of the proposed research. As part of the required risk assessment, minutes should include (as appropriate):
  - The section of the *NIH Guidelines* that applies to the research being proposed.
  - 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.

- Institutions may redact proprietary or private information but must do so judiciously. Articulating criteria for redaction in IBC operating procedures can help promote consistency and proper redaction practices. Examples of information that may be redacted include trade secret information and other confidential commercial information and specific information whose 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 IBC minutes.

Prepared by NIH Office of Science Policy 6/1/2025

- 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.

- All official IBC business should be documented in minutes. 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 NIH Guidelines, those discussions should be captured in the IBC meeting minutes.

- Any other business of the IBC should be documented, as applicable.

- NIH encourages institutions to be maximally transparent regarding their biosafety oversight programs. Matters related to research subject to the NIH Guidelines must be documented in the IBC meeting minutes. Institutions may choose to use the IBC to discuss other matters and document these in their IBC minutes at their discretion.

Other Resources

NIH Guidelines Main Page: https://osp.od.nih.gov/policies/biosafety-and-biosecurity-policy#tab2/

- Latest updates and information from NIH OSP
- FAQs and Fact Sheets
- IBC Self-Assessment Tool
- Incident Reporting Template
- Institutional Biosafety Committee Registration Management System (IBC-RMS) information

Questions any matters related to IBCs or the NIH Guidelines may be addressed to NIH OSP by emailing NIHGuidelines@od.nih.gov.

National Institutes of Health

IBC Meeting Minutes Template

This template outlines information that should be documented in IBC meeting minutes. The use of this specific template is not required and other formats for IBC meeting minutes may be acceptable provided they address the information listed below.

Important: The level of detail captured regarding the IBC's review of registrations will likely 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	*National Institutes of Health, Bethesda Campus*	General location of the institution should be indicated to allow local communities to understand what research is being conducted in their vicinity. Specific facility addresses may be security sensitive and do not need to be included.
Meeting Date	*Monday, June 2, 2025*	Enter date
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 include: • Biological Safety Officer • Plant or Animal containment expert • Human Gene Transfer expert • Gene Drive Modified Organism expert The names of IBC members may not be redacted from minutes. Full IBC rosters are publicly available on the NIH OSP IBC Registration Management (RMS) site.
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 should only be conducted with a quorum present.

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	*The IBC Chair called the meeting to order at 1:05 PM*	Enter time the meeting begins.
Conflicts of Interest	*The IBC Chair reminded all members present to identify any conflicts of interest as each registration is reviewed.*	Committee members with a conflict of interest related to the review of a specific registration may not be involved in the review or approval of a project in which he or she has been or expects to be engaged or has a direct financial interest.
Review and approval of previous meeting minutes	*Date of the meeting minutes to be approved.* *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	*The BSO received confirmation from NIH OSP regarding the Risk Group classification of Oropouche Virus* which is not specifically listed in Appendix B of the *NIH Guidelines. The listing for Bunyaviruses indicates: Other viruses as listed in the reference source, which is the BMBL.* *Oropouche virus is listed in the BMBL with a recommended containment level of BL2. NIH OSP indicated BL2 is the appropriate minimum biosafety level, but the IBC may require additional precautions based on their risk assessment of the specific manipulations and procedures used in the research.*	Add summary of prior business if applicable e.g.: • Actions taken on behalf of the IBC between meetings such 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 OSP.
New IBC Registrations and Amendments for Review (repeat for each registration)		
PI Name(s)	*Name (s)*	Following existing guidance (see IBC Meetings and Minutes FAQ), the names of the PIs may not be redacted from minutes.
Registration Number/Title	*New Registration 2025-123* *Amendment to Registration 2024-456*	Use institutions registration tracking numbers or other unique identifier.

Project Overview	*III-B example - 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. The BSO will request approval from NIH OSP under Section III-B of the NIH Guidelines for this work which is proposed to be conducted at BL2.* *III-D-1-a example - 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 for preclinical evaluation of gene delivery efficiency, immune response, and transgene expression. Administration of virus to mice occur under BL2 conditions and animals will be housed at BL2 in an approved animal facility with strict adherence to protocols for handling viral vectors and animal waste disposal. The IBC noted that CAV is not listed in Appendix B of the NIH Guidelines and asked the BSO to reach out to NIH OSP to determine if BL2 is appropriate for work with this virus.*	• 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 sequences (e.g., species, structural transgene, oncogene, toxin). • Summary host(s) and types 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 levels at which each of these operations will occur. • Any other pertinent information.

NIH Guidelines Section	*III-D-1-b, III-D-4-a, III-E-3*	Cite which applicable section(s) of the NIH Guidelines (Section III-A thru III-E) the research falls under. If the research is not subject to or exempt from the NIH Guidelines indicate why. Such discussion may be included in the minutes at the institution's discretion.
Risk Assessment and Discussion	• *Detail high risk or complex manipulations of the materials (e.g., vortexing, sonicating, centrifuging, use of 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.).*	Summarize the protocol risks and provide details of the risk mitigation measures to be employed. The level of detail captured will vary based on the complexity and potential risks associated with a specific protocol.
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, e.g., for 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* *Staff will be trained in laboratory safety practices, including sharps safety precautions, prior to performing injections in mice.* *All required trainings are complete for all lab staff listed in the registration, or IBC approval is granted pending verification by the BSO that all staff listed in the registration have received required training*	Section IV-B-1-h of the NIH Guidelines requires that institutions ensure appropriate training for laboratory staff regarding laboratory safety and implementation of the NIH Guidelines.. Section IV-B-7-d-(2) of the NIH Guidelines requires PIs to train their laboratory staff in the practices and techniques to ensure safety and familiarity with the procedures for dealing with accidents.

Occupational Health Representative review (if applicable):	• *Vaccination requirements* • *Respiratory protection* • *Periodic review of any medical surveillance* • *Post-exposure response procedures*	Section IV-B-1-i of the NIH Guidelines requires the institution to establish and maintain a health surveillance program for personnel engaged in large-scale research or activities involving viable organisms which require BL3 or higher containment. While not a requirement, it may be helpful to have an Occupational Health representative serve on the IBC or attend IBC meetings when pertinent registrations are being discussed. If such details are discussed in IBC meetings they should be documented in the minutes.
Biosafety Level Assignment	• *BL2 for administration of vector and for the first 72 hours post administration* • *Extra attention to be paid to sharps precautions and animal restraint techniques* • *BL1 for subsequent housing of animals*	Detail approved Biosafety Level and any additional biosafety provisions and document any enhanced work practices, e.g., double gloves, surgical mask, respiratory protection. Detail of any specific requirements that differ from standard intuitional policies (e.g., waste handling).
IBC Vote	• *A motion was made to approve the registration as is* • *A motion was made to approve the registration pending the following changes or conditions to be met (list details)* • *A motion was made to defer the registration pending additional information from the PI (list details)* *Votes:* • *For/Against/Abstain: (number of votes)* • *Conflict(s) of Interest: Committee Member Name(s); or "none."*	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 work may commence, all training must be completed before lab staff may begin work etc.).
New Business/ Additional Topics	*Topic Title: Development of new IBC Application Management System* Discussion*: IBC leadership has been working with IT staff to help develop an IT tool to manage the IBC Application Portfolio.* *Institutional Policy Review/ Updates* *Document IBC vote as above as appliable*	Note any new or additional topics discussed by the IBC. Section IV-B-2-b-(6) of the NIH Guidelines requires IBCs to adopt emergency plans covering personnel contamination, research-related illness, accidental spills, and loss of containment. The IBC should approve new or amended policies by formal vote.

Review of Incidents	*If any – document e.g., safety incidents, non-compliance issues* *If none – state "nothing to report"* *An incident involving a parenteral exposure from a needle used on a mouse exposed to an attenuated strain of <agent> was reported to NIH OSP. NIH responded that no further information was required.*	The NIH Guidelines require that significant incidents, violations and research-related accidents and illnesses be reported to NIH OSP. For information regarding incident reporting requirements please refer to the Incident Reporting FAQs.
Inspections/ Ongoing Oversight	*Results of Inspections for the labs granted approval conditional upon passing the inspection and correction of all deficiencies discussed at a prior meeting.*	Section IV-B-2-b-(5) of the NIH Guidelines requires IBCs to periodically review to ensure compliance with the NIH Guidelines.
IBC Training	*The BSO presented an overview of the new NIH Guidelines requirements pertaining to the oversight of research with GDMOs.*	Note any training conducted for the IBC members during meeting.
Public Comments	*There were no public comments.*	Note any public comments made during the meeting.
Adjournment	*The IBC Chair moved to adjourn the meeting at 3:30 PM.* *The next meeting scheduled is for <Date/Time>me> via Zoom.*	Detail time the meeting was adjourned. It may be helpful to note when the next meeting is scheduled.