

Institutional Biosafety Committee (IBC)

Guideline for IBC Review and Approval of Biological Material Study Proposals: the use of Designated Member Review (DMR) and Full Committee Review (FCR)

I. Background

The Institutional Biosafety Committee (IBC) is responsible for the review and approval of funded and unfunded activities involving biohazardous materials. The IBC's role is to assist the University and Principal Investigators (PIs) in adhering to regulatory requirements and guidelines and to help protect the University, its community, researchers, and the environment. To meet these requirements the IBC reviews proposed biological work via Full Committee Review (FCR, review performed by a convened quorum of IBC members) or Designated Member Review (DMR, review performed by two or more IBC members). Regardless of the review method used, work with biohazardous materials (e.g. recombinant and synthetic nucleic acids; toxins; human, animal, and plant pathogens; select agents that cause disease in humans; any and all materials requiring BSL2 or higher) can only be initiated after a proposed research protocol has been reviewed and approved or determined to be exempt. A protocol for recombinant DNA or synthetic nucleic acid molecules is required whether for BSL1 or BSL2 using plasmid DNA or viral vectors.

II. Review Process

- A. New protocols, amendments¹, 4-yr resubmissions, and closures must be submitted to the IBC@villanova.edu for pre-review and processing.
- B. ORP will conduct a pre-review of the protocol for completion of required training for all personnel listed, a check to see if the NIH room/lab inspection checklist is complete for all locations listed, and completion of the protocol form in its entirety. Queries resulting from pre-review may be sent back to the PI(s) for clarification,
 1. When a submission passes pre-review, it will be sent to the IBC Chair for biosafety level and NIH exempt status determination
 - a. If a submission is determined to be BSL1 and NIH exempt, then the IBC Chair will proceed with review, exempt determination and approval.
 - b. If the submission is determined to be BSL1 and NIH non-exempt then the submission will be prepared for FCR.
 - c. If the submission is determined to be BSL2 and NIH non-exempt then the submission will be prepared for FCR.
 - d. If the submission is determined to be BSL2 and NIH exempt then ORP will initiate the DMR process.

Important Note – Any recombinant nucleic acid molecules or synthetic nucleic acid molecules research that falls under Section III-F of the NIH Guidelines or does not involve genetic manipulation is considered exempt from the NIH guidelines and can be reviewed via DMR.

III. Full Committee Review (FCR)

- A. All members of the IBC are given the opportunity to review and discuss any protocol submission at a fully convened meeting (in person or virtual).

¹ See IBC Amendment Guideline for a description on the amendment review process.

- B. Review outcomes are determined by a majority vote of IBC voting members at a convened meeting with a quorum of members in attendance. Any objections or abstentions to a protocol are recorded in the IBC meeting minutes.
1. If a member has a conflict of interest with any protocol under review, they are excused from the meeting during proposal review (except to provide information requested by the IBC) and are not permitted to cast a vote or contribute to the constitution of a quorum.
 2. When a member recuses themselves from the voting process, the outcome of the review is decided by vote of a quorum of members that remain present at the meeting.
- C. Review of non-exempt protocols that involve recombinant nucleic acid molecules or synthetic nucleic acid molecules, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, and cells, organisms, and viruses containing such molecules **will be reviewed by FCR.**

Note - Administrative amendments for this type of research can be reviewed and approved administratively in accordance with the [IBC Amendment Guidelines](#).

D. FCR may result in the following outcomes:

1. Approval
2. Requirement for modifications (to secure approval)
3. Withholding of approval
 - a. If approval is withheld, the PI will be notified in writing via email by ORP that no biohazard work is permitted as approval has been withheld. Under these circumstances, the PI will be asked to consult with the Biosafety Officer (BSO) and/or the IBC Chair, or specifically designated IBC members to refine the protocol which may then be submitted for IBC review at a future regularly scheduled meeting

IV. **Designated Member Review (DMR)**

- A. All members of the IBC must be given an opportunity to call for FCR, for each protocol prior to the initiation of DMR. If no member requests FCR, the protocol may be reviewed by two or more qualified members appointed by the IBC Chair (at least one of the reviewers should be a subject matter expert). Each DMR reviewer acts on behalf of the IBC to review and evaluate the protocol.
- B. If a protocol is assigned to more than one designated reviewer, the reviewers must review identical versions of the protocol and be unanimous in any decision, including agreement on modifications requested by any one of the reviewers.
1. If designated reviewers are unable to reach a unanimous decision, they must notify the IBC Chair or ORP at IBC@villanova.edu and refer the protocol for FCR. The specific review method for each protocol should be documented, along with the outcome of the review in the IBC meeting minutes. Refer to [Section V](#) for specific details on the FCR/DMR review process.
- C. DMR may result in the following outcomes:
1. Approval
 2. Requirement for modifications (to secure approval)
 3. Referral to the full committee for review.

Important Note - DMR cannot result in withholding approval.

- D. If the DMR reviewer(s) decide to send the protocol to FCR, the ORP will notify the PI in writing (via email) that the protocol will be reviewed via FCR at the next scheduled convened meeting.
- E. When DMR is conducted, the approval date is the date that the designated member(s) approve the study. The approval letter is sent to the Principal Investigator by ORP as soon as possible following that date. Unapproved biohazard work conducted before this date may be reported to the National Institutes of Health's Office of Science Policy (NIH OSP) as a noncompliance
- F. If DMR is initiated, the DMR correspondence will be sent out by ORP once the biosafety level of the submission is determined. The DMR cycle runs on a rolling basis as protocol submissions are received and it is adjusted for holidays.
- G. The DMR reviewers will be assigned by the IBC Chair. IBC members conducting a DMR are expected to indicate their approval, comments or requests for modification **in writing** by emailing IBC@villanova.edu.
 - 1. Reviewers are asked to contact ORP (IBC@villanova.edu) if there are any perceived conflicts related to the review of the assigned DMR submission.
- H. All IBC members are given 2 business days to call for a Full Committee Review (FCR) **in writing** by emailing IBC@villanova.edu. If an FCR is not called by any member, the submissions will proceed through DMR review and approval.
- I. DMR reviewers will send their questions/comments to IBC@villanova.edu.
 - 1. ORP will anonymize and collate this information before sending it out to the PI.
 - 2. The response from the PI will be communicated back to the DMR team by ORP. Reviewers will review the responses and record their determination (Approve, Modifications Required to Secure Approval, Refer to FCR) via an email to IBC@villanova.edu.
 - a. Protocols without unanimous approval will automatically be sent for FCR.
- J. ORP will send out determination (approval or exemption) letters to the PI via email.
- K. Resolutions of previous DMR batches will be provided in the approved table in each DMR batch. Members may request from ORP at any time:
 - 1. Updates related to submission resolutions/determinations.
 - 2. Further information or details regarding amendments that have been administratively approved.

Important Note - ORP will include a list of all DMR outcomes as part of the IBC meeting agenda for each convened meeting.