

# Application Process

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Experiments using Biosafety Levels 1-3 (BL-1, BL-2 or BL-3) containment must be reviewed and approved prior to the initiation of experiments. Experiments using BL-4 are not authorized for conduct at UNMC.

The application process is as follows:

## For the review of a new protocol not using human gene transfer protocols

1. Create an application electronically through [RSS](#).
2. On the black bar, select "IBC". Under the red IBC APPLICATION heading, select "New Protocol." Once the application is complete, sign and submit the application.
3. Following the review process by the IBC Committee, the principal investigator may be asked to amend the pre-application. (During this review process, all laboratories will be requested to have a laboratory inspection by the Biosafety Officer. View the [Laboratory Inspection Checklist forms](#) that are available to you.
4. The PI will submit the amended application with the signature page to the IBC Chair for a final review.
5. Once the protocol successfully complies to the requirements of the [NIH Guidelines](#), a letter approving the protocol authorizing initiation of the experiments will be sent to the PI.

## For the review of a new protocol using human gene transfer protocols

The IRB and IBC review may occur simultaneously. Review per the process above as well as the following points:

1. Include a copy of the documents submitted to the NIH/OBA in fulfillment of the submission requirement for human gene transfer experiments as outlined in the [NIH Guidelines](#), and a copy of the letter from the NIH/OBA to the PI about the results of the Recombinant DNA Advisory Committee's initial review.
2. Provide a copy of the letter from the NIH/OBA to the PI stating that the review process has been satisfactorily completed must also be sent with this application if it was not included with the original submission documents.
3. It is requested that the PI submit a copy of the IRB approval letter to the IBC chair to complete the application.

## Continuing review of approved IBC protocols

IBC protocols are approved for 1 year intervals after which time a re-review is required. Prior to the expiration date, the principal investigator and designated contact will be notified that the IBC protocol is up for re-review and instructed to do the following:

1. Complete a continuing review in RSS and submit.
2. Projects that are active with a change in protocol will require the submission of a Request for Change in Protocol in RSS for review with the continuing review form.
3. Individuals listed as investigators or laboratory support on projects must have active IBC training.
4. A laboratory inspection will be scheduled by the biosafety officer during this review process.
5. Following review by the IBC, if it is determined that the protocol meets re-approval (including that training is current) and the laboratory passes inspection, the proposal will be approved for another year.

## Request for Change of approved IBC protocols

IBC protocols that require any change in personnel, labs, procedures, biohazardous agents, etc. must be reviewed and approved by the IBC prior to initiating any changes:

1. Complete a Request for Change in RSS and submit.
2. Review may be performed, administratively, by the IBC Chair or by the full committee.
3. Following review, approval notice will be sent informing the PI of approval.

## Adverse event reporting

Any event (i.e. laboratory incident) that involves containment of personnel and/or the environment with a biohazardous agent must complete a report form. Please refer to IBC Policy #24 for complete details.

Revision #2

Created 18 December 2024 15:48:19 by Max V. Kuenstling

Updated 18 December 2024 16:12:16 by Max V. Kuenstling