



Institutional Biosafety Committee (IBC)
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OHSU Policy on Annual Institutional Biosafety Committee (IBC) Review

As stated in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, [Section IV-B-2-b-\(5\)](#), the IBC must periodically review recombinant and synthetic nucleic acid molecule research conducted at the institution to ensure compliance with the *NIH Guidelines*. Additionally, [Section IV-B-7-a-\(1\)](#) states that the PI may not initiate or modify recombinant or synthetic nucleic acid molecule research requiring IBC approval until that research or the proposed modification thereof has been approved by the IBC and has met all other requirements of the *NIH Guidelines*.

This policy does not apply to exempt projects. However, if you make any changes to an exempt project that might change the exempt status (e.g., introducing a viral vector), you must notify the IBC of this change and submit a new application for review in advance of beginning the non-exempt experiments.

To satisfy these requirements, the IBC has an annual review requirement which serves to ensure that all modifications to any approved project have been submitted and approved by the IBC, and that the biosafety requirements for each project are reevaluated to ensure continued safety and compliance with the *NIH Guidelines*.

On an annual basis, the PI will need to submit the annual renewal form as long as the IBC project remains active. The due date for subsequent annual renewals will be 1 year after the annual renewal approval, or 1 year after the initial approval for new projects (unless additional revisions have been submitted during the year and a new annual renewal date is set).

Process

- To conduct an annual review, the IBC must receive a completed annual renewal/project modification form signed by the Principal Investigator (PI) of the project. The PI will receive reminder notices prior to the due date for the annual renewal.
- The annual renewal form should include a detailed listing of any planned changes to all grants/projects covered under the registration number, and any “pre-approved changes” that may have occurred during the year. See the IBC Protocol Revision Policy at <http://www.ohsu.edu/xd/about/services/integrity/policies/policy-detail.cfm?policyid=756184>.
- Depending upon the scope of the modifications, the PI may not need to resubmit the entire [Recombinant DNA Research Questionnaire \(RDRQ\)](#) or [Infectious Agent/Toxin Questionnaire \(IAQ\)](#) for the annual review process. When the [Annual Renewal/Project Modification Form](#) is submitted prior to the annual renewal date, the IBC will perform a complete annual review and the renewal date will be bumped forward.

Noncompliance

The PI will receive lapse notices after the due date of the annual review form. If there is no response from the PI after one or both lapse notices the IBC may suspend the project. The decision to suspend the project may depend on the biosafety level of the project, a history of late renewal forms or other noncompliance issues, among other factors. While the IBC tries to remind investigators to submit their annual renewals in advance of the lapse date, a tracking system should also be maintained by the laboratory to keep track of IBC project renewal date(s).