

OHSU Policy on Annual Institutional Biosafety Committee (IBC) Review

As stated in the NIH Guidelines for Research Involving Recombinant DNA Molecules, Section IV-B-2-b-(5), the IBC must periodically review recombinant DNA 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 DNA 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*.

To satisfy these requirements, the IBC has established 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*.

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 a reminder notice 1 month prior to the due date for the annual renewal. A second notice will be sent 1 week prior to the due date if the form has not yet been received by the IBC.
- Each IBC project (as defined by the IBC registration number) may cover several grants or projects in the PI's lab where the same recombinant DNA molecules or infectious agents are used. 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 revision/protocol deviation policy at <http://www.ohsu.edu/research/rda/ibc/ibcpolicies.shtml>.
- The PI does not need to resubmit the entire Recombinant DNA Research Questionnaire for the annual review process. Only changes to the project anticipated for the following year need to be submitted for approval. Changes during the year must be submitted using the project modification/renewal form for Level 2 or Level 3 changes. When such changes are submitted prior to the annual renewal date, the IBC will perform a complete annual review and the renewal date will be bumped forward.
- If there are no changes to the project, the IBC Integrity Manager may perform an expedited annual review and approve the project without review by the full committee. Some modifications may also qualify for expedited review (Level 1 or Level 2 changes as defined in the Protocol Revision policy; see <http://www.ohsu.edu/research/rda/ibc/ibcpolicies.shtml>).

Noncompliance

The PI will receive lapse notices 30 and 60 days 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.

Implementation

The PI will be notified when completion of the annual renewal form is required. During initial implementation of the annual review requirement, this will occur in conjunction with grant submissions under each respective IBC project. Once a particular IBC project has been reviewed under the new annual process, subsequent grant submissions for that IBC registration number will not require additional review if no changes are proposed. Thereafter on an annual basis, the PI will need to submit the annual renewal document as long as the IBC project remains active. The due date for subsequent annual renewals will be 1 year after the initial 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, as described above). See FAQs posted at <http://www.ohsu.edu/research/rda/ibc/ibcpolicies.shtml>