

## OHSU Institutional Biosafety Committee (IBC) New Policy FAQ

### ***What is the new annual review policy? Who does it apply to?***

The IBC has implemented an annual review policy for all registered recombinant DNA (rDNA) and Infectious Agent projects. The annual review policy does not apply to exempt projects. Principal investigators (PIs) will be notified when their annual renewal is due. During the initial implementation of the annual review process, PIs will be notified to submit an annual review in conjunction with submissions to Research Grants & Contracts if the grant or project references an approved IBC registration number.

After the initial implementation, annual reviews will be required based on the last approval date. PIs will continue to be notified when their annual reviews are due. The annual review policy is posted at <http://www.ohsu.edu/research/rda/ibc/ibcpolicies.shtml>

### ***What are the changes to the IBC questions on the PPQ?***

Investigators who are submitting grants/projects that involve rDNA or infectious agents that have already been approved by the IBC may list their IBC approval number (or indicate that the project was exempt) instead of completing a separate form. Note that for new grants, the Initial Recombinant DNA Research Classification form will still be required for exempt projects.

For new or substantially modified rDNA or infectious agent projects, the PI must submit either the Initial Recombinant DNA Research Classification or Infectious Agent Questionnaire form, as applicable. Minor modifications to an already approved project should be submitted to the IBC using the Modification/Renewal form (see next FAQ).

### ***What are the changes to the protocol modification policy?***

The IBC has now qualified certain changes as "pre-approved" (Level 1 change). Such changes do not need to be submitted to the IBC for approval in advance. Instead, the PI may wait until the annual renewal of the approved project in order to submit the change. Other changes that fall under the Level 2 or Level 3 categories must be submitted to the IBC for approval prior to beginning those experiments. ***Note that any change to a select agent project or human gene transfer project needs prior approval.***

### ***What is a protocol deviation?***

The IBC has implemented a protocol deviation policy. A protocol deviation occurs when there is an inconsistency in a research study between the protocol that has been reviewed and approved by the IBC and the actual activities being done. The IBC has defined both minor and major protocol deviations. Only major protocol deviations must be reported to the IBC. Read more about protocol deviations at <http://www.ohsu.edu/research/rda/ibc/ibcpolicies.shtml>.

### ***If I decide to use a different gene insert than what is approved by the IBC, what do I do?***

If the new gene insert does not increase the biohazard risk of the recombinant DNA molecule, this change is "pre-approved" and does not need to be submitted to the IBC until the next annual renewal for that project. ***Note that any change to a select agent project or human gene transfer project needs prior approval.***

### ***What do I do if I forgot to notify the IBC before modifying my recombinant DNA experiments?***

First determine whether the modification is "pre-approved" or not (see <http://www.ohsu.edu/research/rda/ibc/ibcpolicies.shtml>). For pre-approved changes, you must notify the IBC on the next annual review. If you forget to do this, please notify the IBC as soon as possible by submitting a new annual review/modification form. This will be noted by the IBC as a minor protocol deviation. If the modification is not pre-approved, you must notify the IBC immediately by submitting an annual renewal/modification form. When you submit the modification form and assure that you have included all changes to the registered project, this will reset your annual approval date.

### ***Why is the protocol modification form the same as the annual renewal form?***

The IBC annual review process is simply a verification that no changes have been made to the project, and serves as a reminder for investigators to submit any changes that were pre-approved, or any upcoming changes for the next year of the project. However, if an investigator makes a change to the project during the year and submits the modification form, this also serves to assure the IBC that all changes have been submitted for approval up to the date of the modification. Therefore, submitting a modification will re-set the annual renewal date to one year following the date of the modification submission.

***Do these policies apply to me if all of my rDNA work is exempt?***

No, however, if you make any changes to the 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.

***What happens when my annual renewal form is late and the approval lapses?***

The IBC may choose to suspend the IBC project if the approval lapses. This decision 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, you should also maintain your own tracking system to keep track of your IBC project renewal date(s).