

## OHSU Policy on Protocol Revisions in Recombinant DNA and Infectious Agent Research

As stated in the NIH Guidelines for Research Involving Recombinant DNA Molecules [Section IV-B-7-a-\(1\)](#), the Institutional Biosafety Committee (IBC) must review all modifications to recombinant DNA (rDNA) research prior to initiation of those revised experiments.

The IBC considers certain changes to previously registered and approved projects to be “approved as a class”. Such changes need only be reported with the next submission to the IBC under that registration (e.g., next annual renewal).

Other changes require IBC approval in advance. If an investigator fails to seek IBC approval for a change to a project registration that requires advance approval, this is considered a [protocol deviation](#) and will be reviewed as such under that policy. **Note that any change to a select agent project or human gene transfer project needs prior approval.**

All investigators with approved IBC projects must use the [Project Modification form](#) to submit proposed changes for review and approval. The table below outlines the types of revisions that are pre-approved (Level 1), those that require advanced approval but can be approved administratively (Level 2), and those that require review by the full committee (Level 3). All administrative approvals will be reported to the committee at the next meeting. The IBC administrative group may send any change that normally qualifies as an administrative change to the committee for review if determined necessary. If you have a proposed revision and are not sure which category it falls under, please contact the IBC for assistance.

<b>Level 1 Revisions</b>	<b>Level 2 Revisions</b>	<b>Level 3 Revisions</b>
<p><b><u>Pre-Approved</u></b>  <b><u>(assumes no increased risks)<sup>1</sup></u></b>  <b><u>Any change to a select agent<sup>2</sup> project or human gene transfer project needs prior approval</u></b></p>	<p><b><u>Advanced Approval Required</u></b>  <b><u>Administrative approval</u></b>  <b><u>(assumes no increased risks)<sup>1</sup></u></b></p>	<p><b><u>Advanced Approval Required</u></b>  <b><u>Committee Review</u></b></p>
<ul style="list-style-type: none"> <li>• New gene of same gene category (including new mutations in gene(s) to be expressed). For example, if approved for green fluorescent protein, adding yellow fluorescent protein. This does <i>not include</i> new genes where the gene products may be oncogenic or toxic to vertebrates</li> <li>• New Biosafety Level 1 (BSL-1) vector <i>in vitro</i> or <i>in vivo</i><sup>3</sup></li> <li>• New host cells</li> <li>• Change in personnel (note that the PI is responsible for assuring new personnel are properly trained)</li> <li>• New DNA source (e.g., using rat DNA instead of mouse DNA as source of gene to be expressed)</li> </ul>	<ul style="list-style-type: none"> <li>• Modification to previously approved vector system used (e.g., 4th generation lentivirus instead of 3<sup>rd</sup> generation)</li> <li>• New host animal within rodent group (e.g., for those already approved for mice and adding rats or hamsters)</li> <li>• Change in route of administration of previously approved agent</li> <li>• Change in containment area if same biosafety level</li> </ul>	<ul style="list-style-type: none"> <li>• New BSL-2 or BSL-3 vector/agent New recombinant DNA molecule derived from a select agent<sup>2</sup></li> <li>• New <i>in vivo</i> use where previously only approved for <i>in vitro</i> work</li> <li>• New host animal outside rodent group (e.g., dogs, cats, birds, non-human primates, rabbits, pig, sheep)</li> <li>• New gene insert if gene product may be toxic or oncogenic to vertebrates</li> <li>• Investigator proposed decrease in containment level</li> <li>• Any change with increased risk</li> </ul>

<sup>1</sup>-Multiple changes may require a new Recombinant DNA Research Questionnaire (RDRQ) and new committee review (determined on a case by case basis)

<sup>2</sup>See information about Select Agents at [http://www.ohsu.edu/research/rda/ibc/sa\\_faqs.shtml](http://www.ohsu.edu/research/rda/ibc/sa_faqs.shtml)

<sup>3</sup>Applies to only non-exempt rDNA molecules (e.g., baculovirus vectors)