Institutional Biosafety Committee (IBC)
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# OHSU Policy on Protocol Revisions in Recombinant DNA, Synthetic Nucleic Acid Molecule, Infectious Agent, and Toxin Research

As stated in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules Section IV-B-7-a-(1), the Institutional Biosafety Committee (IBC) must review all modifications to recombinant DNA (rDNA) or synthetic nucleic acid molecule research prior to initiation of those revised experiments.

There are three levels of review for revisions to approved IBC protocols (see table below.) Level 1 modifications such as changes in personnel are considered "pre-approved." Such Level 1 changes need only be reported with the next Amendment Request/Continuing review in eIBC for that protocol.

Level 2 and Level 3 changes require IBC review and approval prior to start of work. 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 protocols must submit proposed changes by submitting an Amendment/Continuing Review in eIBC 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 Chair(s) 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.

| Proposed Change | Level 1<br>Pre-approved | Level 2<br>Administrative Review | Level 3<br>Committee Review |
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| **Personnel** | Addition or removal of personnel on the protocol | • Change in PI, if new PI is listed as personnel on the existing IBC protocol<br>• Adding another PI to a protocol | Change in PI |
| **Grants** | | • New grant<br>• Competing renewal or resubmission of a grant with a new PPQ# | |
| **Containment area** | | Change in containment area if biosafety level maintained (eg new or additional lab space) | Investigator proposed decrease in containment level or work practice |
| **New gene insert or DNA source** | • Gene of same category (eg RFP instead of GFP)<br>• New DNA source (eg rat DNA instead of mouse | • Gene of different category | • New gene insert from a risk group IV agent or Select Agent<br>• New gene insert that may be toxic, oncogenic, increases |

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| | DNA as source of gene to be expressed) | | virulence or pathogenicity, or alters immunogenicity |
| **Non-recombinant infectious agent** | | New non-recombinant risk group II agent | New non-recombinant risk group III agent |
| **Toxins** | | New biologically derived toxin with an LD50 <100ng/kg in vertebrates | • Use of toxin in an amount that requires Select Agent registration<br>• New rDNA or synthetic nucleic acid molecule expressing a toxin with an LD50 <100 ng/kg in vertebrates in cells, organisms or viruses |
| **Recombinant vector or agent** | New BSL-1 plasmid vector *in vitro* or *in vivo* | • Modification to previously approved vector system or recombinant infectious agent that does not increase risk<br>• New Risk Group I viral vector system | • New Risk Group II or higher recombinant agent or viral vector system<br>• New recombinant Select Agent<br>• Modification to previously approved vector system or recombinant infectious agent that may increase risk |
| **Synthetic nucleic acid molecule** | | • Addition of a synthetic nucleic acid molecule equivalent to an rDNA molecule on the protocol<br>• Modification to existing synthetic nucleic acid molecule that does not increase risk | • New synthetic nucleic acid molecule that would require BSL-2 or higher containment and work practices<br>• Synthetic nucleic acid molecule that may increase risk |
| **Human Gene Transfer** | | Modifications to existing studies that do not increase biohazard risk and/or are unrelated to the gene transfer component | • New human gene transfer studies<br>• Modifications that may increase risk |
| **Changes in *in vivo* work** | New transgenic strains when previously approved for work with the species (eg zebrafish or transgenic flies)* | • Creation of a new transgenic rodent at the OHSU Transgenic Core<br>• Change in route of administration | • New *in vivo* use where previously only approved for *in vitro* work<br>• New host species outside mice or rats<br>• Change in route of administration or dosing that may increase risk |
| **Host cells** | New host cells that are not known to contain a human pathogen | New host cells that are known to contain a risk group II agent (eg cells known to be infected with hepatitis C) | New host cells that are known to contain a risk group III agent, (eg cells known to be infected with HIV) |

*Most transgenic rodents do not require IBC registration. Please refer to the OHSU IBC Transgenic Animal Policy for addition information and exceptions.