

## III. Review Procedures For Research At The University Of Washington

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### A. Research Project Reviews

#### 1. Policy

The University of Washington Administrative Policy Statement (APS 12.3) regarding review of research projects involving biological hazards and recombinant DNA states that all grant and contract proposals that involve any use of, or exposure to, potential biohazards must be reviewed by the Institutional Biosafety Committee (IBC). All such research proposals, regardless of funding source, are subject to this review. The Institutional Biosafety Committee, not the investigator or department, is charged with the final determination of hazard classifications. In addition, the Institutional Biosafety Committee recommends approval or disapproval to the Executive Director for Health Sciences Administration on each proposal. Certain funding agencies also require the institution to assure biosafety compliance of the principle investigator with the submittal of the proposal.

#### 2. Procedures

##### Initiating Review

Project review is initiated when a researcher submits the Research Project Hazard Assessment (RPHA) form. The RPHA replaced the Recombinant DNA Registration, the Biohazard Activity Review, and the Hazardous Materials Use forms. The Research Project Hazard Assessment form is online at <http://www.ehs.washington.edu/rbsresplan/rpha.shtm>. The completed form and supporting material are to be submitted for review to Biological Safety Officer, (BSO), Environmental Health and Safety, Box 354400, emailed to [rbsso@u.washington.edu](mailto:rbsso@u.washington.edu), or faxed to 206-616-3360. If submitting via email, please mail or fax the signed Page 4 *Statement of Responsibility*.

The submittal shall include:

- 1) The application being submitted for outside grant support, or a statement that this document is available for perusal by members of the committee.
- 2) A completed Research Project Hazard Assessment form.
- 3) An abstract or brief description of research procedures.

If you have questions pertaining to completion of the form, contact the Biological Safety Officer (BSO) at 206-543-7278 or [rbsso@u.washington.edu](mailto:rbsso@u.washington.edu).

### **Approval**

The information is reviewed by the Biological Safety Officer (BSO) and/or the Institutional Biosafety Committee (IBC) depending, in part, upon the project's complexity and risk. The BSO and/or the IBC may request additional information from the Principle Investigator to help in the review of the proposal.

The Principle Investigator will receive notification of IBC review and determination of approval or disapproval. If the notification letter indicates a conditional approval, it will also indicate actions or information that the IBC must receive before approval notification can be issued. Projects may be subject to other university approvals (e.g., IRB and IACUC, see table for rDNA research). If the project involves animals, IACUC approval is always required before project initiation.

### **Project Renewal**

Project approval must be renewed **every year** or when protocol changes.

- If there is no change in the approved protocol
  - Notify the IBC in writing by sending a signed letter to the BSO stipulating the protocol title, the IBC reference number and that there are no changes in the protocol.
- If there is any change in procedure, experiments, hazard assessment, or research location
  - Submit updated Research Project Hazard Assessment Form for review.

## B. Additional Information for Research Involving Recombinant DNA

### 1. For research involving rDNA, NIH required approval(s) and timing.

<a href="#">NIH Guidelines</a> Reference	Timing	RAC Review	NIH/OBA Approval	IBC Approval	Other Approvals
Transfer of drug resistance trait to a microorganism not known to acquire the trait naturally.  <a href="#">NIH Section III-A</a>	Before Initiation	<b>X</b>	<b>X</b> (NIH Director)	<b>X</b>	<b>IRB</b>
Cloning of Toxins.  <a href="#">NIH Section III-B</a>	Before Initiation		<b>X</b>	<b>X</b>	
Gene transfer into humans.  <a href="#">NIH Section III-C</a>	Before Participant Enrollment	<b>X</b>		<b>X</b>	<b>IRB</b>
*Risk Group 2,3,4 or Restricted Agents: o As host-vector systems o Is cloned into non pathogenic or lower eukaryotic host vector systems * Infectious virus or replication incompetent virus in presence of helper virus * Whole Animals * Plants–pathogens / genic * More than 10 L of culture  <a href="#">NIH Section III-D</a>	Before Initiation			<b>X</b> <b>X</b>  <b>X</b>	<b>IACUC</b>
* Those not above * Less than 2/3 eukaryotic virus genome * Whole non-path plants * Transgenic rodents  <a href="#">NIH Section III-E</a>	Simultaneous with Initiation			<b>X</b> <b>X</b>  <b>X</b> <b>X</b>	

