Section 2 – Review Procedures for Research at the University of Washington

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A. RESEARCH PROJECT REVIEWS

1. Policy

Grant and contract proposals that involve any use of, or exposure to, potential biohazards, including recDNA, are reviewed by the IBC and/or EH&S. All such research proposals, regardless of funding source, are subject to this review. The IBC, not the investigator or department, is charged with the final determination of hazard classifications. Certain funding agencies also require the UW to assure the biosafety compliance of the PI with the submittal of the proposal.

2. Procedures

a. Initiating Review

Project review is initiated when a PI submits the BUA application.

b. Approval Process

The information is reviewed by a BSO and/or the IBC, depending, in part, upon the project's complexity and risk. The BSO and/or the IBC may request additional information from the PI to aid in the review of the proposal. Incomplete applications may be returned to the PI.

The PI will receive notification of IBC review and determination of approval or denial. If the notification letter indicates a conditional approval, it will also indicate actions or information that the IBC must receive before final approval notification can be issued. Projects may be subject to other UW approvals (e.g., IRB, Institutional Animal Care and Use Committee (IACUC), DURC; see Table 1: Levels of review required for recDNA research). If the project involves animals, IACUC approval is always required prior to project initiation.

c. Renewals and Changes to Previously Approved Research

Additional IBC review and approval is required:

1) Every three years for projects involving biohazardous agents, including recDNA, and, if animal work is involved, concurrent with expiration of IACUC protocols. To renew the approval, PIs should submit a BUA application two months prior to the expiration

date of their current BUA letter or animal protocol. PIs can check the submission deadlines online.

2) Before modifying or making any significant changes to a research protocol already approved by the IBC (e.g., any changes related to laboratory equipment that may generate aerosols, research procedures, lab locations, gene inserts, biohazardous agents, etc.). This is done by submitting a Request for Change to BUA form to the IBC.

B. LEVELS OF REVIEW REQUIRED FOR RECDNA RESEARCH

Table 1 summarizes the types of approvals and reviews required from various boards and committees for the use of recombinant DNA research.

Table1: Levels of Review Required for recDNA research

NIH Guidelines Section	Experiments covered under *NIH Guidelines*	NIH/ Recombinant DNA Advisory Committee (RAC) Review	NIH Approval	Institutional Approval/Review		
				IBC Approval	EHS Review	IRB/ IACUC Approvals
Section III-A	Transfer of drug resistance trait to a microorganism not known to acquire the trait naturally	YES	YES (NIH Director)	YES		
Section III-B	Cloning of toxin molecules with LD_{50} less than 100ng/kg body weight		YES	YES		
Section III-C	Gene transfer into humans by recDNA	YES		YES		IRB Contingent on IBC Approval
	recDNA in vaccines			YES		IRB Contingent on IBC Approval
Section III-D	Recombinant risk group 2, 3, or restricted agents a. As host-vector systems b. DNA is cloned into non-pathogenic prokaryotic or lower eukaryotic host-vector systems			YES		
	Infectious virus or replication defective virus in presence of helper virus in tissue culture systems (e.g., viral vectors)			YES		
	Whole transgenic animals and recDNA-modified microrganisms tested on whole animals			YES		IACUC

NIH Guidelines Section	Experiments covered under *NIH Guidelines*	NIH/ Recombinant DNA Advisory Committee (RAC) Review	NIH Approval	Institutional Approval/Review		
				IBC Approval	EHS Review	IRB/ IACUC Approvals
	recDNA modified whole plants			YES		
	More than 10 L of recDNA culture			YES		
	Influenza viruses (specific strains) generated by recombinant methods			YES		
Section III-E	Those not above			YES		
	Less than 2/3 eukaryotic virus genome			YES		
	recDNA modified whole non-pathogenic plants and plants associated microorganisms			YES		
	Generation of transgenic rodents that require BSL-1 containment			YES		
Section III-F	Not in organisms, cells, or viruses				YES	
	Nonchromosomal or viral DNA of single source				YES	
	Prokaryotic DNA with indigenous plasmids or viruses when propagated in same system or when transferred				YES	
	Eukaryotic DNA, propagated in same system				YES	
	Physiological exchangers				YES	
	Not a significant risk to health or environment				YES	

Note: For work with human embryonic stem cells (hESC) and induced pluripotent stem cells (iPS), contact the UW Embryonic Stem Cell Research Oversight Committee (ESCRO). These studies require IBC review.