

## UCSB Biosafety Handbook

### 2.0 CHAPTER 2 – BIOHAZARDOUS USE AUTHORIZATION REVIEW APPROVAL & PROCESS

The protocol review process has changed from a grant-centered mode to one in which comprehensive review is made of all work going on or proposed in any given laboratory. Approval given for such work applies for three years, after which it becomes subject to subsequent review and renewal. All labs using biohazardous materials and infectious agents must complete a Biohazardous Use Authorization (BUA) form.

<http://www.ehs.ucsb.edu/programs/biosafety/buaapp.doc>

All proposals presented from the laboratory of a faculty member who has responsibility for assigned space shall be treated as if they belong to that faculty member.

The combination of all work proposed by a laboratory group, regardless of the source of funding (or even lack of funding), shall be subject to a comprehensive "umbrella" review.

Therefore, for the purposes of this proposal review format, a Principal Investigator shall be regarded as the ultimate, single point of accountability and responsibility for a given laboratory. A Principal Investigator is defined as i) a faculty member, ii) who has assigned laboratory space, and iii) who is ultimately responsible for the work carried out in such space.

The review format will request specification and/or identification of all biohazard parameters used in your protocol as shown in the example below:

<b>Infectious Agents</b>	<b>Human/ Primate Tissue</b>	<b>Anim als</b>	<b>rDNA</b>	<b>Vector</b>	<b>Host</b>
Bacteria S. typhi M. tuberculosis	Cornea Myocardium Hela Cells	Mice Rabbit Sheep Monkey Dog Etc.	E1a gag pol Etc.	VSV AAV Etc.	E. coli Etc.
Viruses SV40 Coxsackie B HIV	Brain 293 Fibroblasts CD4+ lymphocytes Etc.				
Rickettsia C. burnetti R. tsutsugamushi					
Protozoa G. lamblia E. histolytica					

Having listed all of the material variables in their various experiments, as shown above, the PI must then specify the various combinations involved with quantitative parameters. For example:  $5.0 \times 10^6$  infectious units/ml, 10 mls HIV into each of 200 mice, etc.

The PI must specify:

- what procedures are being carried out;
- where each aspect of the work is being done; and
- who the researchers, lab workers and collaborators are.

The PI must notify Environmental Health and Safety and receive approval before changing any variable, which may carry increased biohazard risk. As a working principle, PIs must decide if a new agent or protocol poses any new or increased hazards from those indicated in the currently approved proposal. If there are new or increased hazards (or if there is any doubt or question), approval must be sought prior to implementing the change. Approval must be sought and obtained from EH&S and the IBC prior to the initiation of work involving any of the following:

- new viruses, new vector systems
- work with non-human systems being changed into work in human systems
- work with new cell lines
- changes in constructs or systems that result in significantly higher titers
- enhanced replication or infectivity
- expression of toxic products
- partial genomes increased to more than two-thirds of whole genome
- new or altered procedures that pose increased risk of aerosol or other type of exposure
- addition of procedures or agents that require a change in Biosafety Level