

STANFORD UNIVERSITY ADMINISTRATIVE PANELS OFFICE
 NOTICE: USE OF BIOHAZARDOUS AGENTS
 ACTION REQUIRED - SEE BELOW
THIS WILL BE THE ONLY NOTICE YOU RECEIVE: THERE WILL BE NO SECOND NOTICE.

Date:

To:

From: Ellyn Segal, Biosafety Officer, 5-1473

Subject: Use of Recombinant DNA or Biohazardous Agents

Re: Proposal for, _____ (grant agency) (SPO # _____)

entitled, _____
 _____ (grant title)

This form has been generated based on your response to item #14 on the Sponsored Project Proposal Routing Sheet (SU-42 form) for the above listed project. Based on your response to the below questions, review and approval by the Administrative Panel on Biosafety (APB) may be required.

<ul style="list-style-type: none"> • Are biohazardous agents used? YES NO • If yes, provide name and class of agent(s): <p>_____ 1 2 3</p> <p>_____ 1 2 3</p>	<ul style="list-style-type: none"> • Is recombinant DNA used? YES NO • If yes, provide category: <p style="text-align: center;">EXEMPT NON-EXEMPT</p>
<p>See reverse for description of classification of biohazardous agents.</p>	<p>See reverse for description of recombinant DNA Exempt categories.</p>

If the above listed project involves only Class 1 agents and/or exempt recombinant DNA exclusively, stop here- this project does not require APB approval. Sign and return this notice to the address below. Otherwise, continue completing this notice.

Are research procedures using biohazardous agents and/or non- exempt recombinant DNA **IDENTICAL** to a project application which has been approved or renewed by the APB in the last 12 months? YES NO

If NO: You must complete the Administrative Panel on Biosafety Application (forms available in the Biosafety Manual or at <http://www.stanford.edu/dept/EHS/prod/researchlab/bio/docs/APBform.pdf>). Return this notice to the Biosafety Officer with the completed APB Application.

If YES: Has everyone working on this project attended the School of Medicine Safety Class or a similar training session provided by the department: YES NO

Provide the Biosafety Identification Number of the existing approved project application (e.g. ABC-96-01-00): _____

(This Identification Number is required in order to cross reference the above listed project to an existing APB approval. If necessary, call 725-1473 to obtain the Identification Number. Do not provide CRA, A-PLAC, etc. numbers.)

P.I. Signature: _____ Date _____

If you are working with Class 2 or above biohazardous agents and/or non-exempt recombinant DNA then you **MUST** have a current APB approval. If you presently have approval for experiments using the same risk agents and procedures, you can use this form to cross-reference. If you need to update your present approval, use [the APB Update Form](#).

Return this notice to Ellyn Segal (Biosafety Manager); EH&S; MC 8007 (725-1473)

Biohazardous Agents (CDC guidelines): if you are working with **BL-2 or 3** class biohazardous agents you **MUST** have current APB approval. Listing of agents and their associated biosafety level can be found at <http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm> and in the [Stanford University Biosafety Manual](#). BL-1 agents are exempt, and Stanford University does not allow BL-4 or 5.

Recombinant DNA (NIH guidelines): if your experiment is in an exempt category, APB approval is not necessary. If your experiment does not fall within the following exempt categories, you **MUST** have current APB approval.

Is your rDNA never going to be in an organism or virus?	Yes	Exempt (III-F-1)
Is your rDNA solely from a single non-chromosomal or viral source?	Yes	Exempt (III-F-2)
Is your rDNA solely from a prokaryotic host and propagated in the same host or transferred to another host by naturally occurring means?	Yes	Exempt (III-F-3)
Is your rDNA from a eukaryotic host and propagated in the same host?	Yes	Exempt (III-F-4)
Is your rDNA from species that naturally exchange DNA?	Yes	Exempt (III-F-5)
rDNA which does not present a significant risk to health or the environment, as determined by the NIH (rDNA from BL-2 or above agents is not exempt)	Yes	Exempt (III-F-6)

Viral Vectors

Certain viral-based **cloning vectors** are non-exempt as determined by the NIH.

Gene transfer vector ^a	Host range ^b	function ^c	Insert or gene	Laboratory containment level ^d
MMLV based- <i>gag, pol, env</i> deleted	Ecotropic		S, E, M, G, CC, T, MP DR, R, TX, O _v , O _c	BSL-1*
	Amphotropic, VSV-G pseudotyped		S, E, M, T, MP, DR O _v , O _c , R, G, CC TX	BSL-2 BSL-2+/BSL-3 BSL-3
Herpes virus based- nonlytic	Broad host range		S, E, M, MP, DR, T O _v , O _c , R, G, CC TX	BSL-2 BSL-2+ BSL-3
Lentivirus based- HIV, SIV, EIAV, FIV, etc.; <i>gag, pol, env, nef,</i> <i>vpr</i> deleted	Ecotropic, amphotropic, VSV-G pseudotyped	S, E, M, MP, DR,	BSL-2+/BSL-3, until safety issues resolved, then BLS-2/ BSL-2+ may be appropriate	BSL-3
Adenovirus based- Serotype 2, 5, 7; E1 and E3 or E4 deleted	Broad host range, infective for many cell types		S, E, M, T, MP, DR O _v , O _c , R, G, CC TX	BSL-2 BSL-2+ BSL-3
Alphavirus based- SFV, SIN	Broad host range	O _v , O _c , R, G, CC	S, E, M, T, MP, DR BSL-2+	BSL-2
Baculovirus based	Broad mammalian host cell range		S, E, M, T, MP, DR O _v , O _c , R, G, CC TX	BSL-3 BSL-1* BSL-2 BSL-2+/BSL-3
Parvovirus, AAV based- (rep ⁺ , cap ⁺)	Broad host range, infective for many cell types including neurons	S, E, M, T, MP, DR	BSL-1* O _v , O _c , R, G, CC TX	BSL-2 BSL-2+/BSL-3
Poxvirus based- caarypox, vaccinia	Broad host range		S, E, M, T, DR, MP O _v , O _c , R, G, CC, TX	BSL-2 BSL-2+/BSL-3

^aRefers to the parental or wild-type virus.

^bRefers to the ability of vector to infect cells from a range of species. Ecotropic generally means able to infect only cells of species originally isolated from or identified in.

^cGeneral categories of cellular genes and functions: S, structural proteins: actin, myosin, etc.; E, enzymatic proteins: serum proteases, transferases, oxidases, phosphatases, etc.; M, metabolic enzymes: amino acid metabolism, nucleotide synthesis, etc.; G, cell growth, housekeeping; CC, cell cycle, cell division; DR, DNA replication, chromosome segregation, mitosis, meiosis; MP, membrane proteins, ion channels, G-coupled protein receptors, transporters, etc.; T, tracking genes such as GFP, luciferases, photoreactive genes; TX, active subunit genes for toxins such as ricin, botulinum toxin, Shiga, and Shiga-like toxins; R, regulatory genes, transcription, cell activators such as cytokines, lymphokines, tumor suppressors; O_v and O_c, oncogenes identified via transforming potential of viral and cellular analogs, or mutations in tumor suppressor genes, resulting in a protein that inhibits/moderates the normal cellular wild-type protein. This does not include SV40 T antigen.

^dThis is a general assessment of appropriate containment for construction and laboratory use of these vectors for nonproduction quantities only based on the 1999 CDC/NIH BMBL. *Most procedures involving viral vectors are done at BSL-2 to protect cell cultures and viral stocks from contamination. From Biological Safety Principles and Practices, 3rd ed., pg. 594, D.O. Fleming and D.L. Hunt, ed, ASM Press, 2000.