

**CALIFORNIA STATE UNIVERSITY, FRESNO  
BIOHAZARD USE AUTHORIZATION APPLICATION**

**Instructions:**

Please use this form to register your work with biohazardous material and/or recombinant DNA.

You will need to reference the most current applicable guidelines.

- Download the NIH guidelines for work with recombinant DNA via the following link:  
*[http://oba.od.nih.gov/rdna/nih\\_guidelines\\_oba.html](http://oba.od.nih.gov/rdna/nih_guidelines_oba.html)*
- Download the CDC publication "Biosafety in Microbiological and Biomedical Laboratories (BMBL) via the following link: *<http://www.cdc.gov/biosafety/publications/bmb15/>*

If you have any questions regarding the registration process, contact Environmental Health and Safety/ Risk Management at extension 8-7422.

**SECTION A:**

Date of Application: \_\_\_\_\_

Type of application: New \_\_\_\_\_ Addendum \_\_\_\_\_

Principal Investigator/Instructor: \_\_\_\_\_

Phone # \_\_\_\_\_ Email \_\_\_\_\_

Department/Mail Stop #: \_\_\_\_\_

Location of Instruction/Work/Storage Locations (Building, Room Numbers): \_\_\_\_\_

List of activities: \_\_\_\_\_

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(use additional pages if necessary)

**SECTION B:**

- **Does your work involve the generation of recombinant DNA?**

Yes \_\_\_\_\_

No \_\_\_\_\_ (Skip to Section C)

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**Please select all of the exempt categories below that apply to your recombinant DNA work.**

- \_\_\_ rDNA molecules that are not in organisms or viruses
- \_\_\_ rDNA molecules that consist entirely of DNA segments from a single non-chromosomal or viral DNA source
- \_\_\_ rDNA molecules that consist entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host or when transferred to another host by well established physiological means
- \_\_\_ rDNA molecules that consist entirely of DNA from a eukaryotic host, including its chloroplasts, mitochondrial DNA, or plasmids when propagated only in that host or a closely related strain of the same species
- \_\_\_ rDNA molecules that consist entirely of segments from different species that exchange DNA by known physiological processes, though one or more may be a synthetic equivalent; [see Appendices A-I through A-VI of the NIH Guidelines for sublists of natural exchangers.](#)
- \_\_\_ rDNA molecules that are not a significant risk to health or the environment as determined by the NIH Director; [see Appendix C](#) of the NIH Guidelines for a detailed explanation of the following exemptions, and please indicate which of the categories below apply to your work:
  - \_\_\_ Recombinant DNA in tissue culture ([Appendix C-I and C-IA](#))
  - \_\_\_ *Escherichia coli* K-12 host-vector systems ([Appendix C-II and C-II-A](#))
  - \_\_\_ *Saccharomyces* host-vector systems ([Appendix C-III and C-III-A](#))
  - \_\_\_ *Kluyveromyces* Host-Vector Systems ([Appendix C-IV and C-IV-A](#))
  - \_\_\_ *Bacillus subtilis* or *Bacillus licheniformis* host-vector systems ([Appendix C-V and C-V-A](#))
  - \_\_\_ Extrachromosomal elements of gram positive organisms ([Appendix C-VI and C-VI-A](#))
  - \_\_\_ Purchase or transfer of transgenic rodents that require biosafety level1 (BSL 1) containment ([Appendix C-VII](#))
  - \_\_\_ Generation of BL1 transgenic rodents via breeding ([Appendix C-VIII](#))

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**Experiments that require specific approval by both the NIH and the IBC before initiation:**

- \_\_\_ Transfer of a drug-resistance trait to microorganisms if such transfer might compromise use of the drug therapeutically ([see Section III-A-1-a](#) for further information and examples).  
*Note: IBC, RAC review, and NIH Director review and approval are required before initiation.*
  - \_\_\_ Experiments Involving the Cloning of Toxin Molecules with LD<sub>50</sub> of Less than 100 nanograms per Kilogram Body Weight ([see Section III-B-1](#) for further information and examples).  
*Note: IBC approval and NIH review for containment determinations are required before initiation.*
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## Experiments that require Institutional Biosafety Committee and Institutional Review Board approvals and RAC review before research participant enrollment

- \_\_\_ Experiments involving the deliberate transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA, into one or more human research participants (see Section III-C for further information and examples).
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### Experiments that require approval by the IBC *before initiation*:

- \_\_\_ Experiments using human or animal pathogens (Risk Group 2-4 or restricted agents) as DNA source or host/vector system (see Section III-D-1 for further information and examples).
  - \_\_\_ Experiments in which human or animal pathogens (Risk Group 2-4 or restricted agents) are cloned in nonpathogenic prokaryotic or lower eukaryotic host-vector systems (see Section III-D-2 for further information and examples).
  - \_\_\_ Experiments involving the use of infectious animal or plant viruses or defective viruses in the presence of a helper virus in a tissue culture system (see Section III-D-3 for further information and examples).
  - \_\_\_ Experiments involving whole animals or plants (see Section III-D-4 and see Section III-D-5 for further information and examples).
  - \_\_\_ Experiments involving more than 10 liters of culture (see Section III-D-6 for further information and examples).
  - \_\_\_ Experiments involving influenza viruses (see Section III-D-7 for further information and examples).
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### Experiments that require IBC notice *simultaneous with initiation of experiment*:

- \_\_\_ Experiments involving the formation of recombinant DNA molecules containing no more than two-thirds of the genome of any eukaryotic virus (see Section III-E-1 and Section III-F for further information and examples).
  - \_\_\_ Experiments involving whole plants (except those covered in the Section above; see Section III-E-2 and Section III-F for further information and examples).
  - \_\_\_ Experiments involving transgenic rodents (see Section III-E-3 and Section III-F for further information and examples).
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## SECTION C

*Complete this section if your work involves the use of the following biohazardous materials: bacteria, fungi, viruses, including oncogenic viruses, chlamydiae, parasites; human blood, blood products or human tissues, primary human cell cultures, non-human primate blood or tissues; infected animals and animal tissues; toxins (bacterial, plant fungi, etc.).*

- **Does your work involve the use of above-mentioned biohazardous materials?**

Yes \_\_\_\_\_

No \_\_\_\_\_ (Skip to Section D)

• **Is your work with biohazardous materials limited to Biosafety Level 1?**

Yes \_\_\_\_\_

(Only complete item 1 below)

No \_\_\_\_\_

(Please complete items 1 – 7 below)

1. Name of biohazardous agent(s).
2. Brief description of human diseases caused by agent(s), if known.
3. Brief description of the research and use/manner in which agent(s) will be handled.
4. Proposed biosafety level and description of techniques, equipment and procedures used to ensure containment (BSL 2 or above).
5. The method used for disinfection and disposal of the biological materials(s) and waste.
6. Please list largest volume, highest titer and frequency of use.
7. Does this project involve the use of experimental animals?  Yes  No

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## SECTION D

Your signature below indicates that you acknowledge all requirements and restrictions of the most current NIH/CDC guidelines for the biosafety level you have indicated above; that you accept responsibility for the safe conduct of the experiments conducted at this biosafety level and that you have informed all associated personnel of the conditions required for this work.

Signature of Investigator/ Instructor \_\_\_\_\_ Date \_\_\_\_\_

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## SECTION E

I acknowledge that I have seen the Biohazard Use Authorization Application document and I agree to exercise due diligence in ensuring compliance with the University's Biosafety Policy.

Signature of Department Chair \_\_\_\_\_ Date \_\_\_\_\_

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## SECTION F (Institutional Biosafety Committee only)

Comments:

Registration Accepted:  Yes  No

Application Approved:  Yes  No

\_\_\_\_\_  
Chairperson, Institutional Biosafety Committee

\_\_\_\_\_  
Date

*Please return completed form to the Office of Environmental Health and Safety/Risk Management,*

*Mail Stop PO-140, fax to extension 8-1153, or email to [lisak@csufresno.edu](mailto:lisak@csufresno.edu).*

Updated April 2012