INSTITUTIONAL BIOSAFETY COMMITTEE
SAN JOSÉ STATE UNIVERSITY
EXEMPTION REQUEST FORM

Principal Investigator:	BUA #:
Project Title:	

The SJSU IBC Charter distinguishes between projects requiring oversight and those considered exempt from oversight. Projects involving certain biological materials, pathogens, or recombinant DNA molecules generally require IBC review. On the other hand, some projects are considered exempt if they pose minimal risk to personnel and the environment when performed with good microbiological practices.

The projects involving experiments with the following materials are not exempt from the IBC review:

- Recombinant/synthetic nucleic acid molecules (r/s DNA), as covered by the NIH Guidelines
- Biological agents (including bacteria, viruses, parasites, fungi, prions) that can cause disease in healthy humans and/or have a significant environmental impact, or otherwise require BSL-2 containment and practices, as covered by the BMBL
- Human and nonhuman primate blood, serum, plasma, tissues, secretions, excretions or cell lines, unless documented to be free of bloodborne pathogens, as covered by the Bloodborne Pathogens Standard
- Biological toxins (e.g., cholera toxin, snake venom toxin, tetrodotoxin, etc.)
- Poisonous plants posing a risk to humans via dermatological contact, inhalation or another route of exposure
- Diagnostic specimens or environmental samples likely to contain any of the above and posing a significant risk to humans or livestock
- Genetically-modified animals, as covered by the NIH Guidelines
- Dual Use Research of Concern activities
- Other biological materials, as determined necessary by the BSO or IBC Chair

To determine if your project is exempt from the IBC review, please answer the following questions. If you answered **NO** to all of these questions, your project is categorized as **exempt** by the IBC.

Will you introduce recombinant or synthetic DNA into live animals or human subjects?

☐ Yes
☐ No

Will you use transgenic animals other than transgenic mice or rats?

☐ Yes
☐ No

Will you work with nucleic acids from RG 3 or 4 agents (NIH Guidelines), or restricted agents (Select Agent), or with nucleic acids that code for biosynthesis of molecules toxic to vertebrates?

☐ Yes

☐ No

Will recombinant or synthetic nucleic acids be deliberately introduced into any living cells or be modified to make them capable of penetrating into cells (e.g., as for transformation or transfection)?
☐ Yes ☐ No

Will recombinant or synthetic DNA be propagated or expressed using host-vector systems other than *Escherichia coli K-12, Saccharomyces, Bacillus subtilis* or *Bacillus licheniformis*, be shared between microorganisms of different species or strains that do not naturally exchange DNA, or be introduced into cultured eukaryotic cells other than existing cell lines?
☐ Yes ☐ No

Will cell culture experiments use infectious viruses (DNA or RNA), defective viruses in the presence of helper virus, or eukaryotic viral genome segments comprising more than ½ of the full viral genome?
☐ Yes ☐ No

Will you culture organisms (including cells in culture) or viruses containing recombinant DNA in volumes exceeding 10L?
☐ Yes ☐ No

Will you handle human-derived materials (fluids or tissue) or cells?
☐ Yes ☐ No

Will you subculture and isolate microorganisms from an initial culture plate of unknown environmental samples (soil, water, sediments)?
☐ Yes ☐ No

List any materials you are using that could produce biological toxins with an LD50 of less than 100 µg per kg of body weight in vertebrates?

Provide a brief description of your research/teaching project and briefly explain why you believe your experiments fall within the exemption category.

Submit the completed form to biosafety@sjsu.edu. If the IBC Chair, after reviewing the form deems it necessary, you may be required to submit a risk assessment to support your claim that the research is exempt. For additional guidance with this form, contact the IBC at biosafety@sjsu.edu.

Projects determined as exempt by the IBC Chair will receive an acknowledgement letter from EHS, on behalf of the IBC, documenting the exempt determination. No further action will be required, unless there is a change in procedures that would affect the IBC's initial determination as exempt. Exempt BUAs do not require annual reviews.