Instructions:

This template is designed to help aid you in the development of your BSL-2 standard operating procedure, but you may also use your own template. Feel free to add more protocols and information as needed for your particular biohazard. The sections in square brackets highlighted in yellow should be replaced with the appropriate text. The template was made in the College of Science, so please update any information as needed for your college/department. Please also delete this instruction page from the SOP.

**[Name of Course or Lab]**

**San José State University**

**Synthetic and Recombinant Nucleic Acids Standard Operating Procedures**

**[Month and year]**

**SYNOPSIS**

This laboratory is approved to work with recombinant or synthetic nucleic acidmaterials by the Institutional Biosafety Committee. The National Institutes of Health states: “recombinant and synthetic nucleic acids are defined as:

1. molecules that: a) are constructed by joining nucleic acid molecules; and b) that can replicate in a living cell, i.e., recombinant nucleic acids;
2. nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids;
3. molecules that result from the replication of those described in (i) or (ii) above.”

The following restrictions and requirements apply:

1. Laboratory personnel need to obtain specific training in using recombinant and synthetic nucleic acids, as well as appropriate procedures for handling organisms carrying recombinant DNA. Personnel are supervised by the [primary investigator/instructor] who is competent in handling recombinant and synthetic nucleic acids and associated procedures.
2. All laboratory procedures that use recombinant and synthetic nucleic acids in organisms must conform to appropriate handling procedures for the highest risk group utilized in the experiments.
3. Demonstrated competence in procedures for responding to and managing spills, personnel exposures, and emergency situations is required of all affiliated laboratory personnel.

**Contact information: [fill out]**

Primary Investigator/Instructor:

Primary Investigator/Instructor Email:

Office phone number:

Laboratory phone number(s) and room(s):

**Detailed Practices for working with Recombinant DNA**

[Please include specific information about the type of synthetic or recombinant nucleic acid experiments that are proposed, including: procedures (e.g.: Polymerase Chain Reaction (PCR); transfection of cultured mammalian cells; protein expression); species and genus names for host organisms; the biosafety level at which experiments will be conducted.]

***Note: While certain recombinant/synthetic nucleic acid experiments are considered by the*** [***NIH Guidelines***](http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines) ***to be exempt (Section III-F and Appendix C), research of this nature is not exempt from review and oversight from the SJSU IBC.***

*Note: to determine risk group category for bacteria, viral groups, fungi genus and parasite genus refer to:*

<https://my.absa.org/tiki-index.php?page=Riskgroups>

*Note: to determine Bloodborne Pathogens risk, refer to:*

<https://www.dir.ca.gov/title8/5193.html>

*For more information about cultured cell lines, refer to:*

[www.atcc.org](http://www.atcc.org)]

1. **Personnel training:** Laboratory personnel receive specific training in handling recombinant and synthetic nucleic acids. They are trained and supervised by the [PI/instructor] who is competent in handling recombinant and synthetic nucleic acids and associated procedures involving these materials.
2. *Standard microbiological practices:*
	* 1. Personnel must wear appropriate personal protective equipment based on the risk of the agent. Personal protective equipment should be removed before leaving for non-laboratory areas.
		2. All personnel should wash hands after working with potentially hazardous materials and before leaving the laboratory.
		3. No hand or surface to face contact, which includes no eating, drinking, smoking, handling contact lenses, applying cosmetics, or storing food for human consumption is not permitted in the laboratory.
		4. Mouth pipetting is prohibited.
		5. All members of the laboratory must be aware of and follow proper department waste disposal guidelines.
3. *Documentation and additional training:*
4. All personnel will take the CITI “Initial Biosafety Training” and “NIH Recombinant DNA Guidelines” modules. [Alternatively, you can document your own biosafety training materials and have students sign.]
5. Personnel training will be documented and maintained in [room where recombinant DNA work is conducted].
6. Additional training will be provided as needed if new procedures are introduced.
7. Where necessary, additional guidance will be sought from the Institutional Biosafety Committee (IBC).
8. **Laboratory procedures:** Experiments should be conducted at the appropriate level of containment based on the risk of the agent itself. If a recombinant and synthetic nucleic acid molecule is generated from multiple sources, containment should be based on the highest risk level. Any genetic alteration that results in a more hazardous than the wild-type strain should be considered for handling at a higher containment level.
	* + 1. *Procedures for disinfection of laboratory surfaces, equipment and other materials used to work with recombinant and synthetic nucleic acids materials:*
				1. Any laboratory work surface (e.g., bench top) used for experimental procedures is decontaminated with [70% ethanol or other approved disinfectant] before and after each laboratory session.
				2. Liquid waste containing recombinant and synthetic nucleic acids should be decontaminated in bleach (final concentration 1:10) for a minimum of 30 minutes. Once the liquid is decontaminated it can be poured down the drain.
				3. Liquid waste containing recombinant and synthetic nucleic acids and contaminated with hazardous chemicals (e.g., Trizol) should be disposed of as chemical waste and not treated with bleach.
				4. Disposable supplies or equipment that have contacted recombinant and synthetic nucleic acids (e.g., gloves, pipet tips, Eppendorf tubes, etc.) are disposed of in the appropriate biohazard container, approved by the College of Science (COS).
				5. Reusable items are autoclaved in the Microbiology Service Center (MSC, DH 637) or disinfected before being re-used for new experiments.
			2. *Procedures for the management and removal of biohazardous waste from the laboratory and policies for the safe handling of sharps, pipettes and broken glassware:* All materials in contact with recombinant and synthetic nucleic acids are disposed of as outlined in the Biohazardous Waste section of the the [“Waste Disposal Guide for SJSU Laboratories,” 2 “San Jose State University Biological Sciences Department Safety Rules for Teaching Laboratories.”3 and/or “San Jose State University Biological Sciences Department Safety Rules for Research Laboratories.”4] Processing of all biohazard waste is done by trained technicians in the MSC, DH 637. In brief:
				1. General Biohazard Solids Disposal- Biohazard bags to be disposed are closed and transported in secondary containment to the MSC.
				2. Biohazard Sharps Disposal- Biohazard sharps containers ready for disposal are also collected at the MSC.
				3. Serological Pipet Disposal- Used serological pipets are disinfected in secondary containment trays using 3% DC Gold before disposal by the MSC staff.
9. **Procedures for responding to and managing spills and exposures to pathogens.** Any spill or injury to personnel must be immediately reported to the PI and acted upon as outlined in the SJSU Chemical Hygiene Plan guidelines.5 Any significant research-related accidents and illnesses must be reported to the IBC (biosafety@sjsu.edu). Certain incidents, as described in the NIH Guidelines, must be reported to the NIH Office of Science Policy (OSP).
10. *Large biohazardous spills*
11. For classes, during normal business hours: Notify the MSC staff:

Veronica Zavela Arthur Valencia Matthew Voisinet

Office: 408-924-4926 Office: 408-924-4874 Office: 408-924-4928

For research labs, during normal business hours:

Randy Kirchner

 Office: 408-924-5004

1. During any hour contact: Notify the College of Science Safety Coordinator:

 Randy Kirchner

 Office: 408-924-5004

1. Alternative contact: Call the University Police department at 911 on a campus phone or 408-924-2222 on a cell phone.
2. *Injury or exposure to personnel*
	* + 1. Potential modes of transmission include: skin puncture or injection; ingestion; contact with mucous membranes (eyes, nose, mouth); contact with non-intact skin; bite from a recently infected animal; percutaneous contact with body fluids from a recently infeceted animal; aerosols.
			2. Flush eyes, mouth or nose for 15 minutes at the nearest eyewash station. For skin exposure, wash the affected area with soap and water, and flush for 15 minutes.
			3. Notify the University Police department by dialing 911 on a campus phone or 408-924-2222 on a cell phone.
			4. Submit a Student and Visitor Accident Report to Budget & Risk Management.

**Citations**

1. National Institutes of Health (NIH) Guidelines for Research Involving Recombinant or synthetic Nucleic acid molecules, April 2019.

<https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm>

 (accessed June 10, 2020).

2. *Waste Disposal Guide for SJSU Laboratories*, <https://www.sjsu.edu/fdo/docs/ehs/haz-waste/SJSUWasteGuide.pdf> (accessed Mar 30, 2021).

 3. *San Jose State University Biological Sciences Department Safety Rules for Teaching Laboratories*, **2015**. [*https://www.sjsu.edu/biology/docs/Safety%20Rules%20for%20Teaching%20Laboratories%20120115.pdf*](https://www.sjsu.edu/biology/docs/Safety%20Rules%20for%20Teaching%20Laboratories%20120115.pdf) (accessed Jan 30, 2020).

4. *San Jose State University Biological Sciences Department Safety Rules for Research Laboratories*, **2015**. [*http://www.sjsu.edu/biology/docs/Safety%20Rules%20for%20Research%20Laboratories%20120115.pdf*](http://www.sjsu.edu/biology/docs/Safety%20Rules%20for%20Research%20Laboratories%20120115.pdf) (accessed Jan 30, 2020).

5. Ball-Jones, A. *San Jose State University Chemical Hygiene Plan*, **2019**. [*http://www.sjsu.edu/fdo/departments/ehs/lab/Chemical%20Hygiene%20Plan\_20191017-final.pdf*](http://www.sjsu.edu/fdo/departments/ehs/lab/Chemical%20Hygiene%20Plan_20191017-final.pdf)(accessed Jan 30, 2020)