Biological Use Authorization Application

California State University San Marcos • Safety, Health, & Sustainability Services
333 S. Twin Oaks Valley Road • San Marcos, CA 92096 • Craven Hall 4700 • (760) 750-4502

This application is for new research projects and renewals of research projects that involve biohazards and therefore require Biological Use Authorization (BUA) from the campus Institutional Biosafety Committee (IBC).

1. Complete all questions of this BUA Application as they apply to your research project. The CSUSM Biosafety and Chemical Hygiene Manuals will help you complete this application. Additionally, it is recommended that you consult both the CDC's current edition of the Biosafety in Microbiological and Biomedical Laboratories (BMBL) and the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines). *Incomplete applications may be returned to you.*
2. Submit your completed application/supplemental documents to ibc@csusm.edu and shs@csusm.edu
   Assistance is available from Safety, Health & Sustainability they can be reached at # 760-750-4502

General Project Information

Type ☐ New ☐ Renewal: BUA#			Project Title		
	Name	Phone	Campus Email	Advanced Degree(s)	Title
Principal Investigator		. .			
Lab Contact if different than PI		. .			
Department			College		
IACUC Protocol Number(s)			IRB Number(s)		
Funding Source(s)					
☐ Yes ☐ No	Does the funding sponsor require CSUSM SHS and/or IBC review prior to submission to the sponsor? If Yes, provide deadline:				
☐ Yes ☐ No	Do you have/need permits for this project (e.g., USDA-APHIS, CDC, Select Agent)? If Yes, specify and submit permit with this application:				

Research Description

1. Provide a description of the overall goals of the research using laymen's terms.

2. Provide a brief, yet complete, description of the various laboratory procedures involving biohazardous agents, including all research involving recombinant and synthetic DNA/RNA, that you will be performing: (*e.g., genetic engineering of plasmids in laboratory strain E. coli, culture of human cell lines, transplantation of mice with bone marrow transduced with a lentiviral vector expressing a GFP reporter gene, generation of transgenic tobacco plants expressing transgene "X").*

3. Provide a declaration of what you consider to be the element(s) of your research that constitutes the greatest biohazard, and why.

Hazard Identification

Human Research Participants

☐ Yes, this project involves human research participants. Please select appropriate box(es) below.
☐ No, this project does not involve human research participants. Skip remainder of this subsection.

	Yes	No	
4.	☐	☐	This project involves human gene transfer as defined under NIH Guidelines, Section III-C-1.
5.	☐	☐	This project involves administration of recombinant or synthetic nucleic acids to human research participants, even if exempt under NIH Guidelines.

If Yes to either of the above, submit the following as they apply:

a. This application
b. Completed *NIH Guidelines, Appendix M*
c. All correspondence with NIH Office of Biotechnology Activities (OBA) Recombinant DNA Advisory Committee (RAC)
d. Clinical protocol
e. Investigator brochures
f. PI's Curriculum Vitae, in PHS-398 format
g. Proposed consent forms
h. Facility location(s):
i. Additional contact information:
j. IRB approval: IBC approval is required prior to IRB approval for new projects. Provide IRB approval for renewals.

Contact with Animals

☐ Yes, this project involves animal research subjects. Please select appropriate box(es) below.
☐ No, this project does not involve animal research subjects. Skip remainder of this subsection.

	Yes	No	
6.	☐	☐	Small laboratory animals:
7.	☐	☐	Immunodeficient animals:
8.	☐	☐	Non-human primates:
9.	☐	☐	Wild animals:
10.	☐	☐	Large animals:

Please contact the Institutional Animal Care and Use Committee for authorization to work with animals.

Tissue, Blood, and Body Fluids

☐ Yes, this project involves tissues, blood, body fluids. **Primary cell isolates and/or cell lines are included.** Please select appropriate box(es) below.
☐ No, this project does not involve tissues, blood, body fluids. Please check this box, skip remainder of this subsection.

	Yes	No	
11.	☐	☐	Humans:
12.	☐	☐	Laboratory animals:
13.	☐	☐	Non-human primates:
14.	☐	☐	Wild animals:
15.	☐	☐	Other:
16.	☐	☐	Are tissues or cells transplanted between species? If Yes, describe:

Bloodborne Pathogens

	Yes	No	
17.	☐	☐	This project involves drawing, processing, working with, or storing human blood, tissue, cells, cell lines, or body fluids visibly contaminated with blood or other potentially infectious materials (OPIM). See California definition of OPIM. If Yes, the California Bloodborne Pathogens (BBP) Rule and Federal Bloodborne Pathogen Standard apply. BBP program requirements include completion of the following: a. Annual Bloodborne Pathogens for Researchers training. **Please complete before submitting this application.** b. Site-specific BBP Exposure Control Plan: **Submit with this application.**

Bacteria, Viruses, Yeasts, Fungi, Parasites, and Prions

	Yes	No	
18.	☐	☐	This project involves research with bacteria, viruses, yeasts, fungi, parasites, and/or prions. If Yes, fill out the table below. If No, move to the next section.

19. Microorganism Table

List all Virus, Bacteria, Yeasts, Fungi, Parasites, and Prions. If none of these agents are used, state NONE in the first column, move to next section.

a. **Genus/Species/ Strain**	**b.** **Recombinant/ Synthetic DNA?**	**c.** **Administered to cells? (specify species)**	**d.** **Administered to animals or plants? (specify species)**	**e.** **Routes of potential occupational exposure include the following:**	**f.** **Susceptible species include the following:**	**g.** **Risk Group**
Pseudomonas aeruginosa **EXAMPLE**	☒Yes ☐No	☒Yes: human cells ☐No	☒Yes, wild type: ☐Yes, transgenic: ☐No	☒Aerosol ☐Fecal/oral ☒Mucous membrane ☐Other:	☒Humans ☒Animals ☐Plant ☐Bacteria ☐Other:	☐Risk Group 1 ☒Risk Group 2
	☐Yes ☐No	☐Yes: ☐No	☐Yes, wild type: ☐Yes, transgenic: ☐No	☐Aerosol ☐Fecal/oral ☐Mucous membrane ☐Other:	☐Humans ☐Animals ☐Plants ☐Bacteria ☐Other:	☐Risk Group 1 ☐Risk Group 2
	☐Yes ☐No	☐Yes: ☐No	☐Yes, wild type: ☐Yes, transgenic: ☐No	☐Aerosol ☐Fecal/oral ☐Mucous membrane ☐Other:	☐Humans ☐Animals ☐Plants ☐Bacteria ☐Other:	☐Risk Group 1 ☐Risk Group 2
	☐Yes ☐No	☐Yes: ☐No	☐Yes, wild type: ☐Yes, transgenic: ☐No	☐Aerosol ☐Fecal/oral ☐Mucous membrane ☐Other:	☐Humans ☐Animals ☐Plants ☐Bacteria ☐Other:	☐Risk Group 1 ☐Risk Group 2

If you need additional spaces, include multiple copies of this table.

20. **Tissue Culture**

List all cell lines or eukaryotic cells including commercially available human cell lines (e.g. CHO, COS, or HEK 293 cells) to be used in the research. All human and non-human primate primary isolate and cell lines will be handled with BSL2 precautions. If no cells are used, state NONE in the first column, move to next section. If you need additional spaces, include multiple copies of this table. *Pathogen testing is not required, please note if known.

		Source				
a. Cell Line/Primary isolate	**b. Species of Origin, organ**	**c. Company/Collaborator**	**d. Website/Email Address/Phone number**	**e. Physical Address or Catalog Number**	**f. Tested for pathogens*? If yes, which pathogens and status?**	**g. Risk Group (Biosafety)**
HeLa **EXAMPLE**	Homo sapiens, cervix	ATCC	atcc.org	ATCC CCL2	☐ No (Not tested) ☒ Yes: Cells contain human papilloma virus	☐ Risk Group 1 ☒ Risk Group 2
					☐ No (Not tested) ☐ Yes:	☐ Risk Group 1 ☐ Risk Group 2
					☐ No (Not tested) ☐ Yes:	☐ Risk Group 1 ☐ Risk Group 2
					☐ No (Not tested) ☐ Yes:	☐ Risk Group 1 ☐ Risk Group 2

Transgenic Plants

Does this project involve the following?

	Yes	No	
21.	☐	☐	Transgenic plants. If Yes, please describe (provide genus, species): If "No", check box and skip remainder of subsection.
	Yes	No	
a.	☐	☐	Invasive species or noxious weeds. If Yes, describe:
b.	☐	☐	Do you have reason to believe that the proposed transgenic plants can survive in the immediate geographic area? If Yes, describe:
c.	☐	☐	Do you have reason to believe that the proposed transgenic plants can interbreed with regional native species or noxious weeds? If Yes, describe:
d.	☐	☐	Will any of your work involve plant pathogens? If Yes, describe:
22.	☐	☐	Harvest of or work with seeds and/or spores from transgenic plants. If Yes, describe (provide genus, species):
23.	☐	☐	Use of transgenic plants in greenhouse. If Yes, describe:
24.	☐	☐	Use of transgenic plants in the field. If Yes describe:

If Yes to any of the above, complete the Recombinant and Synthetic DNA and RNA section and the Gene Delivery Methods table.

Recombinant and Synthetic DNA and RNA

☐ Yes, this project involves synthetic or recombinant nucleic acids. Please select appropriate box(es) below.
☐ No, this project does not involve synthetic or recombinant nucleic acids. Skip remainder of this subsection.

While answering these questions, you will find the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) useful. The NIH Guidelines are requirements, not merely guidelines.

Which does this project involve?

	Yes	No	
25.	☐	☐	Construction and/or use of synthetic DNA/RNA (e.g., probes, DNA or RNA oligonucleotides, base-pair analogs).
26.	☐	☐	Creation of cDNA/genomic libraries.
27.	☐	☐	DNA/RNA sequencing.
28.	☐	☐	Use of recombinant or synthetic DNA/RNA in microorganisms that are exempt under NIH Guidelines, Section III-F. If Yes, list genus, species and strains.
29.	☐	☐	Use of recombinant or synthetic DNA/RNA in non-exempt microorganisms. If Yes, list genus, species and strains (e.g., lentiviral vectors, *Agrobacterium*).

Recombinant and Synthetic DNA and RNA

30. ☐ ☐ Use of recombinant or synthetic DNA/RNA in animals (somatic cells or germ-line transgenics) including insects, nematodes, and mammals.* If Yes, describe and list species:

*Any research involving veterbrate animals will require separate application to the IACUC.

31. ☐ ☐ Use of recombinant or synthetic DNA/RNA in plants (somatic cells or germ-line transgenics). If Yes, describe.

32. ☐ ☐ Use of recombinant or synthetic DNA/RNA in cell culture. If Yes, describe procedure and list species.

33. ☐ ☐ Potential for toxic products to be produced/released from recombinant cells, animals, or plants. The definition of toxic is an agent with an LD_{50} of less than 100 nanograms per kilogram (ng/kg) body weight. If Yes, list the toxic product(s) and how it functions.

34. ☐ ☐ Potential for infectious agents to be produced/released from recombinant cells, animals, or plants. If Yes, explain.

35. ☐ ☐ Environmental release or field-testing of genetically engineered organisms. If Yes, explain.

36. This project includes research with recombinant or synthetic DNA/RNA using the following enhanced gene delivery techniques (covered under section III-E of the NIH Guidelines):

☐ Liposome complex ☐ Nanomaterial (<100 nm in length)

If you have marked 'Yes' to questions 30-33, complete the Gene Delivery Methods table (next page).

Gene Delivery Methods Table

37. List all gene delivery methods in the table below as they apply to gene transfer experiments and as they apply to the use of recombinant cells and microorganisms (engineered in your laboratory or obtained from another source). For large numbers of genes, attach a complete list of genes. For large numbers of genes not yet identified, see question 43. If not introducing recombinant and synthetic DNA/RNA into cell culture, microorganisms, or animals, proceed to the next section.

A. Gene Delivery Method	**B. Gene Inserts and Key Regulatory Elements** Must use common RefSeq gene names	**C. In Vitro** Specify cell type and activities	**D. In Vivo** Specify species and activities	**E. Source** Choose from dropdown list
EXAMPLE	GFP, viral LTR	☐No ☒Yes: grown in human cells; PCR analysis	☐No ☒Yes: IV injection into mice	Created in my lab.
		☐No ☐Yes:	☐No ☐Yes:	Click and choose: Create
		☐No ☐Yes:	☐No ☐Yes:	Click and choose:
		☐No ☐Yes:	☐No ☐Yes:	Click and choose:
		☐No ☐Yes:	☐No ☐Yes:	Click and choose:
		☐No ☐Yes:	☐No ☐Yes:	Click and choose:
		☐No ☐Yes:	☐No ☐Yes:	Click and choose:
		☐No ☐Yes:	☐No ☐Yes:	Click and choose:

If you need additional spaces, include multiple copies of this table.

38. Yes No N/A

☐ ☐ ☐ Negative replication competent virus testing has been performed on the above viral vectors. If Yes, submit results.

Gene Inserts

☐ Yes, project involves gene inserts, select appropriate box(es) below.
☐ No, check this box, skip remainer of this subsection.

39. For research involving a large number of genes not yet identified, list the categories or general functions of the genes.

Do any of the genes involved in this research influence the following (references to the *NIH Guidelines* are given)? If Yes, explain.

	Yes	No	
40.	☐	☐	Release of biological toxins (NIH Guidelines, Section III-B-1 and Appendix F):
41.	☐	☐	Deliberate transfer of a drug resistance trait to a microorganism when such resistance could compromise the ability to control the disease agent in humans, veterinary medicine, or agriculture (NIH Guidelines, Section III-A):
42.	☐	☐	Increase of tropism (NIH Guidelines, Appendix B-V):
43.	☐	☐	Increase of virulence (NIH Guidelines, Section II-A-3):

Oncogenes and Tumor Suppressor Genes

This section applies to work with oncogenes and tumor suppressor genes.

	Yes	No	
44.	☐	☐	Do any of your proposed genes appear in the following databases (must use common RefSeq gene names)? *a.* *Cancer Gene Census* *b.* Mouse Retrovirus Tagged Cancer Gene Database If Yes, they are known oncogenes. List:

CERTIFICATION: I have checked the above databases and have reported all genes that appear in them. PI Initials: ☐

45.	☐	☐	Are any of your proposed genes well described in the scientific literatures as oncogenes? If Yes, list genes and describe.
46.	☐	☐	Do you have other reasons to believe that your proposed genes are oncogenes? If Yes, list genes and describe reasons.
47.	☐	☐	Do you have reasons to believe that you are silencing or knocking out tumor suppressor genes? If Yes, list and describe.
48.	☐	☐	If Yes to any of the four preceding questions, are there any extenuating circumstances you would like the IBC to consider when setting biocontainment levels for this work? If Yes, describe.

Transgenic Animals

49. If this project involves the use of genetically modified animals, complete the table below. If No, proceed to the next section. **Note: Transgenic animals include vertebrates and invertebrates (e.g., drosophila, zebrafish, *Caenorhabditis elegans*, oysters, frogs, mice, rats, pigs).**
I am not working with transgenic animals. ☐

List species	Species:	Species:	Species:
List all strains			
I am creating transgenic animals	☐No ☐Yes Specify method:	☐No ☐Yes Specify method:	☐No ☐Yes Specify method:
I am breeding transgenic animals Select all that apply	☐No ☐Yes: ☐Breeding of rodents that have a gene encoding more than fifty percent of an exogenous eukaryotic virus ☐Breeding of rodents in which the transgene is under the control of a gammaretroviral long terminal repeat (LTR)	☐No ☐Yes: ☐Breeding of rodents that have a gene encoding more than fifty percent of an exogenous eukaryotic virus ☐Breeding of rodents in which the transgene is under the control of a gammaretroviral long terminal repeat (LTR)	☐No ☐Yes: ☐Breeding of rodents that have a gene encoding more than fifty percent of an exogenous eukaryotic virus ☐Breeding of rodents in which the transgene is under the control of a gammaretroviral long terminal repeat (LTR)
Transgenes include the following Select all that apply	☐ Potential for toxic products to be produced/released from the animal. Explain: ☐ Knock out of tumor suppressor. Explain: ☐ Antibiotic resistance. Explain:	☐ Potential for toxic products to be produced/released from the animal. Explain: ☐ Knock out of tumor suppressor. Explain: ☐ Antibiotic resistance. Explain:	☐ Potential for toxic products to be produced/released from the animal. Explain: ☐ Knock out of tumor suppressor. Explain: ☐ Antibiotic resistance. Explain:

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

Select all sections of the NIH Guidelines that apply to this project. NIH Guidelines can be found at http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines

50.	☐	Section III-A	Experiments that require IBC approval, RAC review and NIH Director approval before initiation (e.g., deliberate transfer of drug resistance to a microorganism that is not known to acquire it naturally, if such acquisition could compromise the ability to control disease agents in humans, animals or agriculture)
51.	☐	Section III-B	Experiments that Require NIH/OBA and IBC Approval Before Initiation (e.g., cloning of toxin molecules with a LD50 less than 100 ng/kg)
52.	☐	Section III-C	Experiments that require IBC and Institutional Review Board (IRB) approvals and RAC review before research participant enrollment (e.g., human gene transfer)

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

53.	☐	Section III-D	Experiments that require IBC approval before initiation (e.g., recombinant and synthetic nucleic acids in pathogenic microorganisms, viral vectors for gene transfer, gene transfer in Risk Group 2 microorganisms)
54.	☐	Section III-E	Experiments that require IBC registration before initiation (e.g., recombinant and synthetic nucleic acids in Risk Group 1 microorganisms or formulated into synthetic or natural vehicles, experiments involving whole plants at BSL-1P)
55.	☐	Section III-F	Exempt experiments (e.g., recombinant and synthetic DNA that is not in organisms or viruses, DNA/RNA in microorganisms that are exempt under III-F)

Hazard Control

Containment Requirements

56. What biosafety level(s) are recommended for your work according to the NIH Guidelines and the CDC's Biosafety in Microbiological and Biomedical Laboratories (BMBL)?

a. ☐ Laboratory: ☐ BSL-1 ☐ BSL-2 ☐ BSL-2 w/3 practices

b. ☐ Animal Facility: ☐ ABSL-1 ☐ ABSL-2 ☐ ABSL-2 w/3 practices

c. ☐ Plant Facility: ☐ BSL-1P ☐ BSL-2P ☐ Field Work

CSUSM does not have the capacity to perform work requiring BSL-3 containment or higher.

Facilities

List each CSUSM research space where you will perform work with biohazardous agents. Identify specific buildings, rooms, and activities.

57. In vitro Use

Building/Room	Activities	Biohazardous Agents	Comments
Science 2, Room 100 **EXAMPLE**	Cell culture of human cells, growth of lentiviral vectors, creation of transgenic plants	AAV, plasmids, human cells, transgenic plant seeds, Pseudomonas aeruginosa	BSL-2 tissue culture room. Certified biosafety cabinet in room.

58. Animal Use

Building/Room	Activities	Biohazardous Agents	Comments
Science 1 Vivarium **EXAMPLE**	(e.g., implanting human cells in mice, perfusions of mice exposed to retrovirus, housing of exposed animals)	(e.g., human cell lines, murine cells transduced with gammaretroviral vectors)	BSL-2 tissue culture room. Certified biosafety cabinet in room.

59. Shared Core Facilities (e.g., MRI, FACS)

Facility/Building/Room	Activities	Biohazardous Agents	Comments
Science 1, Room 109 **EXAMPLE**	(e.g., cell sorting, imaging of animals, flow cytometry)	(e.g., cell lines, animal cells from exposed animals, cells with recombinant DNA)	

Briefly describe any work environment that does not fit the above descriptions (e.g., field work):

Equipment

60. This project includes use of the following equipment with aerosol-generating potential:

☐ Centrifuge ☐ Syringes/needles ☐ French press ☐ Homogenizer

☐ Cell sorter ☐ Sonicator ☐ Automation/robotics

61. This project includes use of the following equipment with engineered safety features.

☐ Biological safety cabinet ☐ Safety cups or sealed rotors for centrifuges

☐ Sharps containers ☐ Engineered safe sharps

☐ Splash shields ☐ Other (specify):

☐ Aerosol management system for cell sorting

Yes No

62. ☐ ☐ This project involves other potential aerosol generating equipment (specify).

General Biosafety Laboratory Practices

Reference the CSUSM Biosafety Manual (BSM)

	Yes	No	
63.	☐	☐	I have a current BSM that is available to staff.
64.	☐	☐	I have written decontamination procedures for equipment and surfaces.
65.	☐	☐	I use appropriate decontaminants with the appropriate contact time for the agents I work with.
66.	☐	☐	Spills are addressed as specified in BSM. If not, written procedures are in place.
67.	☐	☐	I have procedures in place for the safe use and handling of sharps that I work with.
68.	☐	☐	First aid and medical follow-up procedures are in place in the event of an exposure incident.
69.	☐	☐	A biohazard label is affixed to equipment used for biological agents when appropriate.
70.	☐	☐	A biohazard door sign is posted as required. Contact SH&S for assistance.
71.	☐	☐	This project involves shipping of biological materials.
72.	☐	☐	Biological agents are transported within building in leak-proof, secondary containers.
73.	☐	☐	I have other written biosafety standard operating procedures (SOPs). If Yes, list, submit to CSUSM SH&S and with your IBC Application packet.
74.	☐	☐	All biological waste is decontaminated prior to disposal. Methods used include the following: ☐ Chemical (specify): ☐ Steam sterilization (autoclave). Location of autoclave: ☐ Other:
75.	☐	☐	This project involves specific procedures that pose an increased risk for exposure (e.g., aerosol generating procedures performed openly on the lab bench). If Yes, list:
76.	☐	☐	Biohazardous materials are transported between CSUSM buildings. If Yes, state the transportation method.

Personal Protective Equipment

See the Cal/OSHA Guide for applicable regulations. See the CSUSM Chemical Hygiene Plan for guidance. Contact SHS for assistance.

	Yes	No	
77.	☐	☐	I have identified the PPE requirements for each proposed activity associated with this project and will enforce the use of required PPE.
78.	☐	☐	Protective lab coats designed for lab use are worn while working with hazardous materials (for BSL-2 work and higher).

Personal Protective Equipment

79. ☐ ☐ This project involves tasks with the potential for splash/splatter to mucous membranes. These tasks require the following PPE:

    ☐ Safety glasses ☐ Goggles ☐ Face shield

    ☐ Surgical mask ☐ Other (specify):

80. ☐ ☐ This project involves tasks with an inhalation risk from infectious aerosols outside of containment.

81. ☐ ☐ Gloves are inspected before use and are changed when contaminated, when integrity has been compromised, and when otherwise necessary.

82. ☐ ☐ PPE is removed before entering non-contaminated areas (e.g., public hallways, lunchrooms).

83. ☐ ☐ PPE is removed in an order that minimizes cross-contamination.

84. List any other PPE required for your work:

Training

	Yes	No	
85.	☐	☐	CSUSM Biosafety Training is completed. Required for PIs and lab staff at a minimum of every three years.
86.	☐	☐	Lab-specific biosafety training by PI/Supervisor is completed.
87.	☐	☐	SH&S Shipping Hazardous Materials Training is completed. Required for shippers and/or transporters of infectious substances or hazardous materials
88.	☐	☐	SH&S Bloodborne Pathogens for Researchers Training is completed. Required annually
89.	☐	☐	Site-specific BBP exposure control plan training by PI/Supervisor is completed.

Other Hazards

Chemicals

Does this project involve the following? If Yes, please list. Follow the CSUSM Chemical Hygiene Manual, a quick reference for safe work with hazardous chemicals.

	Yes	No	
90.	☐	☐	Particularly Hazardous Substances. Please list or attach appendix:
91.	☐	☐	Toxins of biological origin (e.g., TTX, Botox, Pertussis, Diphtheria).
92.	☐	☐	Nanoparticles (<100 nm in length). If Yes, list and specify use and/or production:
93.	☐	☐	Animals exposed to any of the above. If Yes, describe:
94.	☐	☐	Animals exposed to any of the above via drinking water or food. If Yes, describe:
95.	☐	☐	Anesthetic gases.

Chemicals

Does this project involve the following? If Yes, please list. Follow the CSUSM Chemical Hygiene Manual, a quick reference for safe work with hazardous chemicals.

96. ☐ ☐ Fixing agents:

97. ☐ ☐ I have a current Laboratory Safety Manual with lab-specific chemical SOPs that is available to staff.

Radiation

Does this project involve the following? Reference the CSUSM Radiation Safety Manual. Note: Use of radioactive materials requires prior authorization by SH&S. Contact them at 760.750.4502 or shs@csusm.edu.

	Yes	No	
98.	☐	☐	Radionuclides. If Yes, provide Radioactive Materials Authorization (RAM #):
99.	☐	☐	X-ray or non-ionizing radiation, including lasers. If Yes, describe:

Other Hazards

	Yes	No	
100.	☐	☐	This project involves other significant hazards (e.g., climbing hazards, etc.). If Yes, explain:

Authorized Personnel

Please list all laboratory personnel and the agents they will handle. Approval will only be given for personnel identified below and is specific for the agents listed. Signatures are required to indicate that personnel have been informed of potential hazards, safe work practices, and that they understand and will follow approved laboratory standard operating procedures. All laboratory personnel must complete Laboratory Safety Fundamentals training; lab safety refresher training is required annually thereafter. All laboratory personnel who handle human materials or other potentially infectious material must complete annual bloodborne pathogen training.

Name	Title (PI, PostDoc, Grad Student, Tech)	Agents Handled (ie cell line viral vectors)	Signature	Last Lab Safety Training (Date)	Last Bloodborne Pathogen Training (Date or NA)

Statement of Responsibility

As Principal Investigator for this project, I have the responsibility to assure that my laboratory operates in a safe manner and that all staff and students are informed of risk, appropriately wear protective equipment, and are adequately trained. I will assure that all students and staff working in my laboratory receive orientation to our departmental Health & Safety Plan and departmental Emergency Plan.

I understand that I am responsible for assuring that my laboratory complies with all federal, state, and local environmental laws and regulations. I will comply with shipping requirements for hazardous materials including recombinant and synthetic DNA molecules.

If my work involves recombinant or synthetic DNA/RNA molecules, I acknowledge that I am responsible for full compliance with the NIH Guidelines in the conduct of recombinant and synthetic DNA/RNA research. I will neither initiate nor modify any recombinant or synthetic DNA/RNA research that requires IBC approval prior to initiation until IBC approval is given. I will report the following to the SH&S biosafety officer at 760-750-4502 or shs@csusm.edu as soon as possible: (1) Violations of the NIH Guidelines; (2) Biohazardous spills; (3) Loss of biohazard containment; (4) Research-related accidents; (5) Research-related illnesses; (6) Exposures or potential exposures to biohazards, including recombinant or synthetic DNA/RNA; (7) Exposures or potential exposures involving animals previously exposed to biohazards, including recombinant or synthetic DNA/RNA. If instructed I will also notify the CSUSM IBC and NIH Office of Biotechnology Activities. I will adhere to the IBC-approved emergency plans for handling accidental spills and personnel exposures.

In case of incidents, I will instruct my staff to complete the Online Accident Report form within 24 hours.
To the best of my knowledge, the information reported on this form is correct and accurately reflects my proposed research. I further understand that I must contact IBC/SHS prior to initiating any changes in my research involving biological, or recombinant or synthetic DNA/RNA materials.

Principal Investigator Name (printed or typed)

_____

Principal Investigator Signature/Electronic Signature Date

_____ _____

Email your completed application and supplemental documents to ibc@csusm.edu
Assistance is available from SH&S Office #760-750-4502
Electronic submissions are preferred.