**CALIFORNIA INSTITUTE OF TECHNOLOGY**

**INSTITUTIONAL BIOSAFETY COMMITTEE**

***Biological Protocol Registration Form*** *Email completed form to:* *ibc@caltech.edu*

***Please use this form for new and 3 Year De novo applications, amendments, and annual reviews. For amendments, contact the IBC Administrator to provide you with your completed current protocol form, add the new amendment information in the blue amendment section. Answer/update all other questions in regards to the amendment (especially the RISK ASSESSMENT). Using the same form enables the IBC to review your amendment in the context of your current protocol.***

***USE “REVIEW” > “SHOW COMMENTS” to see additional tips for filling out the application.***

**Instructions for checking boxes: double click on the box and choose “checked” in the pop up screen.**

|  |  |
| --- | --- |
| **Principal Investigator(s):**  | **Primary contact phone:**  |
| **Primary Researcher (s):**  | **Primary contact email:** |
| **Project title:**  |
| **This project registration is:** [ ]  New/De novo [ ]  Amendment [ ]  Annual Review | **Protocol # (assigned by Biosafety):**  |
| Application date:  | **Amendment Application Date:** | **Granting Agency and Number:**  |
| **List building and room numbers where lab work is being conducted or agents are stored:** |
| **Lab Work Location:** |
| **Agent Storage Location:** |
| **Animal Work Location:** |

**This section to be completed by the Biosafety Officer:**

**[ ]  No rDNA work [ ]  The described work falls under the NIH rDNA Guidelines Section**

## Description of Research

### Please describe the objective of the research and include the experiments/assays to be performed.

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| * 1. *Start with a short paragraph using very lay-language to explain the overall goal of the research and the basic approach – 3-4 sentences.*
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| * 1. *IN VITRO WORK:*
		1. *In a little more detail, especially concerning the use of biohazardous material, describe the experimental procedures that are performed in the lab, (do not give much detail about buffers, volume, etc.).*
		2. *Explain the experimental process in a sequence that is logical (example: cloning into E. coli – then transfection of plasmid into human cells – then expression and purification of proteins…). Bullet points and short sentences are encouraged.*
		3. *Complete the CRISPR Evaluation, if applicable.*
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| * 1. *IN VIVO WORK:*

*If you work with animals, add the IN VIVO WORK section following the same principles as above.* |
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### List microorganisms; viral vectors; cell lines; human or nonhuman primate materials. Please be specific e.g. human blood, human primary macrophages, lentiviral vector pLKO.1, pMD2.G VSVg envelope, psPAX2*;* human cell lines: HeLa, Jurkat; P. aeruginosa; E. coli K12

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| --- | --- | --- | --- | --- | --- |
| **AGENT**: please indicate if recombinant or wildtype; For viral vectors include plasmids for packaging and envelope, % viral DNA, rep-defective, ecotropic or amphotropic | **INSERTED EXPRESSED GENES**: list gene(s) or classes of genes, indicate function or activity and microbiological origin, e.g. nipah virus envelope glycoprotein; GFP; transcription factors; siRNA against tumor suppressors; mycobacterial genes | **SOURCE OF AGENT**: e.g. ATCC ; Smith lab, UCLA | **ANIMALSPECIES**  e.g. mice | **BIOSAFETY****LEVEL** | **NIH GUIDE-LINES****SECTION** |
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### Animal experiments with biologicals: [ ] N/A Animal protocol #

**Instructions: double click on the box and choose “checked “box from the pop up screen.**

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| **LIST BIOLOGICAL AGENT:**e.g. human cell line, viral vector | **DOSE & FREQUENCY** | **EXPOSURE ROUTE** | **PROCEDURE ROOM LOCATIONS**Investigator room (IR)OLAR Facility (OF) | **ANIMAL** | **HOUSING AND****BIOSAFETY LEVEL** | **HOUSING LOCATION** |
| Agent:[ ]  wild type[ ] recombinant | [ ] one time[ ] multiple | [ ] IV[ ] IP[ ] IM[ ] SC [ ] oral[ ] IC [ ] IO[ ] IN [ ] other | IR: OF:  | Species: [ ] wild type[ ] transgenic [ ] knockout[ ] immunodeficient[ ] other | [ ] microisolator cage[ ] ABSL-1 practices[ ] ABSL-2 practices for 72 hrs[ ] ABSL-2 practices for life |  |
| Agent:[ ]  wild type[ ] recombinant | [ ] one time[ ] multiple | [ ] IV[ ] IP[ ] IM[ ] SC [ ] oral[ ] IC [ ] IO[ ] IN [ ] other | IR: OF:  | Species: [ ] wild type[ ] transgenic [ ] knockout[ ] immunodeficient[ ] other | [ ] microisolator cage[ ] ABSL-1 practices[ ] ABSL-2 practices for 72 hrs[ ] ABSL-2 practices for life |  |
| Agent:[ ]  wild type[ ] recombinant | [ ] one time[ ] multiple | [ ] IV[ ] IP[ ] IM[ ] SC [ ] oral[ ] IC [ ] IO[ ] IN [ ] other | IR: OF:  | Species: [ ] wild type[ ] transgenic [ ] knockout[ ] immunodeficient[ ] other | [ ] microisolator cage[ ] ABSL-1 practices[ ] ABSL-2 practices for 72 hrs[ ] ABSL-2 practices for life |  |

### Transgenic rodents: [ ] N/A [ ] created at Caltech GEMS [ ]  obtained from a vendor or collaborator

[ ] **created by your own lab staff via means other than breeding**?

**FOR AMENDMENTS ONLY**

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| **Amendment description:** |
| **AGENT** | **INSERTED EXPRESSED GENES** | **AGENT SOURCE** | **SPECIES** | **BSL** | **NIH GUIDELINE** |
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| **LIST BIOLOGICAL AGENT USED IN ANIMALS** | **DOSE & FREQUENCY** | **EXPOSURE ROUTE** | **ANIMAL** | **HOUSING AND****BIOSAFETY LEVEL** | **HOUSING LOCATION** |
| Agent:[ ]  wild type [ ] recombinant | [ ] one time[ ] multiple | [ ] IV[ ] IP[ ] IM[ ] SC [ ] oral[ ] IC [ ] IO[ ] IN [ ] other | Species: [ ] transgenic [ ] knockout [ ] immunodeficient[ ] other | [ ] microisolator cage[ ] ABSL-1 practices[ ] ABSL-2 practices for 72 hrs[ ] ABSL-2 practices for life |  |

## Risk Assessment - General

1. Will you be using unfixed human or nonhuman primate materials (such as cell lines, primary cells, sputum, feces) [ ]  N/A [ ] YES [ ] NO

Known to be infected with an infectious agent [ ] YES [ ] NO If YES, please describe:

Will you be generating or using human iPS cells or using existing or deriving new hESC lines? [ ] YES [ ] NO

If you answered “yes” to the question above, do you have an IRB approval or exemption? [ ] YES [ ] NO

IRB protocol number

1. Are any of the agents listed opportunistic pathogens, e.g., have been associated with disease in immunocompromised individuals? [ ] YES [ ] NO If YES, please list:
2. Do any of the wild type infectious agents have known antibiotic or drug resistance? [ ]  N/A [ ] YES [ ] NO
3. Does the research involve the use or cloning of any of the following regulated biological toxins: abrin, botulinum neurotoxins, conotoxin (short, paralytic alpha), diacetoxyscirpenol (DAS), ricin, saxitoxin, staphylococcal enterotoxin A-E, T-2 toxin, tetrodotoxin (TTX)? [ ] YES [ ] NO If YES, please describe:
4. Which equipment with the potential to generate aerosols will you be using with your BSL-2 materials or toxins?

[ ]  cell sorter [ ]  centrifuge [ ]  lyophilizer [ ]  homogenizer [ ]  bead beater [ ]  other [ ]  None

1. Which of the following sharp items will be used with BSL-2 samples?

[ ]  needles [ ]  scalpels [ ]  pasteur pipettes [ ]  other [ ]  None

1. Will any procedures with BSL-2 materials, other than centrifuging and imaging, be conducted outside a biosafety cabinet? [ ] YES [ ] NO If yes, please describe
2. Will you be shipping or transporting recombinant organisms or BSL-2 material beyond the Caltech campus?

[ ] YES [ ] NO If yes, please describe

Risk Assessment - rDNA[ ] N/A

1. Do the experiments involve the transfer of an antibiotic resistance gene to a human or animal pathogen?

[ ] YES [ ] NO If YES, please list:

If yes, is the antibiotic used to treat the disease in humans or animals (consider antibiotics used outside of U.S. and antibiotics used to treat the disease in specific patient populations)? [ ] YES [ ] NO

1. List any antibiotic resistance genes contained on vectors: [ ] N/A
2. Are the expressed genes known or suspected to be toxic, oncogenic, potentially oncogenic, or to block the activity of a tumor suppressor or alter the cell cycle? [ ] YES [ ] NO If YES, please describe:
3. List replication-competent viral vectors? [ ] N/A
4. Will you be packaging viral vectors in your lab or will you be receiving the viral vectors ready for use in your experiments? [ ] N/A[ ]  Packaging the following [ ]  receiving the following already packaged
5. In your animal experiments, is it likely that viral vector sequences will recombine with endogenous or exogenous viruses to produce a new infectious virus?[ ] N/A[ ] YES [ ] NO If YES, please explain:
6. In your animal experiments, would you expect that the viral segment in the transgene could help mobilize part or all of the transgene either by itself or by interaction with other viruses including endogenous viruses in the animal?[ ] N/A[ ] YES [ ] NO If YES, please explain:
7. Will rDNA be used in plants? [ ] YES [ ] NO
8. Will transgenic insects be used or generated? [ ] YES [ ] NO Will insects host rDNA or rDNA modified microorganisms? [ ] YES [ ] NO

Risk Assessment: Please discuss any potential biosafety risks associated with the organism or procedures.

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| *In this section, list all the items listed in* [*table 2*](#_List_microorganisms;_viral) *and discuss for each item, i) the risk associated with the use of the item; ii) the containment and precautions that will be taken to mitigate the risk.**Example: Human cell lines carry the risk for potential bloodborne pathogens, therefore universal precautions will be followed and these cells will be managed at biosafety level 2.* *Reminder: bullet points to separate the items are encouraged.**UPDATE this section as needed for Amendments that pose a change in risk.*  |
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## Precautions and Procedures for Laboratory Work

1. Will all procedures with BSL-2 materials, except centrifuging, imaging, and those listed above in the General Risk Assessment section, be conducted in an annually certified biosafety cabinet? [ ] YES [ ] NO
2. If procedures with BSL-2 materials will take place outside a biosafety cabinet, please indicate the extra precautions to be taken: [ ] N/A [ ]  centrifuge aerosol-proof rotors or safety caps [ ]  safety glasses [ ]  surgical mask [ ]  full faceshield [ ]  work behind a splash guard [ ]  N95 respirator [ ]  other
3. Disinfection and waste disposal

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| **Item** | Spills | Biosafety cabinet, centrifuge,microscope stage | Liquid waste before drain disposal | Solid BSL-2wste before off-site treatment | Solid BSL-1 wste before regular trash disposal | Sharps (needles, pasture pipettes etc.); syringes |
| **Disinfection method** | [ ] 10% bleach[ ] other  | [ ] 70% EtOH[ ] other [ ]  N/A | [ ] 10% bleach[ ] other [ ]  N/A | [ ] biohz bin[ ] other [ ]  N/A | [ ] autoclave[ ] other [ ]  N/A | [ ] red sharps bin[ ] other [ ]  N/A |

Please list any additional lab-specific equipment or non-disposable items used with BSL-2 materials and disinfection method: [ ] N/A

1. Training for staff working on the project. Contact the biosafety officer (Lquenee@caltech.edu) for information about the required training and training history.

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| --- | --- |
| **Name** | **Position** |
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1. If transporting BSL-2 samples to another lab or building on campus please indicate precautions taken: [ ] N/A

[ ]  sample tube placed in plastic bag or in outer 50 ml screw cap tube with paper towel or kim wipes [ ]  plastic bag is tightly closed with tape, tie, Ziploc or outer screw cap tube is tightly closed [ ]  biohazard label on outer screw cap tube or plastic bag [ ]  plastic bag or screw cap tube or placed inside rigid outer container [ ]  Nalgene biosafe carrier

1. If shipping BSL-2 materials by air or ground transportation, please indicate what steps will be followed: [ ] N/A

[ ]  training in DOT and IATA shipping regulations [ ]  completion of Caltech export form if exporting [ ]  determine whether CDC/APHIS/VS domestic transfer permit is necessary

1. Emergency response to spills, exposures, injuries: [ ]  Emergency response flipchart is posted in lab and discussed at lab-specific training [ ]  Incidents are reported to the safety office. There are no penalties for reporting incidents.
2. Biosafety cabinet certification date: [ ] N/A

*Your protocol will not be approved if date is expired.*

1. Please list any additional safety precautions or attach lab-specific SOPs. [ ] N/A

Precautions and Procedures for Animal Experiments[ ] N/A

1. Will any human cell line, primary human cell/tissues, or human materials (feces, sputum) be used in animals?

 [ ] YES [ ] NO *IF YES animals must be kept at ABSL-2 for life.*

## ABSL-2 Precautions and Procedures

1. Will different viral vectors or pathogens be co-injected or sequentially injected into the same animal? [ ] N/A

[ ] YES [ ] NO If YES, please explain:

1. How long will the animals be handled as if they were biohazardous, e.g. using ABSL-2 procedures?

 [ ]  72 hours (if exposed to replication incompetent viral vectors) [ ]  for the life of the animal (if exposed to primary human cells, established human cell lines, or human pathogens) [ ]  for the life of the animal (if exposed to replication competent viral vectors)

1. Will the animals be handled during the biohazardous period (72 hours or life of the animal) after exposure to the biological agent? [ ] YES [ ] NO If YES, please explain and indicate if a biosafety cabinet will be used:
2. During the time-period that ABSL-2 practices are used, e.g. the biohazardous period, will animals be transported outside the housing area? [ ] N/A [ ] YES [ ] NO If YES, please explain:
3. During the time-period that ABSL-2 practices are used, e.g. the biohazardous period, will necropsy be performed? [ ] YES [ ] NO

If YES, will tape and round-edged scissors and forceps be used in place of pins and scalpel? [ ] YES [ ] NO

If YES, will a biosafety cabinet be used for euthanasia and necropsy? [ ] YES [ ] NO

1. Check all ABSL-2 practices that you will follow for the biohazardous period (either 72 hours post-exposure or for the life of the animal):
	1. [ ]  Animals anesthetized prior to injection of biological agent
	2. [ ]  Dosing with biological agent done in a biosafety cabinet (not required for some ABSL-1 viral vectors)
	3. [ ]  Animals returned to a clean cage after exposure to biological agent
	4. [ ]  Initial cage change performed using a biosafety cabinet, or all cage changes done in a biosafety cabinet
	5. [ ]  Special biohazard cage card on cage
	6. [ ]  Cage card with the date of exposure, agent, contact info, time period using ABSL-2 practices
	7. [ ]  Animal room labeled with biohazard sign
	8. [ ]  Solid contaminated waste collected in biohazard (red-bag) bin
	9. [ ]  Needles will never be left unprotected on the work surface and will never be recapped using a two-handed method. A one-handed recapping will be used, if necessary, or the needle will be placed in a tube or needle holder to prevent needle sticks.
	10. [ ]  Needles disposed of after use in a red sharps container
	11. [ ]  Gloves, disposable gown, surgical mask worn
	12. [ ]   Carcass bagged and labeled as biohazard; bag exterior sprayed with disinfectant and wait 10 minutes before placing in pathologic waste (hazard) container in OLAR carcass freezer
	13. [ ]  Empty cages placed on rack in same location with special biohazard cage card in place
2. Please list any additional safety precautions including additional PPE or attach SOPs: [ ] N/A
3. Disinfection

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| **Item** | Biosafetycabinet[ ] N/A  | Stereotaxic unit[ ] N/A  | Microscope stage[ ] N/A  | Hamilton syringe[ ] N/A  | Non-disposables[ ] N/A  | Exterior bags[ ] N/A  |
| **Disinfection method** | [ ] Accel[ ] 70% EtOH[ ] other  | [ ] Accel[ ] 70% EtOH[ ] other  | [ ] Accel[ ] 70% EtOH[ ] other  | [ ] Accel[ ] 70% EtOH[ ] other  | [ ] Accel[ ] 70% EtOH[ ] autoclave[ ] other  | [ ] Accel[ ] other  |

1. Please list any additional equipment or supplies that will be disinfected and the disinfectant used:

 [ ] N/A