TEXAS A&M UNIVERSITY-SAN ANTONIO

Amendment to Previous IBC-approved Protocol

Name of PI: PI **IBC permit #** Permit #

FOR INTERNAL USE	
version #: version #	**Date:** Date received

Please indicate the type of changes you are proposing to the approved IBC Permit. Check all that apply.

- ☐ Agent(s)/Organism(s) (see Part II tables A&B) ****must fill out risk assessment form at bottom of this amendment**
- ☐ Procedure(s)
- ☐ Biological Safety Level (BSL) Change. (Note: If the level is changing from BSL1 to BSL2, you may be asked to submit a new application.)
- ☐ Rooms (if adding a lab space that is shared with another faculty-please submit shared space form as well)
- ☐ Funding (Please attach copies of the grant proposal being added to the approved IBC Permit)
- ☐ Personnel - Please submit a list of individuals being added to or deleted from an approved protocol (see Part IV: Personnel Information)
- ☐ Other (List below)

Describe "Other"

Describe "Other"

* Please note that upon review of the proposed changes, the IBC may request that additional information be submitted. If additional revised parts of the registration document are required, you will be asked to submit this information within thirty (30) days of the request.

In terms understandable to a non-scientist, please provide a detailed description of the proposed changes to the existing permit (below). This description should provide the goal(s), methodology, and use of biohazardous or recombinant material. Please write this section at an 8th grade reading level.

Describe proposed changes

Signature of PI Date

Signature of submitting party (if different from PI) Date

PART II: Agent Information

Table A: Agent/Sample Type/Vector/Host Characteristics

- In the table below, list each agent, vector (e.g. plasmid), host, or sample type that will be used. Note the ID of the listing for later use in your application.
- If the agent is recombinant, list "Yes" in the appropriate cell and insert information into Table B.
- Note that if a vector is used to generate a recombinant host, both the vector and host need to be entered into Table A.
- If the agent is to be used with animals or plants, give the species, otherwise enter "No".
- For samples only: known pathogens in the sample should be included here; potential pathogens in the sample do not need to be included here, but they should be addressed in the main technical description.

ID	Genus/Species	Strain	Risk Group	Biosafety Level	Animal Biosafety Level	Recombinant? (Yes/No)	List location(s) where agent will be (From Part 1 Sec. E)		Used in animals/plants (list species)
							Used	Stored	
-	Example- *E. coli*	K-12	RG-1	BSL-1	N/A	Yes	1	1, 2, 3	NA
A-#	Enter genus/species	Enter strain	Select RG	Select BSL	Select ABSL	Select Y/N	Enter location	Enter location	Enter species

To add another row: Click on a row, then click the blue plus sign on the right.

Table B: Insert Characteristics

- In the table below, enter information about each **DNA insert expressed/cloned**.
- Enter the appropriate Host ID from Table A to indicate which host will contain the insert.

ID	Host ID (Table A)	Source of Insert (e.g. human)	Insert Source Risk Group	Insert Name (e.g. insulin)	Insert Characteristic of Function (e.g. hormone)
	Example	Human	RG-1	Insulin	Hormone
B-#	**A-#**	Enter insert source	Select RG	Enter insert name	Enter insert function

To add another row: Click on a row, then click the blue plus sign on the right.

PART III: Viral Vector Information

(To add another assessment sheet: Click in the form, then click the blue plus sign at the bottom.)

☐ This work uses viral vectors (fill out a separate table for each Agent listed in Part II Table A).
☐ This work does not use viral vectors.

☐ Yes ☐ No Will your lab be involved in way in constructing and producing the infectious virus?
If 'no' please indicate source from where you will be receiving the infectious virus.
Enter source of virus here if it does not originate for your lab

Note: An MTA may be required.

1. Agent ID from Part II, Table A Agent ID

2. Is the virus replication competent or replication deficient?

☐ Competent

☐ Deficient

If the virus is replication deficient, please provide verification in the box below.

Verification that the virus is replication deficient

3. Will assay systems be used to measure the titer of replication competent viruses that may be present?

☐ Yes

☐ No

If yes, please describe: Describe

4. What is the host range of the viral vector?
Describe

5. Will the vector facilitate the insertion of a gene encoding for toxins or an oncogene? If yes, the toxin or oncogene must be described in detail in the risk assessment.

☐ Yes

☐ No

6. What percent of the original viral genome remains in the vector?
Describe

7. Describe the genome organization of the viral vector. Include information about what genes or genome regions have been removed.
Describe

8. The possibility of homologous recombination with endogenous viruses exists. Indicate the reversion rate and the recombination event of such a possibility. Describe methods you will use to ensure that replication competent viruses are excluded.
Describe

9. Will helper viruses be used?

☐ Yes ☐ No

If yes:

- List in Part I, Section 2 Table E & Table K;
- List in Part II Table A & Table B;
- Complete risk assessment for each helper virus.

10. Laboratory Hazards

Risks include direct contact with skin and mucous membranes of the eye, nose and mouth, parenteral inoculation, ingestion.

Will your work with viral vectors involve any of the following:

☐ Yes ☐ No High energy-creating activities (centrifugation, sonication, high pressure systems, vortexing, tube cap popping)

☐ Yes ☐ No Handling of sharps (needles, scalpels, microtome blades, broken glass, etc.)

☐ Yes ☐ No Splash/droplet-creating activities (shaking incubators, liquid culturing, mechanical pipetting)

☐ Yes ☐ No Equipment contamination

☐ Yes ☐ No Exposed skin/uncovered wounds/broken or chapped skin

☐ Yes ☐ No Other

If you checked yes to any of the above, please address those items in your technical description (Part I, Section 2D) and discuss mitigation strategies.

PART IV: Plants and Derived Biological Materials

1. Will you use plants, including plant parts, plant cell lines, but excluding fungi?

☐NO ☐YES *(Complete this section.)*

Type of material: ☐Whole Plant ☐Plant Part ☐Plant cell lines

2. List all plant species and research locations.
   IF field testing provide location (field allocation #., GPS location of all four corner points).

Plant Species *(include genus species or variety)*	Has this plant been altered? How?	Provide Locations of Research inc. field sites	Greenhouse/ Screen house (Yes/No)	BSL of Greenhouse	Growth Chamber/ Room (Location)

3. Will you use commercially available de-regulated transgenic plants only?

☐NO ☐YES

If no, does it require USDA/FDA approval? ☐NO ☐YES

If yes, identify in the table above.

4. Will biological materials be inserted/inoculated/introduced?

☐NO ☐YES

5. Will you be using exotic, poisonous, dangerous or endangered/threatened plants?
   ☐NO ☐ YES (List below, describe PPE and Biosafety Containment in attachment, and attach a *copy of the permits from Texas Parks & Wildlife, etc.)*

6. Does this project involve a plant pathogen that originated outside of Texas or the United States?
   ☐NO ☐ YES USDA APHIS import/transport permit will be required.
   See www.aphis.usda.gov/import_export/index.shtml or www.aphis.usda.gov/ppq/
7. Are you getting materials from other entities?
   ☐NO ☐ YES
   If yes, do you have an MTA for this? ☐NO ☐YES

PART V: Personnel Information

Personnel List. Only list A&M-SA employees, students (graduate or undergraduate) and volunteers being added or deleted from an approved protocol and notate in the first column listed.

> ***Note**: Students in a teaching lab course will complete training given by the instructor and sign a lab safety agreement to be kept by the teaching lab manager.*

Faculty/Staff

Action type Add/Delete	First Name	Last Name	UIN	Lab Building(s)	Lab Room(s)	Email address
Add/Delete	First name	Last name	UIN	Enter building(s)	Enter room(s)	Enter University email

To add another row: Click on a row, then click the blue plus sign on the right.

Students

Action type Add/Delete	First Name	Last Name	UIN or J/K number	Lab Building(s)	Lab Room(s)	Email address
Add/Delete	First name	Last name	UIN	Enter building(s)	Enter room(s)	Enter University email

To add another row: Click on a row, then click the blue plus sign on the right.

Volunteers **If a volunteer has a previously issued TAMUSA UIN or J/K number, you may list that number.

Action type Add/Delete	First Name	Last Name	Last four of SSN # **	Lab Building(s)	Lab Room(s)	Email address
Add/Delete	First name	Last name	Last 4	Enter building(s)	Enter room(s)	Enter email address

To add another row: Click on a row, then click the blue plus sign on the right.

PI Risk Assessment Form

(To add another assessment sheet: Click in the form, then click the blue plus sign at the bottom.)

APPENDIX LETTER

Appendix letter

AGENT or SAMPLE TYPE

Number: Number from Part II Table A

Name: Agent/Sample name

ASSESSMENT of the AGENT

1. Is there a Risk Group (RG) description for this species provided by the NIH guidelines (mark one):

☐ Yes ☐ No

If yes, please include information provided by the NIH guidelines:

NIH Guidelines information

2. If the NIH guidelines do not address the RG for this species, does the BMBL 6th edition provide an RG for this organism?

☐ Yes ☐ No

If yes, please include the information provided by the BMBL 6th edition.
(The BMBL only provides guidance and suggestions in the use of human and non-human primate cell lines and tissues. It also recommends BSL-2 precautions when handling cell lines of unknown origins. If there is a suspected human pathogen present, then the appropriate RG and corresponding BSL should be used.)

BMBL information

3. If the BMBL 6th edition does not address the RG for this species, does the Health Canada Pathogen Safety Datasheet (https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment.html) provide information regarding the RG for this species?

☐ Yes ☐ No

Health Canada information

4. If none of the above sources provide information regarding the RG for this species, please provide information from the primary literature that supports designation of a Risk Group for this species.

Additional information

5. Is this species considered a pathogen in healthy adult humans?

☐ Yes ☐ No

Based on the above sources of information, the principal investigator proposes that the Risk Group designation of this species be:

☐ Risk Group 1 ☐ Risk Group 2

ASSESSMENT of the PROCEDURES and PRECAUTIONS

Please describe the laboratory procedures in which this agent will be used that might create risk (e.g. concentration of the agent, volumes used, potential for aerosolization, use of sharps etc.)

- Agent concentration ☐ N/A or Provide agent concentration
- Suspension volume ☐ N/A or Provide suspension volume
- Risk of aerosol or airborne droplet formation (both equipment and procedure generated) ☐ N/A or List procedures/equipment
- Use of sharps ☐ N/A or List sharps
- Other (list) ☐ N/A or List other procedures with elevated risk

6. Describe any precautions (personal protective equipment, procedure modifications, and special equipment such as a biosafety cabinet) that will be used to mitigate any risks described in the procedures above.

Describe precautions that will be taken

Based on the above descriptions of procedures and precautions, the principal investigator proposes that the agent be handled at:

☐ BSL-1 ☐ BSL-2

PROFICIENCY of the PRINCIPAL INVESTIGATOR and other PERSONNEL/STUDENTS

7. Please describe the expertise of the Principal Investigator.

PI expertise

8. Please describe the expertise of the personnel/students who will work with this agent.

Other personnel expertise

9. Have all personnel received appropriate biosafety level training for working with this agent?

☐ Yes ☐ No

10. Describe below how any deficiencies in lab-specific training are being addressed prior to beginning the work:

Describe deficiencies and training plan

All required biosafety training at the appropriate level (BSL-1 or BSL-2) must be completed and documented with the IBC prior to obtaining final approval and registration. Please be sure to initiate these training courses as soon as possible to avoid any further delay to a protocol.