Annual Review

FOR INTERNAL USE ONLY

IBC #

Original Approval Date

AUP # \_\_\_\_\_\_\_\_\_\_\_\_\_

IRB # \_\_\_\_\_\_\_\_\_\_\_\_\_\_

for IBC PROTOCOL

**1. Principal Investigator Information**

 Last Name:       First Name:

 Department:       College:

 Office location: Building       Room number

 Address

 City State Zip

 Phone:

 Office Laboratory Emergency/after hours Fax

Email:       (Please provide official University email)

**2. Investigator Assurance**

* I attest that the information contained in this annual review is accurate and complete.
* I agree to comply with all Texas A&M International University IBC requirements regarding research involving biohazardous and / or recombinant materials.
* I agree not to initiate any research subject to IBC approval unless I have received such approval.
* I agree to notify the IBC via the IBC Chair and Safety/Risk Manager immediately of incidents involving biohazardous or recombinant agents
* I acknowledge my responsibility for the conduct of this research in accordance with Section IV-B-7 of the *NIH Guidelines*.
* I have the knowledge and training required to safely handle the materials described.
* I agree to train all of my laboratory personnel according to the BSL of the laboratory.
* Entry doors to the laboratory will be closed and locked when the laboratory is unattended.
* I agree to provide all personnel working in the laboratory notification, information and training on the hazards, laboratory security and emergency policies and procedures associated with working in my laboratory. **I agree to inform all personnel working in the laboratory that potentially all microorganisms can be pathogens under certain conditions. When necessary, work procedures and protocols are in place to prevent aerosols and exposure to microorganisms. All personnel are provided training in sterile technique, the use of automatic pipettes and the proper disposal of biohazardous materials. All personnel are advised that if they are in an immunocompromised/ immunosuppressed condition that they are at risk for infection from the general environment and susceptible to infections that would normally not be a problem for an immunocompetent individual. All personnel are further advised that working in a laboratory that conducts experiments using live microorganisms could increase their risk of infection and be hazardous to their health.**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Principal Investigator Date Typed/Printed Name

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Principal Investigator Supervisor Date Typed/Printed Name

**Protocol Title:**

**3. Status of Project:** Please indicate (X) the status of the project

# Request Protocol Continuance

 1a. [ ]  Active – project ongoing

 1b. [ ]  Currently inactive – project was initiated but is presently inactive

 1c. [ ]  Inactive- project never initiated but anticipated start date is:\_\_\_\_\_\_\_\_\_\_\_

**Request Protocol Termination**

 1d. [ ]  Inactive – project never initiated

 1e. [ ]  Currently inactive – project initiated has not/will not be completed.

 1f. [ ]  Completed- no further activities with animals will be done.

**4.** **Modifications to the Project** (in past 12 months)? [ ]  No [ ]  Yes

 (If yes, explain on a separate sheet and attach to this form. If changes were previously approved via an amendment, give the date of the approval of the amendment. You need not repeat the details of the modifications here. If changes were not previously approved by amendment, submit a completed amendment with this form and explain why an amendment was not filled out at the time that modifications were initially made.)

**5. Progress Report**

 If the project is continuing and has been active for any time during the past 12 months, provide a brief update on the progress made in achieving the specific aims of the protocol.

**[Type text in the text box --- Spacing will adjust to accommodate the length of the narrative]**

**6. Problems/adverse events.**

If the project is continuing and has been active for any time during the past 12 months, describe any unanticipated adverse events, the cause(s), if known, and how these problems were resolved. If NONE, this should be indicated.

**[Type text in the text box --- Spacing will adjust to accommodate the length of the narrative]**

**7. Future Plans**

[ ]  No changes are planned and the project will continue as previously approved by the IBC.

[ ]  Changes are planned. Attach a completed IBC Protocol Amendment Form to this Annual Review in which a full description and justification for the proposed changes are detailed. Please note that if the modifications are significant, you may be required to complete a new Protocol Application.

**8.** **All appropriate personnel participate in the Occupational Health Program.**

[ ] Yes [ ] No If **no**, please explain:

**[Type text in the text box --- Spacing will adjust to accommodate the length of the narrative]**

**9. Do all personnel have current IBC training?** [ ] Yes [ ] No.

 If **no** please explain:

**[Type text in the text box --- Spacing will adjust to accommodate the length of the narrative]**

**10. Have there been any changes in personnel not already documented via amendment to the protocol?** [ ] Yes [ ] No If **yes**, please fill in table on next page and submit signature page for any new personnel being added to Protocol.

**Personnel Information**

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**Personnel List**

*To be completed by the lab director (or PI) for personnel working on this protocol.*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Action TypeAdd – ADelete – DModify- M | First Name | Last Name | Will personnel be associated with an AUP? Yes – Y No - N | List all organism(s) (Pathogens, Toxins, rDNA) employees will have access | Laboratory Buildings | Laboratory Rooms | Position Title and Email Address |
|       |       |       |       |       |       |       |       |
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**(Please reproduce this page as needed.)**

**Personnel Information**

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**Information Signature Page**

**Is the protocol a BSL 1 protocol? Yes [ ]  No [ ]**

**Only if “No” is checked, does this page need to be filled out**.

Each employee working in BSL2 and above laboratories must complete this page.

*Employees working in laboratories containing Select Agents may submit copies of training certificates instead of signature pages.*

By my signature below, I certify that I have read and understand the laboratory security and emergency policies and procedures for working with       in laboratory building       and room(s)       under the direction of       .

I further certify that I understand the hazards of working with       ; the indications of infection or intoxication by this biological material; the reporting system for potential exposure and accidents; how to seek evaluation and therapy; the standard microbiological practices for this laboratory; the special Biosafety practices required for Biosafety level       work, in accordance with the Biosafety in Microbiological and Biomedical Laboratories (BMBL) Guidebook and standard operating procedures for this laboratory.

Finally, I certify that any transfer of this biological material will be done in accordance with Texas A&M International University policies and regulations and under the supervision of the Texas A&M International Office of Environmental Health and Safety. In addition, I ensure that the detailed records of information necessary to account for all activities related to this agent will be maintained.

Signature Date Laboratory director/Supervisor’s signature Date

Personnel Printed/Typed name, Position/Title Laboratory director/Supervisor’s Printed/Typed Name

Have you completed lab-specific training for this research? Yes [ ]  No [ ]

If yes, provide date of lab-specific training:

**(Please reproduce this page as needed.)**

**PROTOCOL APPROVAL**

**(FOR OFFICE USE ONLY)**

|  |
| --- |
| [ ]  **ADMINISTRATIVE (IBC CHAIR)** |
| Approved: |  | Date: |  |

|  |
| --- |
| [ ]  **FULL IBC COMMITTEE REVIEW** |
|  |
| Referred for Full Review: |  | Date: |  |
|  |
|  |
| Approved: |  | Date: |  |
|  |
|  |
| Minutes Attached: | [ ]  Yes [ ]  No | Date of Full Review: |  |