**TEXAS WOMAN’S UNIVERSITY**

**INSTITUTIONAL BIOSAFETY COMMITTEE**

**Instructions for completing the**

 **Recombinant DNA and Biohazardous Agent Application**

The Texas Woman’s University Institutional Biosafety Committee (IBC) is responsible for biosafety review and oversight of research involving recombinant DNA. Two types of experiments involving recombinant DNA and/or biohazardous agents are reviewed and considered for approval by the IBC:

1. those that require IBC approval (see [*Section III-D*](http://www4.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261566) of the NIH Guidelines), and
2. those that are exempt from the *NIH Guidelines* (see [*Section III-F*](http://www4.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261577) of the NIH Guidelines) but require IBC registration.

This application is to be used for type 1 only. Exempt projects use the [*IBC Registration Form*](file:///%5C%5Cxdrive.twu.edu%5CDLaGrone%5CMy%20Shared%20Folders%5CRschGrantsAdm%5CIBC%20-%20Institutional%20Biosafety%20Committee%5CIBC%5CRegistration%20Form) located on the ORSP website.

**Training Requirements**:

All members of laboratories housing rDNA or biohazardous agents are required to attend the TWU Annual Safety Seminar and to complete the [*IBC online training*](file:///%5C%5Cxdrive.twu.edu%5CDLaGrone%5CMy%20Shared%20Folders%5CRschGrantsAdm%5CIBC%20-%20Institutional%20Biosafety%20Committee%5CIBC%5Ctraining.html). Copies of certificates of completion for each member must be attached to the application. Certificates of completion are valid for 4 years.

**Submission of Application**:

Please complete the interactive [*IBC Application Form*](file:///%5C%5Cxdrive.twu.edu%5CDLaGrone%5CMy%20Shared%20Folders%5CRschGrantsAdm%5CIBC%20-%20Institutional%20Biosafety%20Committee%5CIBC%5CApplication%20Form.doc) found on the Office of Research and Sponsored Programs (ORSP) website, save it to your computer and print for signatures. Include additional pages if necessary. Handwritten applications will not be accepted. Deliver or mail the **original and 6 copies** of the **application** to:

TWU Office of Research and Sponsored Programs (ORSP)

ACT 7th Floor

P. O. Box 425619

Denton, TX 76204-5619

Applications must be submitted to ORSP at least 2 weeks prior to committee meetings. A yearly schedule of IBC meetings can be found on the ORSP website at <http://www.twu.edu/research>. Applicants can expect a response within 2 weeks following committee review unless revisions are required.

Incomplete or inaccurate applications will be returned for revisions, thus delaying the approval process. You may also be asked to make adjustments in your protocol or laboratory environment before approval is granted.

**Application Approval:**

IBC approved protocols are active as long as there are no significant changes and the Annual Continuation Form is submitted on the anniversary of the initial IBC approval.

**If you have questions regarding your IBC application, please contact the IBC Chair or the IBC Liaison in the Office of Research and Sponsored Programs at (940)898-3375.**

Texas Woman’s University

Institutional Biosafety Committee

Application Form

Recombinant DNA and Biohazardous Agent Research

**NOTE: Blue text indicates links to additional resources**

**I. GENERAL INFORMATION**

|  |  |
| --- | --- |
| **Principal Investigator:**  | **Department:**  |
| **Phone:**  | **Email:**  |
| **Project Title (if applicable**)**:**  |
| **Funding Agency (if applicable**)**:**  |

I am using **recombinant DNA**. YES [ ]  NO [ ]

(If YES, complete Sections II and IV.)

I am using **recombinant DNA** but my project is exempt. YES [ ]  NO [ ]

(If YES, complete Sections II and IV.)

I am using **biohazardous agents.** YES [ ]  NO [ ]

(If YES, complete Sections III and IV.)

#### II. RECOMBINANT DNA

1. **Outline the overall goal(s) of the project.** Give enough information so the techniques used and the purpose of the experiments are clear. Be as concise as possible using reasonably non-technical terms.
2. Goal:

1. List of hosts:

1. Inserts source:

1. Vectors type:

1. Description of recombinant molecule:

1. Biosafety level (BL) (check all that apply): BL1 [ ]  BL2 [ ]

**B. Answer specific questions as appropriate.**

 **Source of Gene, Insert, or Clone:**

1. Specify DNA/RNA source (or probe) and nature of insert:

Is a protein expressed? YES [ ]  NO [ ]

If YES, which protein?

Percent of any viral genome in construct:

1. Does the sequence code for a toxin? YES [ ]  NO [ ]  Unknown sequence [ ]

 If so, what LD50?

1. Is the DNA source from a USDA-regulated plant or animal? YES [ ]  NO [ ]

 If the regulated organism is grown or stored at TWU, please include a copy of the USDA permit.

**C. Large-Scale Research:**

 Do experiments involve growth of more than 10 liters of culture at a time? YES [ ]  NO [ ]

 If YES, identify culture room and type of equipment used for culture growth and handling.

**D. Course or Teaching Lab:**

 Is this project part of a course or teaching lab? YES [ ]  NO [ ]

If YES, what is the course number?

**E. Location of Proposed Research:**

List ALL laboratories/facilities where the research project is to be conducted and the corresponding biosafety level. Include cold/warm rooms and tissue culture rooms, if appropriate. Please indicate room(s) where biosafety cabinets are located.

|  |  |
| --- | --- |
| **Laboratory/Facility (Bldg. & Rm. #)** | **Biosafety Level**  |
|       |       |
|       |       |
|       |       |
|       |       |

**F. Safety Procedures:**

1. How will you dispose of cultures?
2. What are the procedures for cleanup of spills?
3. Are special safety procedures beyond BL2 required? YES [ ]  NO [ ]
	1. If YES, what are they?

**III. BIOHAZARDOUS AGENTS**

#### A. Description of Agent

1. Agent:
2. Agent Classification (fungal, bacterial, etc.):
3. Risk Group (see [*NIH Guidelines, Appendix B*](http://www4.od.nih.gov/oba/rac/guidelines_02/APPENDIX_B.htm))
4. Biosafety Level (check all that apply): BL1 [ ]  BL2 [ ]
	1. Brief description of use:
5. Source of infectious agent (i.e., new isolate from human tissue, blood, animal, tissue culture, another laboratory, ATCC, etc.):
	1. Host range:
	2. Length of time agent has been maintained in laboratory culture:
	3. Is this agent periodically passaged in animals? YES [ ]  NO [ ]
	4. Describe disease pathology and mode of transmission:
6. Is this a zoonotic agent- naturally transmitted between vertebrate animals and man? YES [ ]  NO [ ]
7. Is a vaccine or therapeutic treatment available for the agent? YES [ ]  NO [ ]

**B. Experimental Procedures:**

1. Describe procedures involving use of infectious agent (indicate culture volume, maximum concentration). How and at what stage of the experiment is the infectious agent inactivated or lysed?
2. Will experiments result in acquisition of new characteristics such as enhanced virulence, infectivity, drug resistance, or change in host range? YES [ ]  NO [ ]

 If YES, explain:

**C. Location of Proposed Research:**

 List ALL laboratories/facilities where the research project is to be conducted and the corresponding biosafety level. Include cold/warm rooms and tissue culture rooms, if appropriate. Please indicate room(s) where biosafety cabinets are located.

|  |  |
| --- | --- |
| **Laboratory building and room #** | **Biosafety Level** |
|       |       |
|       |       |
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**D.** **Safety Procedures:**

How will you dispose of cultures?

What are the procedures for cleanup of spills?

Are special safety procedures beyond BL2 required? YES [ ]  NO [ ]

 If YES, what are they?

**E. Laboratory Members:**

List all laboratory members. Attach training certificates for each member.

|  |  |  |
| --- | --- | --- |
| Laboratory Members | Safety Seminar(Date attended) | IBC Training(Date completed) |
| PI: |  |  |
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###### IV. CERTIFICATION

The information contained in this application is accurate and complete. I am familiar with and agree to abide by the provisions of the current [*NIH Guidelines*](http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html), CDC biosafety recommendations, TWU IBC Policies and Procedures, TWU safety standards, and local, state, and federal regulations pertaining to the proposed project.

In addition, I agree to abide by the following requirements:

|  |  |
| --- | --- |
| [ ]  | I will initiate no recombinant DNA/biohazardous research subject to the [*NIH Guidelines*](http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html) until that research has been reviewed and approved/registered with the IBC. |
| [ ]  | I will follow appropriate biosafety level laboratory techniques in the research. |
| [ ]  | I will comply with all shipping requirements for recombinant DNA and biohazardous agents. |
| [ ]  | I will post and make available to the laboratory staff copies of the approved safety protocols that describe the potential biohazards and the precautions to be taken. |
| [ ]  | I will train staff in good microbiological practices and techniques required to ensure safety for this project, in the procedures for dealing with accidents, and in waste management procedures. |
| [ ]  |  I will ensure that laboratory members receive all required training. |
| [ ]  | I will supervise staff and correct work errors and conditions that could result in breaches of the *NIH Guidelines* and TWU policies and safety standards. |
| [ ]  | I will notify the IBC in writing of project termination, completion, or modification.  |
| [ ]  | I will complete the *Recombinant DNA and Biohazardous Agent Research Annual Continuation Form* on the anniversary of IBC approval of my project. |
| [ ]  | I will report any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses in writing to the IBC and NIH/OBA within 30 days.  |

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Signature of Principal Investigator Date

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Signature of Department Chair, Associate Dean, or Director Date

IBC Approval Number: \_\_\_\_\_\_\_\_\_\_\_\_ Biosafety Level: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature, TWU IBC Chair: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_