**Texas Woman's University**

**Annual Continuation Form**

 This annual continuation form allows the IBC to screen for changes that may indicate the need for a change in containment level. Note: references to R/S NA mean “Recombinant DNA or Synthetic Nucleic Acid” research joining natural or synthetic DNA/RNA segments outside the cell that can then be introduced and replicated in a living cell; this includes derivatives that occur upon replication.

**BSL-1 work without R/S NA OR BSL-1 work with R/S NA that is EXEMPT from NIH Guidelines:**

* After initial submission, this form is required annually for BSL-1 work that does not utilize R/S NA or BSL-1 work that utilizes R/S NA that is EXEMPT from NIH Guidelines.

**BSL-1 work with R/S NA that is NOT EXEMPT from NIH Guidelines OR any BSL-2 work:**

* After initial submission, this form is required annually UNTIL it is the 5th year after the ‘full’ submission for BSL-1 R/S NA agents that are NOT EXEMPT from NIH Guidelines OR BSL-2 work
* If it is the 5th year after the ‘full’ submission, **a re-submission** of the BSL-2 & Non-exempt RS/NA Biosafety Review Form **is required**.
	+ E.g., the BSL-2 & Non-exempt RS/NA Biosafety Review Form was submitted in 2023, making the next submission due in 2028.
	+ Annual continuation forms would be submitted in 2024, 2025, 2026, and 2027.
* It is highly recommended to make sure you keep an **editable** copy of the initial BSL-2 & Non-exempt RS/NA Biosafety Review Form for ease of re-submission in the 5th year.

**If there are *significant modifications* from the original submitted protocol**:

* Especially those that affect the containment level (i.e., study on new organisms, a new host-vector-donor system, or any other modifications that may affect the containment level), do NOT complete the Annual Continuation Form. Instead, complete the BSL-1/Exempt R/S NA or BSL-2 & Non-exempt RS/NA Biosafety Review Form, whichever is most applicable.

**Note:** If conducting with animals, you must complete IACUC forms and the required IBC forms.

If you have questions about which form to submit, please contact EH&S at ehs@twu.edu. Please email the completed form to ORSP (Lbyford@twu.edu).

**Annual Continuation Form**

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| --- |
| **Table 1. PI Information** |
| **PI Name**  | **Email address** | **Department** | **\*IBC Protocol No AND date of last full form submission****\*if applicable** |
|  |  |  |  |

**Location & Transport**

1. **Have the Laboratory location(s) (building(s) and/or room number(s)) changed since**

**the approval of your IBC registration?**

|  |  |  |  |
| --- | --- | --- | --- |
| **Yes** |  | **No** |  |

If yes, **1a. Specify what locations have changed.**

**1b. Are new biosafety cabinets, autoclaves, etc. utilized due to the change in space?**

|  |  |  |  |
| --- | --- | --- | --- |
| **Yes** |  | **No** |  |

If yes, **1c. Detail what equipment is located in which spaces.**

**1d. What new transport practices are utilized, if applicable?**

**Research Protocols**

1. **Have your Research Protocols changed since the approval of your IBC registration?**

|  |  |  |  |
| --- | --- | --- | --- |
| **Yes** |  | **No** |  |

If yes**, 2a. Specify what protocols have changed.**

**Research Agents**

1. **Have your agent(s)/organism(s) changed since the approval of your IBC registration?**

|  |  |  |  |
| --- | --- | --- | --- |
| **Yes** |  | **No** |  |

If yes**, 3a. Specify what agent(s)/organism(s) have changed.**

**Disinfection**

1. **Are there any changes to how biological material will be decontaminated or inactivated?**

|  |  |  |  |
| --- | --- | --- | --- |
| **Yes** |  | **No** |  |

If yes**, 4a. How will biological material be decontaminated or inactivated?**

☐ Autoclave

 Autoclave location:

☐ Chemical disinfection

 Please specify chemical, contact time, and waste disposal procedures:

☐ Incineration

☐ Other (please explain)

**Adverse Events**

**5. Have there been any biological agent problems or adverse events such as spills, injuries or exposure incidents in the past year?**

|  |  |  |  |
| --- | --- | --- | --- |
| **Yes** |  | **No** |  |

If yes, **5a. Detail the problems or adverse events that occurred and the corrective actions taken.**

**Training**

Lab Safety/Chemical Hygiene Training is only required to be taken once (unless major changes to the training occur). Biosafety training is required every 4 years by everyone working with biohazardous agents. If an individual works with Blood/OPIM, they must also take Bloodborne Pathogens Training *annually*.

In addition to online training, the PI is required to provide hands-on training for lab users addressing the biohazardous agent, discussing routes of exposure, signs and symptoms of exposure, safety precautions for handling, etc.

1. **Provide names of all CURRENT lab personnel and their *most recent* training completion in Table 6.**

|  |
| --- |
| **Table 6. Personnel Training Information** |
| **Name**  | **Lab Safety/ Chemical Hygiene Training****Completion Date** | **Biosafety Training Completion Date** | **Bloodborne Pathogens Training Completion Date** \*If not applicable, write N/A | **PI Hands-On Training Completion Date** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

**6a. Is there a vaccine or therapeutic agent for the biohazardous agent/s?**

Yes\_\_\_\_\_ No\_\_\_\_\_

If yes, **6b. Please specify the vaccine and/or therapeutic agent**

If yes**, 6c.** **Are you offering applicable vaccines and keeping vaccine records or declinations for all employees (including student employees) requiring a vaccine? Students must be informed of applicable vaccines and the receipt of this information should be documented. Note: department storage of records is acceptable.**

 Yes\_\_\_\_\_ No\_\_\_\_\_

**6d. Acknowledge supervisor requirements by placing initials where indicated in the box below.**

|  |  |
| --- | --- |
| ‘Electronic’ (typed) initials | As PI, I understand it is my responsibility to ensure that ALL new individuals who enter my lab to work with the materials registered on this Form 1) complete and document all appropriate trainings (*e.g.,* Biosafety Training, BBP training, lab-specific training) and 2) complete documentation of any available safeguards (*e.g.,* vaccinations, etc.) required for the biohazards they will work with.  |
|  |

**Certification**

The following signatures certifies that the Principal Investigator will continue to conduct this research in accordance with the policy and procedures of the Institutional Biosafety Committee (IBC), the Biosafety in Biomedical and Microbiological Laboratories (BMBL) manual BMBL Manual, Section IV-B-7 of the NIH Guidelines (April 2019), NIH\_Guidelines.pdf and Texas Department of State Health Services (DSHS) Blood Borne Pathogens Program, as well as required training previously stipulated in IBC approval permit.

‘Electronic’ (typed) signature of PI Date

­ ‘Electronic’ (typed) signature of Department Head Date

 ‘Electronic’ (typed) signature of IBC Chair Date