**FOR OFFICE USE ONLY: IBC PROTOCOL # _____STATUS: _____ANIMAL WORK: _____**
**CONTAINMENT BSL: _____ RECOMBINANT DNA: _____**
**TRAINING COMPLETE: _____**

# University of North Dakota
# Institutional Biosafety Committee (IBC)
# Annual Review Form/Protocol Change Form
# Please send your completed document to the Institutional Review Board (IRB) Office

**INSTRUCTIONS**

Be sure to save the application PDF to your computer before you begin completing the form. You may not be able to save your changes if you edit this form in a web browser. Mac users please use Adobe Acrobat Reader or Adobe Acrobat Pro to fill out the Annual Review Form/Protocol Change Form.

All Principal Investigators conducting biological research must register with the University of North Dakota (UND) Institutional Biosafety Committee (IBC) to ensure that their research complies with UND biosafety regulations and National Institutes of Health (NIH) recombinant DNA guidelines. Consequently, it is critical that the IBC receive sufficiently detailed information to fulfill its review and approval mandate. This IBC Annual Review Form/Protocol Change Form is the critical instrument for the IBC to accomplish that review and approval responsibility. **If you are performing rDNA or infectious/tumorigenic material activities or biological research that are not detailed in an approved Registration Document (RD), you may be in violation of federal regulations and/or university policies.**

***This Annual Review Form/Protocol Change form must be completed and submitted to UND's Institutional Review Board Office if your research involves recombinant DNA and/or infectious agents, as described in the NIH and Centers for Disease Control and Prevention (CDC) guidelines.***

FAILURE TO PROVIDE ALL INFORMATION REQUESTED WILL LEAD TO A DELAY IN PROCESSING YOUR REQUEST!

**NOTE: Research Registration Documents are approved for a period of 3 years. Continued activity past 3 years will require a new Registration Document to be submitted. However, the annual review form needs to be submitted every year. Similarly, this form needs to be submitted if there are any changes to the existing approved Research Registration Document. Submitting a Modification is Not a Renewal of an existing Research Registration Document.**

If you need help or have questions about how to complete this application, please contact the IBC chair, Matthew Nilles, at matthew.nilles@med.UND.edu, or the Biological Safety Officer, Sumit Ghosh, at sumit.ghosh@UND.edu.

Complete this form, sign it, and send it to the IBC, Stop 7134, or bring it to Twamley Hall, Room 106. Or, if you prefer, you may email a signed copy of the application to: UND.ibc@UND.edu.

**PLEASE CONTINUE TO THE NEXT PAGE TO BEGIN COMPLETING THE FORM**

☐ **ANNUAL REVIEW FORM IBC PROTOCOL # _____**

☐ **PROTOCOL CHANGE FORM IBC PROTOCOL # _____**

## I. ADMINISTRATIVE INFORMATION:

| | | | | |
|---|---|---|---|---|
| **Principal Investigator:** | | | | |
| **Department:** | | | **Phone No:** | |
| **Building, Office Room No., Mail Code** | | | **Email:** | |
| **Co-Investigator:** | | | | |
| **Department:** | | | **Phone No:** | |
| **Building, Office Room No., Mail Code** | | | **Email:** | |
| **PROJECT TITLE:** | | | | |
| **Funding Agency:** | | **UND Proposal or Award #:** | | |
| **Dates of Project:** | **From:** | | **To:** | |

**II. NON-TECHNICAL SYNOPSIS:** Describe revisions to original disclosure in enough detail to allow for committee review and ***include any pertinent safety information****:*

**III. CHANGE IN SCOPE OF WORK:** ☐ No ☐ Yes

Please explain:

| |
|---|
| |

**IV. CHANGE IN MATERIALS:** ☐ No ☐ Yes

Please explain:

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**Please list specific cell lines and if purchasing from an outside source (e.g. ATCC), please include the product number.**

**V. CHANGE IN BIOSAFETY LEVEL:** ☐ No ☐ Yes

Please explain:

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**VI. CHANGE IN LAB LOCATION:** ☐ No ☐ Yes

Please list all lab and storage locations:

| |
|---|
| |

**VII. OTHER CHANGES:** ☐ No ☐ Yes

Please describe:

| |
|---|
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**VIII. ACCIDENTS, EXPOSURES, & EMERGENCY RESPONSE**

1. In the event of an accident/potential exposure, do you agree to follow the procedures listed below?
   ☐ YES ☐ NO

**Actions to take in the event of an exposure.....**

**A.** Flush the exposed area with water. If your eyes, nose or mouth were exposed to blood or other potentially infectious materials, flush these areas for 15 minutes. If your skin was exposed, thoroughly wash these areas with soap and water. Bandage the affected area if needed to control bleeding.

**B.** Notify your supervisor if he or she is available. The Supervisor/PI is responsible to submit the Incident Reporting form to Office of Safety and the IBC adverse event reporting form to IBC within 24 hrs of the incident.

**C.** Report to the designated medical care provider as soon as possible for follow-up. Take any applicable biological material description documents with you as well.

**D.** For exposure incidents involving human-derived materials (i.e., human cells or blood products), report immediately to designated medical care provider. Identify yourself to staff as a UND employee/student who has had a bloodborne pathogens exposure. **[Refer to UND's Bloodborne Pathogens Exposure Control Plan]**

**E.** For all other biological material exposures, report as soon as possible to the designated medical care provider.

**F.** For any accidents/exposures involving biohazardous materials, notify the Office of Safety (777-3341) as soon as possible. Both medical evaluation and safety practices follow-up must be completed and documented for such incidents per the provisions of CDC, NIH, and University of North Dakota Policies.

**IX. PERSONNEL:** Identify **ALL** personnel conducting the experiments (including Students and Staff). Specify degree, applicable training and experience including duration (e.g. 2 years), and project responsibilities.

| Participant Name | Degree | Project Responsibilities | Prior Experience or Training Related to these Responsibilities | FOR IBC USE ONLY TRAINING VERIFICATION |
|---|---|---|---|---|
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**List the names of any individuals no longer involved with the experiments (these individuals will be removed from the disclosure):**

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____

By signing below you are agreeing that all work on this project will be conducted using biosafety practices described in the CDC/NIH Publication entitled *Biosafety in Medical and Biomedical Laboratories (BMBL, 5th Edition).* Additional stipulations required by the IBC on behalf of University of North Dakota will also be followed.

_____ _____

**Signature of Principal Investigator** **Date**

| FOR IBC COMMITTEE USE ONLY | | |
|---|---|---|
| | **IBC Chair or Designee** | **Date** |
| ☐ Approved by IBC | | |

**Please return the completed form to:**
**UND Institutional Review Board, Twamley Hall, Room 106, or via intra-campus mail to Stop 7134**