UNIVERSITY OF WYOMING Institutional Biosafety Committee

Procedure for Registering Research with the IBC

OVERVIEW IBC review process:

1. Low-level or Teaching Protocols:
    a. Submit appropriate document(s) to the Biological Safety Specialist (BSS) at biosafety@uwyo.edu
    b. BSS conducts a Pre-Review of the submitted registration to ensure all information has been given and is adequate.
        i. If the registration is missing information or little information is given, expect this process to take longer due to failure to submit a completed document.
    c. BSS will send the registration will comments back to PI.
    d. PI will address the comments and send back to BSS.
    e. BSS will review.
        i. If registration is sufficient, BSS will approve.
        ii. If registration reaches a higher level of review, BSS will submit to full committee review.
            1. IBC will review at the next scheduled meeting. If comments or corrections are necessary, then the BSS will submit comments to PI.
            2. PI will address comments and corrections. PI will submit back to BSS for the Chair to review. Chair will either approve or submit comments back.
    f. Approval: PI will receive a memo statement of approval.

Note: For teaching protocols, if the approval is semester-based, make sure to submit a project completion at the end of the semester.

2. BSL- 2 or Higher:
    a. Submit appropriate document(s) to the Biological Safety Specialist (BSS) at biosafety@uwyo.edu
    b. BSS conducts a Pre-Review of the submitted registration to ensure all information has been given and is adequate.
        i. If the registration is missing information or little information is given, expect this process to take longer due to failure to submit a completed document.
    c. BSS will send the registration with comments back to PI.
    d. PI will address the comments and send them back to BSS.
    e. BSS will submit registration to full committee review at the next scheduled meeting.
    f. Full Committee Review occurs.

   i. BSS will send comments and corrections to the PI, if necessary. PI will address comments and corrections and submit them back to BSS. IBC Chair and BSO will review and determine approval or additional comments to be sent out.
   ii. Approval will be motioned.
g. Approval: PI will receive a memo statement of approval.

3. PI must keep IBC informed: Annual updates, significant changes to the project, accidents or incidents, and final disposition of biological agents after project is completed.

PI Registration Procedures:

1. Determine if project needs IBC approval. Yes, if using:
    a. Research and other activities involve potential exposure to susceptible human, animal or plant hosts to infectious agents, biological toxins, or to other biohazardous materials. Such projects include:
        i. research involving infectious agents or materials,
        ii. teaching programs involving infectious agents or materials,
        iii. archival collections of infectious materials,
        iv. field research involving infectious agents or materials
            1. examples include wildlife, water or soil sampling, and others
        v. occupational exposures to potential biohazards.
    b. Research and other activities involving experimentally infected animals and those naturally harboring zoonotic infectious agents.
    c. Research and other activities involving human cell lines and other materials of human origin.
    d. Research and other activities involving recombinant and synthetic nucleic acid molecules (rDNA).
    e. Research and other activities involving gene drive modified organisms. Such as the impact on ecosystems.
    f. Research and other activities involving Select agents and toxins
    g. Research and other activities involving Transgenic plants and animals
    h. Research and other activities involving arthropod and plant containment

2. Biosafety Training <u>Before</u> IBC submission
   <u>All personnel</u> named in the forms (including the PI) must complete CITI online training ("Training for Investigators, Staff and Students Handling Biohazards", "NIH Recombinant DNA (rDNA) Guidelines", and other appropriate modules such as "Animal Biosafety" or "Bloodborne Pathogens training") and UW Laboratory Safety Series before initiating the protocol. Personnel <u>will not</u> be able to work in lab until they are up to date with UW safety training programs.

Follow instructions on the last page on how to register for CITI training and UW Lab Safety Series

   a. First-time researchers at UW must take the "Training for Investigators, Staff and Students Handling Biohazards. (ID: 62063)" through CITI program.
   b. If a first-time researcher at UW is working with recombinant DNA, they must take "NIH Recombinant DNA (rDNA) Guidelines (ID: 62071)" through CITI Program.
   c. If the researcher has already taken the above training, or previously approved training, and has now expired (three (3) years after completion), they must take "Biosafety Retraining Course (ID: 62064)" through the CITI program.

i. If a renewing researcher is working with recombinant DNA they will need to retake "NIH Recombinant DNA (rDNA) Guidelines (ID: 62071)" through the CITI program.
ii. If a renewing researcher is working with animals, they will need to retake "Animal Biosafety (ID: 62065)" through the CITI program.

d. All UW researchers working in UW laboratories must take the UW Lab Safety Series, and it is to be renewed every three (3) years.
e. If any other applicable training is required, such as bloodborne pathogen training, Select Agent Training, or radiation safety training, please indicate what the additional safety training along with the date of completion.

3. Submit Registration(s) to the IBC.
Information and forms can be found on the UW-IBC website. Send all forms electronically to the BSS at biosafety@uwyo.edu . Subject Line: "New IBC Project Submission"
If a project contains:
   a. Recombinant DNA:
      i. Complete a "Recombinant DNA Registration Document"
      ii. Complete a "Medical Card form", if applicable.
      iii. Submit the form electronically with an abstract including information on procedures, volumes of pathogens, experiment timeline, and descriptions of the locations involved. Section 3.n. must be filled out with an appropriate designation. For assistance, use the NIH Guidelines- Section III EXPERIMENTS COVERED BY THE NIH GUIDELINES (https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf)
      iv. Exempt work must still be submitted to IBC for review exemption.
      v. Submit to the BSS.
   b. Biological Agents and Toxins:
      i. Complete the "Biological Agent and Toxin Usage Form"
      ii. Complete a "Medical Card form", if applicable.
      iii. Submit the form electronically with an abstract including information on procedures, volumes of pathogens, experiment timeline, and descriptions of the locations involved.
      iv. Submit to the BSS.

Note: The University must ensure levels of certain biological toxins are below the limit delineated by the Select Agent Regulations.

IBC Review Process:

1. The BSS receives the registration and reviews it for clarity and completeness.
    a. If not completed and filled out fully, it will not be sent off for approvals.
    b. Recombinant DNA research exempt from the NIH Guidelines will be reviewed by the BSS and the IBC Chair.
    c. BSS will review low-level (BL-1) and teaching protocols.
    d. All other registrations will be reviewed by the IBC for a full committee review.
2. Registrations must be received on the **last Wednesday of every month** before the next monthly IBC meeting to be included in the agenda. Anything submitted after this deadline will be a part of the following monthly meeting. *PLAN ACCORDINGLY.*
3. The BSS will send registrations via email to the IBC Seven (7) calendar days before the next monthly meeting of the IBC.
   Tentative monthly meeting schedules can be found on the IBC website.
4. The IBC reviews registrations prior to meeting and comes to the meeting prepared to discuss the projects.
    a. The PI may* attend the meeting and participate in the discussion, answering questions or providing more details of the project. *Highly encouraged.
5. At the IBC meeting, a decision is made to approve the project as written, request amendments or changes, and resubmit to the IBC, or to not approve.
6. The BSS informs the submitter of the IBC decision along with comments, if necessary.
7. Once the project is approved for registration by the IBC, the BSS will send the submitter a memo stating the approval.
8. The PI must provide annual updates to the IBC via the BSS.
    a. The BSS will send to the PI a reminder email and a copy of the current documents on records.
    b. The PI will submit an "IBC Annual Update/Changes Form" whether the project is still in progress. Any significant changes to an updated Biological Agent or Recombinant DNA form(s) must be resubmitted to BSS with changes in red.
9. The PI must keep IBC informed via the BSS of:
    a. Significant changes of project:
        i. Change of agents
        ii. Change of outcome
        iii. Change in risk
        iv. Change in location if it affects biosafety aspects
        v. Change of personnel
    b. Accidents or incidents
    c. Final disposition of biological agents after project is completed

10. The expiration date of the registered protocol is three years from the date of IBC registration. **Research cannot be conduct after the expiration date.**
    a. BSS will send out an email when the project is expiring. PI's decision to resubmit a renewal project prior to the expiration.

Contact Biological Safety Specialist with any additional questions at biosafety@uwyo.edu or 766-2723.

SAFETY TRAINING INSTRUCTIONS

Instructions for UW Safety training:

Laboratory Safety Series that includes: https://uwyo3.catalog.instructure.com/browse/14/21

1. New Researchers at UW:
    a. Online / Cy- [current year] New Employee Safety Orientation
    b. Online / laboratory Safety "Chemical Hygiene & GHS/OSHA"
    c. Online/ Regulated Waste Generator Training
2. Returning Researchers: (every three years)
    a. Online – Cy- [current year] Review Laboratory Safety

Instructions for biosafety training

1. Enter https://about.citiprogram.org/ into your web browser.
2. Select "Register Here" next to "New Users."
3. Select University of Wyoming from the drop-down list under "Participating Institutions."
4. Select your username and password.
5. Enter your name.
6. Enter your e-mail.
7. Select "Submit" at the bottom of the page.
8. Fill in the applicable information requested by the University of Wyoming.
9. Select "Submit" at the bottom of the page.
10. To add a course:
    a. Click "Biosafety/Biosecurity"
    b. For "Training for Investigators, Staff and Students Handling Biohazards. (ID: 62063)" Click "Basic Biosafety Training".
    c. For "NIH Recombinant DNA (rDNA) Guidelines (ID: 62071)" Click "NIH Recombinant DNA (rDNA) Guidelines"
    d. For "Animal Biosafety (ID 13654)" Click "Animal Biosafety"
    e. For "Dual Use Research of Concern (DURC) (ID 16263)" Click "Dual Use Research of Concern (DURC)"

UW Bloodborne Pathogen links:

- Students/UW employees (hourly/salaried): Go to WyoCloud (through the Financial Management & HCM link on WyoWeb) Click "Learning" tab. Type: "UW Bloodborne Pathogens [current year]". Enroll into course.
- Students/members who are not getting paid by the university: Go to WyoLearn (https://uwyo3.catalog.instructure.com/browse/14/21)