Procedure for Registering Research with the Institutional Biosafety Committee

Overview:

1. Determine if project needs IBC approval.
2. Submit appropriate document to the Biological Safety Specialist.
3. IBC Reviews at next monthly meeting.
4. IBC makes final decision and PI receives a memo of approval from the Biological Safety Specialist.
5. PI must keep IBC informed.

Approval Procedures

1. IBC approval if using:
    a. Synthetic or Recombinant DNA.
        i. All research using synthetic or recombinant DNA is reviewed by the UW IBC
        ii. Categories of Synthetic and Recombinant DNA Checklist in the NIH Guidelines: http://www.uwyo.edu/risk/safety/biological/ibc.html.

    b. Microorganisms and viruses including vaccine strains.
    c. Toxins derived from a living organisms such as and including but not limited to:
        i. Abrin
        ii. Botulinum neurotoxins
        iii. Short, paralytic alpha conotoxins
        iv. Diacetoxyscirpenol (DAS)
        v. Ricin
        vi. Saxitoxin
        vii. Staphylococcal Enterotoxins (Subtypes A, B, C, D, and E)
        viii. T-2 toxin
        ix. Tetrodotoxin
2. Submit information to the IBC: www.uwyo.edu/risk/safety/biological/ibc.html.

    a. Recombinant DNA:
        i. Use the “Recombinant DNA Research Checklist for NIH Guidelines” to determine the category of the experiment.
        ii. Complete a “Recombinant DNA Registration Document”.
        iii. Submit to the Biological Safety Specialist.
    b. Microorganisms and viruses:
        i. Complete “Biological Agent and Toxin Usage Form” questions 1 through 4 for all risk group 1-4 microorganisms (microorganisms that may infect other organisms).
        ii. Submit the form electronically with an abstract including information on procedures, volumes of pathogens, experiment time line, and descriptions of the laboratories and animals rooms involved.
    c. Biological Toxins:

i. Complete the Biological Agent and Toxin Usage Form.
ii. Submit the form electronically with an abstract including information of procedures, volumes of the toxin used in research as well as maintained in stock, experiment time line, and descriptions of the laboratories and animal rooms involved.
iii. Note: the University must ensure levels of certain biological toxins are below the limit delineated by the Select Agent Regulations.

d. Send all forms electronically to the Biological Safety Specialist uwehs@uwyo.edu.

3. Project Review and Registration:
   a. The Biological Safety Specialist receives the form and reviews it for clarity and completeness.
   b. All synthetic and recombinant DNA research will be reviewed by the IBC.
   c. Forms must be received no later than 10 calendar days before the next monthly IBC meeting to be included in the agenda.
   d. The Biological Safety Specialist will send forms via email to the IBC seven calendar days before the next monthly meeting of the IBC.
   e. The IBC reviews and come to the IBC meeting prepared to discuss the projects.
   f. The PI may attend the meeting and participate in the discussion, answering questions or providing more details of the project.
   g. At the IBC meeting a decision is made whether to approve the project as written, request amendments or changes and resubmit to the IBC, or to not approve.
   h. The Biological Safety specialist informs the submitter of the IBC Decision.
   i. Once the project is approved for registration by the IBC, the Biological Safety Specialist sends the submitter a memo stating the approval.
4. PI receives memo of registration from the Biological Safety Specialist.
5. All personnel named in the forms including the PI must take online CITI training "Basic Biosafety Training", "NIH Recombinant DNA Guidelines" if using synthetic or recombinant DNA, and other appropriate modules as stated in the correspondence with the IBC.
6. The PI must provide annual updates to the IBC via the Biosafety Specialist uwehs@uwyo.edu
   a. The Biosafety Specialist will send to the PI a reminder email and copy of the current documents on records.
   b. The PI will confirm whether the project is still in progress and any significant changes on an updated Biological Agent or Recombinant DNA form(s).
7. The PI must keep IBC informed via the Biosafety Specialist uwehs@uwyo.edu 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.
   b. Accidents or incidents.
   c. Final disposition of biological agents after project is completed.
8. The expiration date of the registered protocol is three years from the date of IBC registration.