Miami University Institutional Biosafety Committee (IBC) Meeting Minutes

May 20, 2025 Meeting Minutes

Location: Zoom

Members Present:

- Dr. Joseph Carlin (Chair, Microbiology)
- Dr. Eileen Bridge (Microbiology)
- Mr. Jeffrey Johnson (Environmental Health and Safety)
- Dr. Andrew Jones (Chemical, Paper, and Biomedical Engineering)
- Dr. Carole Dabney-Smith (Plant Expert, Chemistry & Biochemistry)
- Dr. Richard Page (Associate Vice President of Research and Innovation, *ex officio*)
- Ms. Patricia Mueller (Unaffiliated Member)
- Ms. Jazzminn Hembree (Animal Expert, Laboratory Animal Resources)
- Dr. Tom Crist (Department of Biology)
- Ms. Carol Durrough (Unaffiliated Member)

Members Absent:

- Dr. Matthew Saxton (Biological Sciences)
- Dr. Rock Mancini (Chemistry & Biochemistry)

Staff Present:

- Dr. Susan McDowell (Vice President for Research and Innovation)
- Ms. Amanda Stewart (Assistant Director of Lab Safety)

Guests Present:

- None

I. Call to Order
   a. 2:02 p.m.
   b. Quorum established. Seven voting members present. Two additional members joined after quorum was established.
   c. Conflict of Interest Statement: IBC members with a conflict of interest related to the review of a specific application may not be involved in the review of approval of the application if the IBC member expects to be engaged in research described in the application or has a direct financial interest.

II. Review of Previous Meeting Minutes
   a. Review of meeting minutes from April 29, 2025.
      i. Comments: None
      ii. Motion to approve.
      iii. Vote: For: 8; Against: 0; Abstain: 0; Absent: 3

III. Announcements

a. Mandy Karper from Cayuse will be joining the IBC meeting today from 3:00 p.m. - 3:30 p.m. to provide an overview of the review process in Cayuse.

IV. Reports of Non-Compliance or Incidents
   a. None reported.

V. Protocol Review

   a. Application Title: Miami0051_James_2025_04_16
      i. Principal Investigator: Dr. Paul James
      ii. Primary Reviewer Name: [IBC Member]
      iii. Additional Reviewer(s) Name(s): N/A
      iv. Project Overview:
      Recombinant DNA: expression vectors to express ion transport proteins from mice, rats, humans, and sea urchin in cultured cells and transgenic mice, PCR cloning vectors to clone DNA fragments from mice, rats, and humans for DNA sequencing, vectors with potential DNA sequence regulatory elements from mice, rats, and humans as promoters to drive reporter proteins (luciferase, fluorescent proteins, etc.), and vectors to express guide RNAs (gRNAs), active Cas9, and inactive Cas9 (dCas9) in cells to disrupt ion transporter gene function or regulatory elements. Mice with modified genomes - knockout mice containing genome modifications that constitutively inactive ion transport genes, contain floxed (flanked by LoxP sites) ion transporter gene alleles for conditional (tissue-specific) inactivation of ion transporter genes, and containing transgenes for the tissue-specific expression of the cre recombinant (used in combination with the floxed allele mice to generate the tissue-specific knockout mice).
      Microbial/Infectious Agents: *E. coli* to amplify vectors described above.
      Human/Non-Human Primate Derived Materials: Established human cell lines (HEK293, HeLa, etc.) for expression ion transport proteins and reporter proteins and for a source of potential human DNA sequence regulatory elements. Fixed human tissues for identifying location of expression of human ion transport proteins. Fresh frozen human tissues used as a source for DNA for potential DNA sequence regulatory elements, RNA for analysis of expression patterns for the transcripts encoding the ion transport proteins, and as a protein source for western blot analysis of protein expression patterns of ion transporters.
      v. Agent Names:
         1. Na/H Exchanger
         2. Na,K-ATPase
         3. Luciferase
         4. Green Fluorescent Protein
         5. Cas9
         6. Cre recombinase
         7. gRNAs
         8. *Escherichia coli* (Strain: DH5α)
         9. *Escherichia coli* (Strain: DH10B)

10. Established Human Cell Lines (HEK293, HeLa)
11. Human Tissues (Fixed tissue and fresh frozen tissue)

v. BSL: Biosafety Level 2
vi. Applicable NIH Guidelines: Section III-D-1, Section III-D-4
vii. Potential for Dual-Use: No
viii. Training Assigned:
1. Basic Introduction to Biosafety
2. NIH Recombinant DNA Guidelines
3. Fundamentals of Working in Biological Safety Cabinet
4. OSHA Bloodborne Pathogens
ix. Risk Assessment and Discussion:
1. The IBC members discussed the biosafety containment level and determined that Biosafety Level 2 was appropriate.
2. The IBC members discussed the information present in Form D pertaining to animals. An approved Institutional Animal Care and Use Committee protocol was in place.
3. The IBC members discussed the information pertaining to biosafety and personal protective equipment indicated in the application and determined it was appropriate.
x. Information to be communicated with PI:
1. All personnel listed on the application must complete the assigned training.
xi. IBC Lab Assessment Results:
1. Site assessment was completed on May 15, 2025.
xii. Motion: Motion to approve pending completion of training.
xiii. Vote: For: 8; Against: 0; Abstain: 0; Absent: 3

b. Application Title: Miami0026_Castillo_2024_10_28
i. Principal Investigator: Dr. Dean Castillo
ii. Primary Reviewer Name: [IBC Member]
iii. Additional Reviewer(s) Name(s): N/A
iv. Project Overview:
BIO 115. Biological Concepts: Ecology, Evolution, Genetics, and Diversity. Integrated study of microbes, plants, and animals emphasizing biological diversity and interdependence of life and environment. Experimentation outlined in laboratory manual, including: Experimental Design and Statistics, Introduction to the Microscope, Seed Germination, Evolution in Action, Soil Invertebrate Biodiversity, Bacteriological Examination of Water, Growth and Development Lab, Angiosperm Leaf and Flower Morphology, and Animal Behavior.
v. Agent Names:
1. *Escherichia coli*
2. *Enterobacter aerogenes*
3. Unknown bacteria from water samples

v. BSL: Biosafety Level 2
vi. Applicable NIH Guidelines: Section III-E
vii. Potential for Dual-Use: No
viii. Training Assigned:
    1. Basic Introduction to Biosafety
ix. Risk Assessment and Discussion:
    1. The IBC members discussed the biosafety containment level and determined that Biosafety Level 2 was appropriate for the experimentation described.
    2. The IBC members discussed the experimentation utilizing unknown water samples and determined that alternative methods for achieving the sample learning objectives were needed.
    3. The IBC members discussed the information listed in Form B and determined additional information regarding the source of the strains identified was needed.
x. Information to be communicated with PI:
    1. For plate counts from environmental water samples, these are fine as long as the plates are sealed, perhaps with Parafilm. Since you would be growing unknown bacteria, the possibility of pathogenic bacteria is real. Sealed plates would alleviate that risk.
    2. For the identification of coliform bacteria, expansion of coliform numbers and subculturing them onto EMB plates is an unnecessary risk. We recommend creating your own “environmental” water by spiking it with known BSL-1 bacterial species, as they do on the Oxford campus. In addition, there are coliform water testing kits that are commercially available, but they are likely more expensive, and I prefer the experience that students gain by actually setting up the plates.
    3. For Form B, we need more than [Science Stores Specialist] for the course of your bacterial strains. What is the provenance of these strains? What commercial source and ATCC number are these strains?
xi. IBC Lab Assessment Results:
    1. Site assessment was completed on December 13, 2024.
xii. Motion: Motion to approve pending requested modifications.
xiii. Vote: For: 9; Against: 0; Abstain: 0; Absent: 2

c. Application Title: Miami0034_Taylor_2024_10_30
    i. Principal Investigator: Dr. Sydney Taylor
    ii. Primary Reviewer Name: [IBC Member]
    iii. Additional Reviewer(s) Name(s): N/A
    iv. Project Overview:
    UNV 172. First-Year Research Experience II.
    Scientific Method Lab: Students get hands-on exposure to designing experiments and going through the scientific method using everyday and readily available supplies.

Bacteriological Examination of Water: Students get to determine if natural water sources are contaminated with potentially harmful bacteria.

Invertebrate Soil Diversity: Students get to look at biodiversity based on collected samples of dirt in two different locations.

Determination of gene regulation in the human obesity and cellular senescence pathways of HB-EGF and ADAM 12S co-infected HEK 293 cells. HB-EGF, ADAM 12S, and MOCK adenovirus are used to infect HEK 293 cells and then RNA is isolated from those cells to look at differential gene regulation using RT2 Profiler arrays for the human obesity disease pathway and the cellular senescence pathway.

The experimentation is outlined in the course manual.

iv. Agent Names:
    1. HB-EGF gene
    2. ADAM 12S gene
    3. *Escherichia coli*
    4. *Enterobacter aerogenes*
    5. Unknown bacteria from water samples
    6. Ad-ADAM 12S
    7. Ad-HB-EGF
    8. Ad-MOCK
v. BSL: Biosafety Level 2
vi. Applicable NIH Guidelines: Section III-D-1
vii. Potential for Dual-Use: No
viii. Training Assigned:
    1. Basic Introduction to Biosafety
    2. NIH Recombinant DNA Guidelines
    3. Fundamentals of Working Safely in a Biological Safety Cabinet
ix. Risk Assessment and Discussion:
    1. The IBC members discussed the experimentation described and indicated that additional clarification was needed regarding what experimentation will take place in the course versus the experimentation that occurs in the Harding lab.
    2. The IBC members indicated that additional forms were needed based on the experimentation described, including Form A, Form B, and Form C.
    3. The IBC members discussed the experimentation utilizing unknown water samples and determined that alternative methods for achieving the sample learning objectives were needed.
    4. The IBC members indicated that additional information pertaining to the bacteria that will be utilized is needed, including the specific strain and source of the materials.
    5. The IBC members indicated that if HEK 293 will be utilized by the students in the course versus the Harding lab, IBC Form C is needed.

6. The IBC members indicated, based on the information present in the application, Biosafety Level 2 was appropriate; however, the IBC members indicated that safer methodology may be available to achieve the same learning outcomes.

x. Information to be communicated with PI:
    1. There was some confusion trying to separate the experiments being done in the course by the undergraduates vs. materials that will be provided by the Harding lab. It would be better to refer to a Harding lab approved protocol instead of trying to include everything the Harding lab does with respect to materials. It was difficult to know who does what as it was described.
    2. In Main Form, Section IIA, you should check all of these boxes: Recombinant/Synthetic Nucleic Acids (PCR), Microbial/Infectious Agents (Bacteria in water), Human/Non-Human Primate Derived Materials (Cell lines), as your exercises utilized all three.
    3. We are concerned about the request for BSL-2 in this teaching lab. After reviewing several sources online, there are safer ways to perform these exercises than as you have described. These changes parallel the changes we requested for a similar application from the Middletown Campus. Please resubmit the application after addressing the issues we discovered.
    4. For plate counts from environmental samples, these are fine as long as the plates are sealed, perhaps with Parafilm. Since you would be growing unknown bacteria, the possibility of pathogenic bacteria is real. Sealed plates would alleviate that risk.
    5. For the identification of coliform bacteria, expansion of coliform numbers and subculturing them onto EMB plates is an unnecessary risk. We recommend creating your own "environmental" water by spiking it with known BSL-1 bacterial species, as they do on the Oxford campus. In addition, there are coliform water testing kits that are commercially available, but they are likely more expensive, and I prefer the experience that students gain by actually setting up the plates.
    6. In Form B, we need more than [Science Stores Specialist] for the course of your bacterial strains. What is the provenance of these strains? What commercial source and ATCC number are these strains?
    7. You will need to submit Form C.

xi. IBC Lab Assessment Results:
    1. Site assessment was completed on May 19, 2025. Previous site assessments were conducted on May 6, 2024, December 13, 2024, May 7, 2025, and June 6, 2025.
        a. Can you indicate what materials are utilized in this room? We are trying to understand what activities occur and what materials are used at each location listed on your IBC application.

b. Do you generate infectious waste in [Laboratory Room]? If so, can you please indicate what type of containers are used to collect this waste and the process for final waste disposition?
c. Do you utilize needles, razor blades, or other similar sharp objects in this lab space? If so, can you please indicate what type of waste container is utilized?
d. Do you prohibit eating, drinking, smoking, applying cosmetics or lip balm, lotion, or handling of contact lenses in this space?
e. Do you have written procedures in place and have researchers been trained to appropriately decontaminate equipment and work surfaces?
f. Do you prohibit mouth-pipetting or suctioning of any hazardous material in this lab space?

xii. Motion: Motion to approve pending all modifications requested.
xiii. Vote: For: 9; Against: 0; Abstain: 0; Absent: 2

d. Application Title: Miami0032_Ferguson_2024_10_29
i. Principal Investigator: Dr. D.J. Ferguson
ii. Primary Reviewer Name: [IBC Member]
iii. Additional Reviewer(s) Name(s): N/A
iv. Project Overview:
BSC 313. Microbial Diversity.
Molecular, biochemical and evolutionary diversity of the microbial world, including Bacteria, Archaea, and Eukaryotes.
The experimentation is outlined in the course manual and includes: Use of the Microscope, Growing Bacteria in the Lab, Microbes Around Us, Staining Methods, Fermentation, Serial Dilution and Plate Count, 3-Phase Streak Plate Method for Isolation of Bacteria, Metabolic Activities of Bacteria, UV Light, Genetic Diversity, Bacteriophage Assay, Enterotubes, and Winogradsky Column.
v. Agent Names:
1. 16S rDNA gene
2. *Anabaena sp., living*
3. *Bacillus subtilis*
4. *Citrobacter freundii*
5. *Enterobacter aerogenes*
6. *Escherichia coli*
7. *Micrococcus luteus*
8. *Rhizobium leguminosarum*
9. *Serratia marcescens*
10. *Staphylococcus epidermis*
11. Unknown bacteria from water samples
12. Baker's Yeast

13. *Rhodotorula glutinis*

v. BSL: Biosafety Level 2
vi. Applicable NIH Guidelines: Section III-F-1, Section III-F-2, Section III-F-3
vii. Potential for Dual-Use: No
viii. Training Assigned:
    1. Basic Introduction to Biosafety
    2. NIH Recombinant DNA Guidelines
ix. Risk Assessment and Discussion:
    1. The IBC members discussed the proposed experimentation and determined that Biosafety Level 2 was appropriate.
    2. The IBC members discussed the personal protective equipment and engineering controls described and indicated that they were appropriate.
    3. An IBC member indicated that the Main Form must be revised to include the use of recombinant and synthetic nucleic acids.
    4. The IBC members discussed the information presented in Form B and indicated that additional information regarding the provenance of the strains was needed.
x. Information to be communicated with PI:
    1. In the Main Form, Section II.A, you should check the Recombinant Synthetic Nucleic Acids box, since you will be doing PCR.
    2. For Form B, we need more than [Science Stores Specialist] for the source of your bacterial strains. What is the provenance of these strains? What commercial source and ATCC number are these strains?
    3. The Primary Investigator must complete the assigned training.
xi. IBC Lab Assessment Results:
    1. Site assessment was completed on December 13, 2024.
xii. Motion: Motion to approve pending modifications and completion of training.
xiii. Vote: For: 9; Against: 0; Abstain: 0; Absent: 2

e. Application Title: Miami0050_Love_2025_04_13
    i. Principal Investigator: Dr. Ashley Love
    ii. Primary Reviewer Name: [IBC Member]
    iii. Additional Reviewer(s) Name(s): N/A
    iv. Project Overview:
    Blood samples will be collected from wild songbirds to quantify avian health and immune metrics in response to different social and environmental variables. Blood samples will also be screened for vector-borne avian blood parasites (*Plasmodium* spp., *Leucocytozoon* spp., *Haemoproteus* spp.) which commonly infect wild birds in the United States, including Ohio. We will be surveying wild birds for avian blood parasites which are vector borne and are not infectious to humans. Gloves will be worn while collecting samples in the field. Wild birds will be

released after sample collection. Samples collected from birds will be immediately placed in a preservative in the field (ethanol, DNAshield, FTA cards) and then frozen, which together will inactivate/kill the parasites, so that we will not be working with any infectious material in the lab. Blood smear samples will be dried on glass slides in the field, placed in a sealed slide box for transportation to the lab, and then immediately fixed in methanol and stained upon returning to the lab (while wearing appropriate PPE: gloves, lab coat, safety goggles). The fixation process will inactivate/kill any parasites. Fixed/stained slides will be stored in the lab in a sealed slide box. Used needles and hematocrit capillary tubes will be placed in a biohazardous sharps container. As samples are processed (DNA extractions, etc.) any remaining sample will remain in its given storage preservative (ethanol, DNAshield, FTA cards) and be refrozen until the project is completed. If samples are no longer needed, they will be disposed of as biohazardous waste.

iv. Agent Names:
    1. *Plasmodium* spp. (avian)
    2. *Leucocytozoon* spp.
    3. *Haemoproteus* spp.
v. BSL: Biosafety Level 1
vi. Applicable NIH Guidelines: Section III-E
vii. Potential for Dual-Use: No
viii. Training Assigned:
    1. Basic Introduction to Biosafety
ix. Risk Assessment and Discussion:
    1. The IBC members discussed the biosafety containment level and determined that a revision to Biosafety Level 2 was required. The IBC members indicated that the Primary Investigator must take into consideration the risks in the field, in addition to the risks in the lab.
    2. The IBC members indicated that the Primary Investigator must ensure that the appropriate PPE is utilized in the field when collecting the samples from the live specimens.
    3. An approved Institutional Animal Care and Use Committee protocol was in place.
x. Information to be communicated with PI:
    1. The IBC has determined that a modification of the Main Form, Section II.C to Biosafety Level 2 is required. You should indicate Biosafety Level 2 since the biosafety level refers to the level experienced by investigators, including in the field. Ensure appropriate personal protective equipment is employed in the field.
xi. IBC Lab Assessment Results:
    1. Site assessment was completed on May 12, 2025.
xii. Motion: Motion to approve pending modifications requested.
xiii. Vote: For: 9; Against: 0; Abstain: 0; Absent: 2

VI. New Business

a. Summer Meeting Schedule

i. Proposed Dates:

1. June 24th at 1:00 p.m.
2. July 22nd at 2:00 p.m.
3. August 18th at 1:00 p.m.

a. The Assistant Director of Lab Safety will send meeting invitations to all committee members.

b. The National Institutes of Health, Office of Science Policy has indicated "for IBC meetings taking place on or after June 1, 2025, institutions must post the approved minutes of their IBC meetings to an institution's public-facing website. Minutes from meetings taking place before June 1, 2025, must still be made available to the public upon request as described in the NIH Guidelines."

i. The Office of Research and Innovation will be updating the IBC website to include a page designated for IBC meeting minutes.

c. The National Institutes of Health, Office of Science Policy has communicated the following information: "On May 5, 2025, President Trump issued an Executive Order on Improving the Safety and Security of Biological Research, which pauses dangerous research that could or wil make a naturally occurring pathogen or toxin more dangerous to American citizens, and directs the Director of the Office of Science and Technology Policy (OSTP) and the National Security Advisor to work with funding agencies to develop such a policy within 120 days. This new Policy is intended to replace the 2024 *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential* (DURC/PEPP Policy) and supersedes its implementation at NIH previously set to take effect today." The NIH also indicated that they will provide additional guidance.

i. The Office of Research and Innovation will update the processes currently used to review IBC applications for Dual Use Research of Concern as additional information is provided to us. In addition, any changes to the IBC application will be communicated to the IBC members.

VII. Old Business

a. The Office of Research and Innovation has received the customized samples of the signage for BSL-1 and BSL-2 lab spaces. Please see the IBC Meeting Packet to view the signage.

b. In the Cayuse Protocol Application Overview page, it states "Provide an overview of the research goals. Briefly describe how each biohazardous material will be utilized to meet the goals described." Please indicate any additional edits to this question.

i. The IBC members indicated that the Principal Investigator must indicate in the description what materials will be utilized and how each of the materials will be used.

VIII. IBC Training and Continuing Education

a. American Biological Safety Association. Introduction to Biosafety: Biosafety Curriculum for Undergraduate and Graduate Students.

IX. Meeting Adjournment

a. 2:52 p.m.