

Institutional Biosafety Committee (IBC)

Date: March 25, 2026

Time: 8:00AM- 8:35 AM

Location: Virtual (Microsoft Teams)

Attendees:

Matt Finley, Ph.D.: IBC Chair

Dr. Bindu Kumar, MD: IBC Member

Judy Daviau, VMD: Veterinary Consultant

Lauren Merlo, Ph.D.: IBC Member

Gwendolyn Gillard: IBC Member (Community Member)

John III Medendorp, MS, BSN, RN, CIP: IBC Member

Kamilia Bedelbaeva: IBC Member

Guests:

Amy Rosenfeld, Ph.D.: Principal Investigator

1. Approval of Previous Meeting Minutes

Matt requested confirmation of prior meeting minutes.

- Talulla Palumbo forgot to attached to the meeting materials.

Outcome:

- Approval of prior minutes is deferred to the next meeting.

2. New Business

2.1 B22-2919: Three-Year Rewrite – Dr. Anthony Ashton Protocol

Matt introduced the protocol as a three-year continuation/renewal of an existing study involving:

- Recombinant DNA
- Engineered, non-pathogenic microorganisms
- Human blood, tissue, and cell lines

Matt noted:

- Organisms described are commonly used and considered low risk.
- Protocol content is highly detailed and comprehensive, likely incorporating language from grant applications.
- Level of detail was commended as aligning with expectations for clarity and experimental transparency.

Committee Review and Discussion

A. Disinfection Procedures (Bleach Concentration)

- Lauren Merlo identified inconsistent bleach concentrations:
 - 1%
 - 8%
- These values conflict with standard 10% bleach practices.
- Concern:
 - Potential ineffectiveness of disinfection protocols.
- Required Action:
 - Clarify and standardize bleach concentration across protocol (Section 6.1 and elsewhere).

B. Animal Facility Procedures – Contaminated Bedding

- Question raised regarding:
 - Decontamination method for contaminated bedding
 - Disposal pathway
- Discussion:
 - Clarification sought on whether disposable caging systems are used.
 - It was suggested that procedures may be managed by laboratory staff rather than centralized animal facility (Annex).
 - Concern:

- Lack of explicit procedural details.
- Required Action:
 - Clearly define:
 - Decontamination process
 - Disposal method
 - Responsible personnel

C. *Drosophila* Reference

- A reference to *Drosophila expression* was identified in a table.
- Discussion:
 - Uncertainty whether:
 - This refers to a model organism used on-site
 - A plasmid/vector system
 - Matt suggested it likely represents a vector/plasmid designation.
- Required Action:
 - Clarify reference and correct if misapplied.

D. Personal Protective Equipment (PPE)

- Dr. Bindu Kumar noted absence of surgical masks in PPE selection.
- Concern:
 - Risk of mucous membrane exposure (oral) during procedures involving potential splashes.
- Discussion Points:
 - Eye protection alone is considered insufficient.
 - Mouth exposure represents a significant biosafety risk pathway.
- Recommendation:
 - Include surgical masks as standard PPE.
- Committee Consensus:
 - Agreement that omission is likely oversight, not intentional.

E. Personnel Status & Training

- Clarification requested regarding personnel:
 - Current lab personnel consist of:
 - Principal Investigator
 - Drexel University co-op students

Discussion:

- Confirmation that:
 - Students are covered under institutional affiliation agreements
 - They meet health and safety requirements

F. Human Materials – Source and Screening

- Significant discussion focused on human-derived materials:
 - Issues Identified:
 - Protocol indicates:
 - Use of commercially sourced cell lines (e.g., ATCC)
 - Possible use of primary human samples (blood/biopsy via IRB protocols)
 - Concerns:
 - Screening status for:
 - HIV
 - Hepatitis B
 - Hepatitis C
 - Risk management in case of occupational exposure
 - Clarifications Provided:
 - Commercial cell lines (ATCC) are typically screened.

- Paraffin-embedded tissues are fixed and lower risk. Primary samples (if used) may not be pre-screened.

G. Exposure Response Preparedness

- Dr. Kumar emphasized need for:
 - Clear documentation for exposure incidents
 - Immediate access to:
 - Sample source information
 - Risk profile
- Recommendation:
 - Develop a one-page exposure guidance document (“job aid”) including:
- Protocol summary
 - Exposure risks
 - Instructions for medical providers
- Action:
 - Talulla to develop documents with support from Dr. Kumar.

H. ATCC Screening Limitations

- Judy Daviau raised concern that:
 - ATCC screening may be less comprehensive than assumed
- Additional Risk:
 - Cell line contamination via:
 - Culture media
 - Serum components
- Example provided:
 - Contaminated serum leading to introduction of pathogens (e.g., ectromelia)
- Required Action:
 - Investigator to provide:
 - ATCC screening documentation
 - Any additional verification of cell line safety

I. Motion and Vote

- Motion:
 - To require resolution of all identified issues prior to approval and proceed via Designated Member Review (DMR) upon completion.
 - Moved by: Dr. Matt Finley
 - Seconded by: Lauren Merlo

3. Administrative Review

- Administrative actions since last meeting were acknowledged as listed in the agenda.
- No further discussion.

4. Old Business

4.1 Dr. Amy Rosenfeld Protocols (B26-3071 & B26-3083)

A. Status Update

- Protocols remain:
 - Unapproved
 - Incomplete
 - Stalled at initial review stage
- No revisions submitted since prior committee feedback.
- Dr. Amy Rosenfeld joined the meeting.

B. Matt Inquiry

- Matt requested confirmation that:

- No viral work has been initiated.
- Response:
 - Investigator confirmed:
 - No viral work conducted
 - Activities limited to:
 - Antibody purification
 - ELISA assays

C. Committee Discussion with Investigator

- Protocol Deficiencies
- Matt noted that committee cannot proceed without:
 - Revisions
 - Clarifications

D. Investigator Response

- Investigator indicated:
 - No questions regarding feedback
 - Delays attributed to computer access issues

E. Biosafety Signage

- Investigator stated signage has been posted at lab entry.

F. Virus Nomenclature Concerns

- Judy raised concerns regarding:
 - Use of alphanumeric virus identifiers
 - Lack of clear classification (e.g., family/genus)
- Discussion:
- Amy stated:
 - Work focuses on enteroviruses and related viruses
- Committee requested:
 - Simplified labeling (e.g., EV68)
 - Clear identification of virus family
- Investigator Response:
 - Agreed to update nomenclature for clarity.

G. Post-Discussion Committee Deliberation

- The committee discussed:
 - Inadequate Detail
 - Multiple sections incomplete or unclear
 - Prevents meaningful risk assessment
 - Regulatory Risk
 - Concern that protocols:
 - Would not withstand external audit
 - Could not be defended by committee
 - Communication Concerns
 - Members expressed discomfort with:
 - Tone of responses
 - Lack of engagement with feedback
 - Workflow Concern
 - Question raised regarding:
 - Repeated review cycles without progress
 - Committee Decision
 - Protocols will not be re-reviewed until:
 - All requested revisions are completed

- Adequate detail is provided
- Institutional Escalation
 - Institutional Official (George) to:
 - Address delays directly with investigator
 - Ensure compliance and progress
- Additional Actions
 - Ad Hoc Expert Review
 - Proposal to involve virology experts:
 - Dr. Matt Charman
 - Plan:
 - Review protocols after revisions
 - Attend future meetings if needed
- Contextual Factors
 - Amy:
 - Joined December 2025
 - No approved biosafety protocols to date
 - Staffing:
 - No current lab staff
 - Planned hires in May/June
- Possible adjustment challenges noted

5. Additional New Business

A) Annual Safety Training

- Annual LIMR-wide training scheduled.
- Discussion:
 - Dr. Bindu Kumar confirmed participation:
 - 5–10 minute presentation on health and safety
- Next Steps:
 - Coordination to occur offline regarding:
 - Content
 - Timing
 - Scope

6. Adjournment

The meeting was adjourned at approximately 8:35 PM by Matt