Institutional Biosafety Committee Minutes

Meeting Information

Location	Virtual via MS Teams
Date and Time	November 12, 2026, 12:00 PM
End Time	November 12, 2026, 1:30 PM
Chair	Edward Mougey, PhD
Recorder	Jasmine Jackson, Administrative Coordinator

Attendance

Name	**Status**
Mona Batish	External Member
Karl Mann	Process Coordinator
Peter Phelan	Orlando Representative
Carrie Paquette-Straub	Wilmington Representative
Meenu Madan	Orlando Representative
Michael Primiani	Administrative Liaison
Amanda Hernan, PhD	Wilmington Representative
Mike Wendeler	Guest
Amanda Foxx	Guest

Minutes from Previous Meeting

Approval of October IBC Meeting Minute without changes

Expedited Protocols

None

Protocol Review

PI	Shaukut Khan
Study ID	2779
Title	Small activating RNA therapy for Hurler syndrome
Modification	Possible Renewal
Primary Reviewer	Carrie Paquette-Straub
Secondary Reviewer	Michael Primiani

Agents	AAV and RNA
Applicable NIH Guidelines	Section III-D-4
Motion	Tabled – Pending additional documents
Vote (Yes/No/Abstain)	Unanimous
Recuse/Absent	N/a

PI	Dr. Amy O'Connell
Study ID	2715
Title	Immune and intestinal investigations in neonates
Modification	New Investigato
Primary Reviewer	Amanda Hernan
Secondary Reviewer	Edward Mougey
Agents	Human cells
Applicable NIH Guidelines	Section III-F-1, III-F-8, Appendix C-VI and C-VII
Motion	Approved with Stipulations
Vote (Yes/No/Abstain)	Unanimous
Recuse/Absent	N/a

PI	Dr. Scott Weiss
Study ID	2810
Title	Mitochondrial Dysfunction in Pediatric Sepsis (MitoPSe): 2.0
Modification	Renewal
Primary Reviewer	Carrie Paquette-Straub
Secondary Reviewer	Mona Batish
Agents	Human Samples
Applicable NIH Guidelines	Section III-F
Motion	Tabled – Pending additional documents
Vote (Yes/No/Abstain)	Unanimous
Recuse/Absent	N/a

PI	Dr. Jennifer Nelson
Study ID	UCF- SPROTO202500000029
Title	Comparison of DNA methylation patterns in infants with heart disease
Modification	UCF Review
Primary Reviewer	Edward Mougey
Secondary Reviewer	
Agents	Human Samples

Applicable NIH Guidelines	Section III-F
Motion	Reliance on UCF Determination – Request additional documents for confirmation
Vote (Yes/No/Abstain)	Unanimous
Recuse/Absent	Peter Phelen recused

Discussion Items

Waived Procedures – See attached Excel spreadsheet.

- Total protocols waived: 34
- No concerns were raised regarding the waived protocols.

Facilities Issues/Updates

None

Old Business

Reliance Agreements and Regulatory Oversight

- The committee discussed the challenges associated with requiring review by multiple institutional biosafety committees.
- Members agreed that duplicative review creates a significant administrative burden for investigators and committees and is not a sustainable long-term solution.
- Until formal reliance agreements are finalized, the institution remains responsible for ensuring regulatory requirements are addressed.
- A temporary approach was approved whereby supplementary information will be provided to address outstanding concerns while relying on the external committee's review and approval process.

Administrative Burden and Exempt Research Activities

- Discussion focused on whether all research activities should undergo full biosafety committee review.
- Concerns were raised regarding studies involving:
    - Retrospective chart reviews
    - Computational/in silico research
    - Projects with no biological materials or laboratory activities
- Members acknowledged the value of institutional oversight while recognizing that current requirements may create unnecessary burden for low-risk activities.
- The committee agreed that broader leadership input is needed before modifying review requirements or exemption criteria.

Screening and Audit Processes for Exempt Projects

- Several approaches were discussed for determining whether projects require biosafety review, including:
    - Initial screening questionnaires
    - Automated review pathways
    - Preliminary review by environmental health and safety personnel
- Members emphasized the need for an auditable process documenting that projects were evaluated, even if exempted from full committee review.
- It was agreed that self-determination by investigators without documentation could create compliance and oversight concerns.

New Business

Role of Environmental Health & Safety (EH&S)

- Significant discussion focused on clarifying responsibilities between the biosafety committee and EH&S.
- Members noted that biosafety committees are currently reviewing many issues that traditionally fall under chemical safety or general laboratory safety programs.
- Consensus emerged that enhanced EH&S involvement could:
    - Improve efficiency.
    - Ensure subject matter experts review chemical safety concerns.
    - Reduce unnecessary burden on biosafety committees.
    - Allow biosafety committees to focus more directly on biological and biosafety risks.
- Implementation would likely require additional resources, infrastructure, and institutional support.

SOP Library and Standardization Efforts

- Progress was reported on establishing a centralized library of approved standard operating procedures (SOPs).
- Goals include:
    - Improving accessibility for investigators.
    - Reducing duplicate document creation.
    - Providing reference materials during protocol development.
    - Linking approved procedures directly within submission systems.
- Members agreed that SOP resources should be maintained, regularly updated, and subject to appropriate version control.

SOP Management and Version Control

- Members highlighted concerns regarding:
    - Duplicate SOPs covering similar activities.
    - Conflicting instructions across documents.
    - Outdated procedures remaining in circulation.
- There was broad agreement that a centralized system with strong version control and document management practices is necessary to maintain consistency and compliance.

Future Process Improvements

- Several opportunities for long-term improvement were discussed, including:
    - Greater integration of institutional SOPs into protocol submission systems.
    - Use of standardized hazard assessments.
    - Expanded reliance agreements with partner institutions.
    - Increased automation of screening and routing processes.
    - Streamlining of protocol submissions to reduce administrative burden without compromising regulatory compliance.

Additional Administrative Updates

Updates were provided on upcoming laboratory inspections, external oversight discussions, development of collaborative oversight agreements, and ongoing efforts to improve institutional research support processes.

Committee Membership and Engagement

The committee discussed recruitment of additional members with relevant research expertise and emphasized the importance of maintaining investigator representation while being mindful of service expectations for newer faculty members.

Open Discussion/Other

- No additional business was brought forward by committee members.
- The next IBC meeting is scheduled for December.
- Meeting adjourned.

Future Meeting Dates: November 12, December 10, 2026 (12:00 PM–1:30 PM).

2027 Meeting Dates: January 14, 2027; February 11, 2027; March 11, 2027; April 8, 2027; May 13, 2027; June 10, 2027; July 8, 2027; August 12, 2027; September 9, 2027; October 14, 2027; November 11, 2027; December 9, 2027 (12:00-1:30PM)