Institutional Biosafety Committee Minutes

Meeting Information

Location	Virtual via MS Teams
Date and Time	October 8, 2026, 12:00 PM
End Time	October 8, 2026, 1:30 PM
Acting Chair	Amanda Hernan, PhD
Recorder	Jasmine Jackson, Administrative Coordinator

Attendance

Name	**Status**
Eric Egelund, Pharm D., Ph (Absent)	External Member
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
Ben Favret	External Member
Michael Haas	External Member
Mike Wendeler	Guest
Dawn Pittinger	Guest
Lauren Skelly and Associates	ChristianaCare Gene Editing Cohort

Minutes from Previous Meeting

Approval of September IBC Meeting Minute without changes

Expedited Protocols

None

Protocol Review

PI	Dr. Lauren Skelly
Study ID	2759

Title	CRISPR Gene Editing in Cancer: Using Single Cell Transcriptomics to Reveal Expression Patterns in Genetically Complex Populations
Modification	ChristianaCare Application
Primary Reviewer	Amanda Hernan
Secondary Reviewer	Edward Mougey
Agents	Lipid nanoparticles (LNP)
Applicable NIH Guidelines	Section III-C
Motion	Tabled – Pending laboratory inspection and additional documents
Vote (Yes/No/Abstain)	Unanimous
Recuse/Absent	N/a

PI	Dr. Edward Mougey
Study ID	2787
Title	Patient-specific organoids: a new tool for studying therapeutic mechanisms, precision dosing, and efficacy in the treatment of pediatric gastrointestinal disease
Modification	Renewal
Primary Reviewer	Amanda Hernan
Secondary Reviewer	Michael Primiani
Agents	Human EPC2-hTERT
Applicable NIH Guidelines	Section III-F
Motion	Approved with Stipulations
Vote (Yes/No/Abstain)	Unanimous
Recuse/Absent	Dr. Mougey excused

PI	Dr. Edward Mougey
Study ID	2788
Title	Accelerating Individualized Medicine in Pediatric Gastrointestinal Disorders (AIM-GI for Kids): a Prospective Observational Study
Modification	Renewal
Primary Reviewer	Amanda Hernan
Secondary Reviewer	Michael Primiani
Agents	Human Samples
Applicable NIH Guidelines	Section III-C Section III-D

Motion	Approved with Stipulations
Vote (Yes/No/Abstain)	Unanimous
Recuse/Absent	Dr. Mougey excused

Discussion Items

Waived Procedures – See attached Excel spreadsheet.

- Total protocols waived: 21
- Most were retrospective or observational studies not requiring additional IBC oversight.
- No concerns were raised regarding the waived protocols.

Facilities Issues/Updates

- An inspection was completed for Dr. Ifland's new laboratory space in E400.
- Minor corrective actions were identified and documented.
- No significant deficiencies were reported during the inspection.
- An inspection memorandum is under review prior to issuance.

Old Business

1. Administrative Effort Offset
    - Ongoing discussions continue regarding administrative support or effort offset for IBC committee service.
    - Committee members noted the substantial time commitment required for protocol review activities.
    - Information was prepared for leadership outlining the potential impact of inadequate committee support on institutional review capacity and compliance.

New Business

1. IBC Protocol Review Process
    - Committee members discussed recent changes to protocol distribution, with all protocol packages now being provided to all IBC members rather than only designated reviewers.
    - This change was made to align with proposed updates to the IBC Charter and Policy, which indicate that all IBC members should have access to and review protocol materials under consideration.
    - Primary and secondary reviewers will continue to be assigned, but all members will have access to protocol submissions.
2. New Member Training and Onboarding
    - Newer committee members reported that receiving the full protocol packages was helpful for learning the review process.

- Discussion occurred regarding developing a more structured onboarding and training process for new IBC members.
- Members noted that protocol review expectations, particularly review of supporting SOPs, may not always be intuitive for new reviewers.

3. SOP Burden and Review Efficiency
    - Committee members discussed the significant time burden associated with reviewing large numbers of SOPs during protocol review.
    - Concerns were raised regarding the need to review numerous site-specific SOPs for each protocol submission.
    - Members suggested developing broader institution-approved SOPs that could serve as umbrella documents, with investigators only submitting deviations or site-specific procedures.
    - Existing approved institutional SOPs and the Chemical Hygiene Plan may provide opportunities to reduce duplication and streamline protocol reviews.
4. Principal Investigator (PI) Burden Reduction
    - Updates were provided regarding a recent institutional working session focused on reducing PI administrative burden.
    - Recommendations discussed included:
        - Streamlining regulatory review processes.
        - Improving visibility of protocol approval status across oversight committees.
        - Reducing unnecessary protocol submissions that do not involve biohazards.
        - Creating centralized systems for chemical inventories and compliance tracking.
5. Regulatory Coordination and Compliance Tracking
    - Members discussed challenges associated with limited visibility between regulatory committees (IBC, IACUC, IRB, etc.).
    - Concerns were raised regarding compliance risks when approvals from one committee are not readily visible to another.
    - Discussion emphasized the need for integrated regulatory tracking and approval workflows.
6. Huron Research Administration System
    - Discussion centered on expanding use of the Huron platform and its compliance management capabilities.
    - Members noted that Huron can:
        - Integrate approvals across multiple compliance committees.
        - Generate automated notifications and reminders.
        - Provide protocol status tracking and audit trails.

        - Improve transparency for investigators and administrators.
    - Research Administration representatives reported ongoing efforts to implement additional Huron compliance functionality and ancillary review workflows.
7. Protocol Expiration and Notification Tracking
    - Members discussed the limitations of the current REDCap-based system for tracking protocol status and expiration dates.
    - Concerns were expressed that manual reminder processes should not rely on a single administrator.
    - Automated investigator notifications and protocol tracking functionality were identified as institutional priorities.
8. IBC Policy and Charter Revisions
    - Updated drafts of the IBC Policy and Charter were distributed to committee members for review and comment.
    - Discussion focused on language requiring all research studies to be submitted to the IBC.
    - Members noted ongoing institutional discussions regarding whether projects without biohazardous materials should continue to require IBC review.
    - Further discussion was deferred pending additional input from Research Administration and related stakeholders.
9. Biosafety Waiver and Exemption Process
    - Members discussed the possibility of establishing a formal biosafety screening process similar to IRB exemption reviews.
    - Discussion included:
        - Initial biosafety review by qualified personnel.
        - Issuance of waivers or exemptions for studies that do not present biosafety concerns.
        - Improved documentation for audit and compliance purposes.

Open Discussion/Other

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

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