IBC Meeting Minutes
10/9/2025 12:10 PM

CMRI Conference Room 31 & Teams

MEETING TIME RECORDS

Meeting start time: 12:03
Meeting end time: 13:17

VOTING MEMBER ATTENDANCE

Name of IBC Member	Committee Role	Late Arrival Time	Early Departure Time
Daniel Heruth	Chair, Animal Expert, Lab Rep		
Todd Bradley	Co-Chair, Lab Rep		
Paul Ramlow	BSO, Animal Expert, Lab Rep		
Vivekanand Yadav	Alternate Lab Rep (Srivastava)	Arrived at 12:14	Recused at 12:35
James Slaughter	Local Non-Affiliated		
Judy Dilts	Local Non-Affiliated		
Tamie Crutchfield	Occupational Health		
VOTING MEMBERS ABSENT			
Tarak Srivastava	Lab Rep		
ALTERNATES PRESENT BUT NON-VOTING			
None			
NON-VOTING MEMBERS PRESENT			
Foster St. Claire	AV & Ex-Officio		
ADMINISTRATIVE STAFF			
Saskia Miller	Director of the ORI		
Daniel Crabtree	Sr. IBC Manager		
Kelleigh Pearson	Administrative Project Coordinator		

QUORUM INFORMATION

Number of SAFETY members on the roster: 7
Number required for quorum: 4

GUEST NAMES

Lara Castillo, Nuria, PhD
Orrick, Johanna, I
Thompson-Wright, Susanne, E
Wickham, Azadeh, P

Conflict of Interest (COI): Chair reminded the Committee to declare any COI.

Previous Meeting minutes:
A Member moved to approve, seconded, and motion passed. 7 yes.

Biosafety Committee Updates:

1. **BSO Updates**
   The BSO is reformatting how lab surveys are conducted. Going forward, surveys will be completed annually, alongside de novo submissions and annual reviews, with results reported to the IBC.

2. **ORI Updates**
   mySafety upgrades begin October 24. Researchers will be notified of changes.
   New questions added to the Recombinant/Synthetic Nucleic Acid Work Description page:
   - Storage location
   - Usage locations

   NIH Guideline updates (April 2024):
   - Focus on Gene Drive Modified Organisms (GDMOs)
   - New Section III-D-8 for GDMO experiments
   - Cross-references added in other sections

   New Gene Drives/GDMO selection in Biosafety Summary and SmartForm
   DURC section updated to align with U.S. Government DURC and PEPP oversight policies

3. **Chair Updates**
   None

REVIEW OF SUBMISSIONS

De Novo Review

4. **Review of IBC00108**

Title:	Identify the new therapeutic targets in pediatric high-grade glioma
Investigator:	Vivekanand Yadav
Submission ID	IBC00108
Attempt to Express Foreign Genes:	We will clone cancer related genes into the piggyBac transposon vector system. We then generate a de nova brain tumor by injecting cancer related genes cloned into a plasmid vector into a mouse embryo lateral ventricle.
Protein Produced:	Cancer related protiens
Agents:	• Human cell lines • Escherichia coli (DH5 alpha, One Shot Top10, and Mach1)

	• Mouse Tissue • Peripheral Blood Mononuclear Cells (PBMC) • Commercial human cell lines
Agent Characteristics:	Biological Agent Sources: • Animal vivarium • Thermo Fisher Cat # 18265017 • University of Michigan • Sigma cat # SCC127 • Zen-Bio, Cat# SER-PBMC-F • this is routinely produce in the lab using TransIT lentivirus system kit • University of Michigan vectro core Recombinant Nucleic Acid Work: A lentivirus vector with different shRNAs, sgRNAs, or over-expression of cancer related genes will be generated by transfecting into 293T cells. Media collected from 293 cells with lentivirus particles will be used to knock down or overexpress vectors to counteract potential driving mutations. The CAR vector, which is often a lentivirus or retrovirus, is used to engineer donor T cells to express the CAR genetically. The vector carries the DNA that codes for the entire CAR protein, including the single-chain variable fragment (scFv). We use lentiviral or retroviral vectors to express scFv fragments on T cells. These scFv domains form the key component of the CAR construct, enabling the engineered T cells to specifically recognize and bind to target antigens on the surface of cancer cells. Vectors: For In vivo experiment: PiggyBac Transposon vectors expressing cancer related genes Lenti and Retrovirus vectors for different CAR expression Of cancer related genes For the in vitro experiment, Lentivirus vectors with shRNA against cancer related genes will be purchased from different vendors (Sigma, Add Gene, Vector Builders, etc.)
Agent Containment:	Biological Containment Levels: • Mouse Tissue: BSL-1 • Escherichia coli (DH5 alpha, One Shot Top10, and Mach1): BSL-2 • Human Cell Lines with genetic variants: BSL-2 • U of Michigan - Human Cell Lines: BSL-2

	• Peripheral Blood Mononuclear Cells (PBMC): BSL-2 • Lentivirus (specify generation): BSL-2 • Murine leukemia virus (Retrovirus): BSL-2
Applicable NIH Guidelines:	• Section III-D-4 • Section III-D-1 • Section III-D

Determination: Modifications Required to Secure Approval

Last day of continuing review period: N/A

Comments:
The Chair invited the Principal Investigator (PI) to provide an overview of the de novo protocol. Following discussion, the PI recused himself at 12:35.

The Biosafety Officer (BSO) presented a review of the protocol, highlighting associated risks.

The Ex-Officio member, serving as the Attending Veterinarian (AV), provided input on the animal-related components of the protocol.

A Member requested that occupational health information be moved from the waste management section to the exposure assessment section.

A Member asked for more lay-friendly descriptions of the knockdown genes.

A Member inquired about the pilot experiment listed in the protocol. The Sr. Manager explained the IACUC process for pilot studies, and the IBC Chair clarified the scientific rationale for the pilot. The Member was satisfied with the explanation. The AV noted that the pilot study may have concluded. The Committee requested the PI remove references to the pilot study from the IBC protocol if it is no longer active.

A Member questioned the biosafety level assigned to mouse tissue. The Chair confirmed it should be listed as BSL-2, instead of BSL-1.

A Member requested the PI replace vague references to University of Michigan **human** cell lines with specific details or remove and submit an amendment when available.

A Member requested the PI to replace any “NO” responses with “N/A” where appropriate.

A Member requested a clearer description of PiggyBac transposons and potential safety implications be added to the exposure assessment section, question 1.

The genes listed throughout the protocol are inconsistent. The protocol will need to be revised to ensure consistency in gene targets.

The use of shRNA, overexpression methods, and lentivirus was inconsistent. Clarification is needed in Recombinant/Synthetic Nucleic Acid section, Question 1 and elsewhere.

CRISPR-related work (e.g., sgRNAs) was mentioned but not adequately described in the Recombinant/Synthetic Nucleic Acid section, Question 1

Vendor information in the Recombinant/Synthetic Nucleic Acid section was found to be inconsistent. The PI should review and revise responses to ensure clarity and consistency.

The exposure assessment section should be revised to align with standard procedures. It currently includes a reference to PCP health consultations, which are not required. Please consult with the BSO.

Grammar issues were noted throughout the protocol and should be corrected.

A Member moved to require modifications for approval via Member Review. The motion was seconded and passed.

The Sr. IBC Manager stated, at the pre-review stage, the ORI staff will remind PIs to thoroughly reevaluate protocols during de novo review to remove outdated experiments and add current work as needed.

Supporting documents:
None

Votes:
For: 6
Against: 0
Recused: 1
Absent: 0
Abstained: 0

REVIEW OF OTHER AGENDA ITEMS

5. Review of Minors in Research Labs:

Description:	Initial documentation/publication. The Children's Mercy Research Institute is committed to providing educational opportunities, when they arise, to high school students participating in officially sanctioned educational programs. Principal Investigators are allowed to have high-school students perform work in a laboratory with appropriate training and monitoring. This policy establishes clear guidelines for the participation of minors (individuals under the age of 18) in research laboratory environments at the CMRI, ensuring their safety and compliance with institutional, legal, and regulatory standards.
Notes:	The Chair provided an overview of the new policy, then turned the discussion over to the Biosafety Officer (BSO), who outlined the conditions for allowing minors into CMRI laboratories. After further discussion, the Committee expressed support for the policy and its structure, particularly regarding restrictions on the types of work minors may perform. The Occupational Health Director raised a question about PPE compliance on page 3, specifically regarding fit testing. The BSO clarified that PPE requirements will depend on the minors' activities. Since minors will not work in the animal facility, respiratory PPE will not be required. Work involving higher biosafety levels will not be permitted for minors. A Member suggested including language on how risks are communicated to minors and what responsibilities the Hospital assumes or does not assume. Another Member asked about data considerations from a human subjects perspective. The BSO responded that the current policy focuses on wet lab activities and that Human Subects Research (HSR) would be addressed under a separate policy. The ORI Director mentioned the STAR 2.0 program, which involves high school students and the IRB. She noted that onboarding students as external researchers could be an option if they participate in HSR. The Chair noted this is the first review and the policy will be

	routed through other leadership departments before returning to the IBC for final approval. Committee members were asked to submit revisions and comments on the draft policy.

ACKNOWLEDGMENTS SECTION

The following items were approved outside of a convened IBC meeting. The Committee reviewed and acknowledged the following items during this meeting.

ID	Name	State	Specialist	Agenda Type
CR202500009	Continuing Review for IBC00073	Approved	Daniel Crabtree	Admin Approval
CR202500010	Continuing Review for IBC00098	Approved	Elizabeth Short	Admin Approval
CR202500012	Continuing Review for IBC00092	Approved	Daniel Crabtree	Admin Approval
CR202500014	Continuing Review for IBC00088	Approved	Daniel Crabtree	Admin Approval
SAMEND202500000003	Amendment for IBC00057	Approved	Daniel Crabtree	Admin Approval
SAMEND202500040	Amendment for IBC00077	Approved	Daniel Crabtree	Admin Approval
SAMEND202500041	Amendment for IBC00086	Approved	Daniel Crabtree	Admin Approval
SAMEND202500042	Amendment for IBC00100	Approved	Elizabeth Short	Admin Approval
SAMEND202500043	Adding Anil	Approved	Daniel Crabtree	Admin Approval
SAMEND202500044	Addition of personnel	Approved	Daniel Crabtree	Admin Approval
SAMEND202500045	Amendment for IBC00077	Approved	Daniel Crabtree	Admin Approval
SAMEND202500046	Amendment for IBC00094	Approved	Daniel Crabtree	Admin Approval

ID	Name	State	Specialist	Agenda Type
SAMEND202500047	Amendment for IBC00086	Approved	Elizabeth Short	Admin Approval
SAMEND202500048	Amendment for IBC00082	Approved	Daniel Crabtree	Admin Approval
SAMENDCR202500006	Lab Technician I addition	Approved	Daniel Crabtree	Admin Approval
SAMENDCR202500007	9-25 Amendment/CR for IBC00099	Approved	Elizabeth Short	Admin Approval
SAMENDCR202500010	Amendment/CR for IBC00101	Approved	Daniel Crabtree	Admin Approval