Houston Methodist Research Institute IBC Meeting Minutes

4/2/2026

Meeting Time Records

Meeting start time: 10:50 am

Meeting end time: 11:50 am

VOTING MEMBER ATTENDANCE				
Name of Member	**Status (member or alternate)**	**IBC role**	**If Voting Alternate, Member Substitution**	**Present in Person or Virtually (TEAMS)?**
Biana Godin, PhD, M.Sc. Pharm	Chair	Scientific, affiliated		Yes, in Person
Vicente Zuno, BS, RBP	Member	Biosafety Officer, affiliated		No
Joan E. Nichols, PhD	Member	Scientific, affiliated		No
Chas Gray, RPh	Member	Scientific, affiliated		Yes, Virtually
Tanya Herzog, DVM	Member	Animal Expert, affiliated		Yes, Virtually
Edward Graviss, PhD	Member	Scientific, affiliated		Yes, Virtually
Wenhao Chen, PhD	Member	Scientific, Affiliated		Yes, Virtually
Daniel Kiss, PhD	Member	Scientific, affiliated		Yes, Virtually
Tamara Steele, BS	Member	Community member, Non-affiliated		Yes, Virtually
Jillian Chahal, MPH, CSP	Member	Community member, Non-affiliated		Yes, Virtually
Francesca Taraballi, PhD	Member	Scientific, Affiliated		No
Jiangyong Shao, MS	Member	Scientific, Affiliated		No
Nagendran Tharmalingam, PhD	Member	Laboratory representative, Affiliated		Yes, Virtually
Anjana Tiwari, PhD	Member	Laboratory representative, Affiliated		Yes, Virtually
Dimitrios Wagner, MD PhD	Member	Human gene transfer expert, Non-affiliated		No
Gretchen Gotlieb, MS	Member	Safety representative,		Yes, Virtually

		Affiliated		

NON-VOTING MEMBER ATTENDANCE		
Name of Member	**IBC Role**	**Present in Person or Virtually (TEAMS)?**
Brenda Hartman BA	Ex-officio, Director, Central Laboratory Operations	Yes, Virtually
Enid Burns	Ex-officio, Central Laboratory Operations Safety Representative	Yes, Virtually
Michael Smith	Ex-officio, Legal Counsel	Yes, Virtually
Michael Metcalf	Ex-officio, Environmental Safety	No
Tiffany Gunter	Ex-officio, Employee Health Representative	Yes, Virtually
Astrid Marcela Quiroga	Ex-officio, Employee Health Representative	No
Leon Brown, MS	Ex officio, Radiation safety officer	Yes, Virtually
Wanda Quezada, CIP	Ex officio, Director Regulatory Oversight	Yes, Virtually

QUORUM INFORMATION

Number of IBC members on the roster: 16

Number required for quorum: 9

All members present by TEAMs received all pertinent material before the meeting and were able to actively and equally participate in all discussions.

ATTENDANCE OFFICE OF RESEARCH PROTECTIONS STAFF
Malissa Mayer-Diaz, Safety Committees Manager
Perla J. Rodriguez, Sr. Analyst
Shane Wilson, Analyst
Rebecca Corrigan, IACUC Manager
Joylise Mitchell, IACUC Analyst
Joanna Espinosa, Analyst QI & Education

ATTENDANCE STATUS AND VOTING KEY	
ABSTAIN:	Present for the vote, but not voting “For” or “Against.”
ABSENT:	Absent for discussion and voting for reasons other than a conflicting interest.
RECUSED:	Absent from the meeting during discussion and voting because of a conflicting interest.
SUBSTITUTION:	When regular members and their alternate(s) are listed in the ATTENDANCE

	table above and an alternate member substitutes for the regulator member this identifies the name of the alternate to indicate which individual is serving as the voting member for this vote. May be deleted if there are no substitutions.

CALL TO ORDER

The Institutional Biosafety Committee convened a virtual meeting via Microsoft Teams on April 2, 2026. The meeting was called to order at 10:50 a.m., with 11 members participating, exceeding the quorum requirement of 9 members.

REPORTS

BSO Report:

- None

EDUCATION

None

CONFLICT OF INTEREST

Committee members were reminded by the IBC Chair to recuse themselves in the event of any conflicts of interest.

OLD BUSINESS

- A list of approved protocols was shown to committee members prior to and during the meeting.

NEW BUSINESS

- **Discussion Topic: NIH Guidance Document Draft**
    - After the committee reviewed the NIH guidance document draft discussed during the IBC meeting in March, the committee voted on approving the document. The motion was seconded and approved
    - **Motion**: **Approve the NIH Guidance Document**

      Votes
        - Yes: 11
        - No: 0
        - Abstained: 0

- A list of approved amendments via designated member review was distributed to the committee members one week prior to the meeting and shown during the meeting.
- A list of approved administrative amendments was distributed to the committee members one week prior to the meeting and shown during the meeting.
- A list of approved continuing reviews via designated member review was distributed to the committee members one week prior to the meeting and shown to the committee members

during the meeting.

MINUTES REVIEW

The meeting minutes from March 5, 2026, were reviewed. A motion to approve was made and seconded, and the minutes were subsequently approved.

Motion: Approved

- Yes votes: 11
- No votes: 0
- Abstained: 0

AGENDA ITEMS

IBC NEW APPLICATIONS

IBC00002664
Title: IBC for Studies requiring the use of fluorescently labelled cells for imaging
Principal Investigator: Francesca Taraballi

Study Overview: This IBC protocol supports both laboratory and animal studies that use fluorescently labeled cell lines to better understand disease progression and treatment response. The fluorescent labeling allows researchers to track cells over time using imaging methods, helping to evaluate how cells grow, spread, and respond to therapies.

All work involving nanoparticles is covered under HSC00002889. Cell culture activities are conducted using approved biosafety practices, including the use of appropriate containment equipment and personal protective measures to ensure safe handling.

The laboratory works only with previously approved, stably fluorescent cell lines. These cells are prepared in the laboratory and then transferred to the animal facility for use in established animal study protocols. The fluorescent markers enable noninvasive monitoring of disease models and treatment outcomes throughout the course of the study.

- **Training**: All staff members have completed training.
- **Applicable NIH Guidelines**: Section III-D-4
- **Containment Conditions to be implemented**: BSL2
- **Risk assessment and Discussion**: The protocol supports in vitro and in vivo studies using stably fluorescent cell lines for noninvasive imaging of disease progression and treatment response. Laboratory work is limited to standard cell culture practices conducted with appropriate biosafety controls. All nanoparticle-related activities are covered under an approved HSC protocol (HSC00002889). Cells are transferred to the animal facility for use in approved animal protocols. No new infectious agents or increased biosafety risks were identified. The committee determined the work presents low risk when conducted as described, with existing BSL2 controls deemed adequate.

- **Comments sent to the PI for clarification:** In the hazard identification description MDA-MB-231-tomato cell line listed as 'mouse', needs to be corrected to 'humans'.
- **The motion to approve the study by administrative review was seconded and passed.**

Motion: Approve by administrative review

- Yes Votes: 11
- No Votes: 0
- Abstained: 0
- Recused: 0
- Absent: 0

IBC00002627
Title: Phase 1/2 First-in-Human Study of NVC-001 (AAV9 Vector Expressing Dominant Negative SUN1) to Assess Safety, Tolerability & Preliminary Efficacy in LMNA-Related Dilated Cardiomyopathy
Principal Investigator: Barry Trachtenberg

Study Overview: This is a first-in-human, Phase 1/2 clinical study evaluating NVC-001, an investigational gene therapy for patients with LMNA-related dilated cardiomyopathy. NVC-001 uses a non-replicating viral vector to deliver a therapeutic gene intended to help protect heart cells and potentially improve cardiac function. The starting dose evaluated in SAD Cohort 1 will be 3.0 × 10^13 vg (vector genomes) per kilogram of body weight (vg/kg). The high-dose to be tested in Cohort 2 is 6.0 × 10^13 vg/kg of NVC-001.

The primary objectives of the study are to assess the safety, tolerability, and preliminary efficacy of the investigational product. The study will enroll approximately 18–24 patients across multiple international sites.

Participants will receive the study drug following a defined pre-treatment regimen and will be closely monitored throughout the study period. The investigational product will be shipped to the site pharmacy as needed and administered by controlled intravenous infusion under clinical supervision.

- **Training**: All staff members have completed training.
- **Applicable NIH Guidelines**: Section III-C-1
- **Containment Conditions to be implemented**: BSL1
- **Risk Assessment & Discussion**: The investigational agent, NVC-001, is a Phase 1 gene therapy product utilizing a replication-defective recombinant AAV9 vector classified as Risk Group 1 / BSL-1. The vector is non-pathogenic, incapable of replication, and does not present an environmental hazard when handled using standard biologic precautions. The doses described are well below the maximum tolerated dose administered to non-human primates. Nonclinical studies demonstrated no evidence of vector-related toxicity, infection, or pathological organ damage. Minor, transient liver enzyme elevations were observed in animal studies without associated adverse findings. Clinical experience with

AAV vectors indicates that infusion-related reactions, including immune-mediated responses, may occur; therefore, administration is performed under full medical supervision. Standard personal protective equipment is considered adequate. Due to the potential for temporary viral shedding, standard precautions are recommended when handling patient bodily fluids. The investigational product is stored under frozen conditions and managed using routine biologic handling controls. While the reproductive risk of NVC-001 in humans is unknown, available nonclinical data and published literature indicate that germline transmission is highly unlikely following a single administration. Overall, the committee determined that the agent presents low biosafety risk to personnel and the environment when handled and administered as described.

- **Comments sent to the PI for clarification**:
    - **Section Exposure Management** - Please update that engineering controls to a BSC Class II Type A2 (Vented). The Committee requests a transport SOP that specifically describes how this product will be transported from the pharmacy to patient care areas.
    - **Section Viral Studies -** The Committee requests that the study team include a statement confirming that the sponsor will conduct testing to ensure the viral vector remains consistently replication-incompetent.
- **The motion to approve the study by administrative review was seconded and passed.**

Motion: Approvable by Administrative Review

- Yes Votes: 11
- No Votes: 0
- Abstained: 0
- Recused: 0
- Absent: 0

IBC00002690
Title: Using viral vector to overexpress or knock-down Stearoyl-CoA desaturase (SCD) in ovarian cancer cells to study role of unsaturated fatty acids regulated by SCD in promoting metastatic progression in ovarian cancer
Principal Investigator: Daniela Matei

Study Overview: This is a new IBC protocol submitted by Dr. Matei, who recently joined Houston Methodist Hospital as an HMNCC Director. The work is supported by an NIH R01 grant, which is included with the submission. The study involves the use of previously generated, stably modified human ovarian cancer cell lines that were developed at the PI's prior institution. Specifically, OVCAR5 and OVCAR8 cell lines were lentivirally modified to allow either overexpression or knockdown of Stearoyl-CoA desaturase (SCD) and include a luciferase reporter. No active viral work will be conducted at Houston Methodist. The cells will be expanded in the laboratory and implanted into mice to establish human ovarian cancer xenograft models. A transport SOP is included with the submission. The protocol is well written, and all proposed activities are consistent with the approved grant aims.

- **Training**: All staff members have completed their required training.
- **Applicable NIH Guidelines**: Section III-D-4
- **Containment Conditions to be implemented**: BSL2
- **Risk Assessment & Discussion**: Use of previously established, stably transduced lentiviral OVCAR5 cell lines present reduced biosafety risk, as no replication-competent or active lentiviral particles are handled. Residual risk is limited to standard BSL-2 containment for genetically modified human cell lines, with minimal risk to personnel or the environment when managed under existing BSL2 controls.
- **Comments sent to the PI for clarification**: Once the laboratory has been assigned physical laboratory space, the transport SOP and locations must to be updated.
- **The motion to approve the study was seconded and passed.**

Motion: Approved

- Yes Votes: 11
- No Votes: 0
- Abstained: 0
- Recused: 0
- Absent: 0

IBC00002636
Title: Using iRNA and CRISPR to modify Notch signaling in human and mouse cells to study hematopoiesis, tumor biology, and cell-therapy mechanisms.
Principal Investigator: Lan Zhou

Study Overview: Dr. Zhou's laboratory submitted a three year resubmission for ongoing studies. The research team conducts research focused on hematopoiesis and cancer biology, with two primary research areas. One aim examines blood cell progenitors and regenerative mechanisms to better understand lymphopoietic aging and to support improvements in hematopoietic cell therapies. A second focus area investigates pancreatic cancer biology, including mechanisms of therapy resistance and tumor–immune interactions, with the goal of identifying strategies to enhance anti-tumor immune responses.

The work involves the use of human cell lines, including patient-derived and established pancreatic cancer cell lines, mouse bone marrow progenitor cells, and recombinant DNA introduced into cells using new-generation lentiviral vectors engineered to reduce pathogenicity and replication potential. Genes of interest include the following: Notch ligand (Dll1, Dll3, Dll4, JAG1, JAG2, CRABP2), Notch targets (Hes family genes and Hey family genes), Notch regulators (Fringe family genes including L-Fringe, R-Fringe, and M-Fringe), ER stress modulators (PERK, Xbp1, IREa), and genes of junctional adhesion (Occludin, Zonula occludens family genes, Junctional adhesion molecules, and Claudin family genes).

- **Training**: All staff members have completed their required training.
- **Applicable NIH Guidelines**: Section III-D-1, & 4
- **Containment Conditions to be implemented**: BSL2
- **Risk Assessment & Discussion**: CRISPR–lentiviral systems are engineered, high-efficiency viral vectors used to deliver CRISPR-Cas9 components, including guide RNAs and the Cas9 endonuclease, into both dividing and non-dividing mammalian cells. These vectors enable stable and long-term gene editing through genomic integration and are widely used in functional genomics research. Although integrating retroviral vectors have the theoretical potential for insertional mutagenesis, murine retroviruses are inactivated by human complement and are not known to cause human disease. In addition, current-generation lentiviral vectors are specifically designed to minimize the risk of recombination events that could result in replication-competent virus. These vectors are typically pseudotyped with heterologous envelope proteins to enhance safety and transduction efficiency and are not considered to pose a significant risk to human health or the environment when handled appropriately. The proposed laboratory and animal containment practices are consistent with institutional and NIH Guidelines for recombinant research, and personnel are experienced in the use of these systems. The laboratory has no prior history of biosafety concerns.
- **Comments sent to the PI for clarification**: None
- **The motion to approve the study was seconded and approved.**

Motion: Approved

- Yes Votes: 11
- No Votes: 0
- Abstained: 0
- Recused: 0
- Absent: 0

IBC00002650
Title: Phase 1/2 Multicenter, Open-Label Dose-Escalation and Expansion Trial Evaluating Safety, Tolerability, Pharmacodynamics, and Preliminary Efficacy of AFTX-201 in Adults with BAG3 Mutation-Associated Dilated Cardiomyopathy
Principal Investigator: Arvind Bhimaraj

Study Overview: AFTX-201 is an investigational Advanced Therapy Medicinal Product (ATMP) consisting of a replication-defective recombinant adeno-associated virus (AAV)–based gene therapy designed to deliver the human *BAG3* gene. The vector is classified as Risk Group 1 and presents low biosafety risk to personnel and the environment when handled under standard biologic controls.

The product is supplied at a target concentration of 2.5×10^{13} vector genomes/mL. Vials are thawed under controlled conditions in the hospital pharmacy. Preparation and dilution are performed by

trained pharmacy personnel within a BSC, using properly labeled containers and following established aseptic techniques. Following preparation, the product is administered without delay, with infusion initiated within the specified time limits.

AFTX-201 is administered as a single intravenous infusion by the Principal Investigator or designee in a controlled clinical setting. Standard precautions are used for product handling and administration.

- **Training**: All staff members have completed their required training.
- **Applicable NIH Guidelines**: Section III-C-1
- **Containment Conditions to be implemented**: BSL1
- **Risk Assessment & Discussion**: AFTX-201 presents low risk to clinical staff, the public, and the environment. The investigational product utilizes an engineered, replication-defective AAV9 vector that is non-pathogenic and incapable of independent replication. Standard aseptic handling procedures are sufficient to mitigate occupational exposure risk, and inadvertent skin or mucosal exposure is unlikely to result in meaningful transduction due to the intravenous route of administration. Transient vector shedding may occur following dosing and has been observed in nonclinical studies across multiple bodily fluids. Shedding is monitored using sensitive molecular detection methods, which identify viral genetic material and do not indicate the presence of infectious virus. Participants receive education on routine hygiene practices to minimize secondary exposure during the monitoring period. Based on the properties of the vector and the controls in place, the committee determined that the study poses minimal biosafety risk, and existing precautions are adequate.
- **Comments sent to PI for clarification**:
    - **Section Summary of Proposed Research**: Please attach the pharmacy manual that is mentioned in the brochure and send the pharmacy manual to the Houston Methodist IDS pharmacy personnel.
    - **Section Viral Studies**: The Committee requests that the study team include a statement confirming that the sponsor will conduct testing to ensure the viral vector remains consistently replication-incompetent.
    - **Section Exposure Management Pharmacy**: Please update engineering controls to a BSC Class II Type A2 (Vented)
    - **Section Exposure Management Hospital**: The attached SOP is significantly outdated. The Committee requests a transport SOP that specifically describes how this product will be transported from the pharmacy to patient care areas.
- **The motion to approve the study after administrative review was seconded and passed.**

Motion: Approvable by administrative review

- Yes Votes: 11
- No Votes: 0
- Abstained: 0

- Recused: 0
- Absent: 0

IBC00002689
Title: Research using recombinant plasmids, siRNA, and viral vectors to express or silence lipid metabolism genes in in vitro and in vivo models to study angiogenesis, lymphangiogenesis, and hematopoiesis
Principal Investigator: Longhou Fang

Study Overview: This study investigates the role of lipid metabolism in vascular biology, including angiogenesis, lymphangiogenesis, and hematopoiesis. Research activities are conducted using cell culture and animal models, including zebrafish and mice, to evaluate the function of genes involved in these processes.

The work involves manipulation of lipid-regulatory and signaling genes, including AIBP, SREBP1/2, SCAP, INSIG, YAP/TAZ, MMRN2, VEGFR, NRP, Src, and Akt, using recombinant DNA technologies. Viral vectors are used to support gene expression and gene silencing studies. Commercially obtained AAV vectors expressing genes such as AIBP, VEGFC, or GFP are administered to mice. Lentiviral vectors are used in cell culture models to support targeted genetic modifications.

Additional molecular biology methods, including recombinant protein-based gene editing and plasmid amplification in standard bacterial systems, are utilized to support construct development. All activities are conducted under appropriate, approved biosafety containment and institutional controls.

- **Training**: All staff members have completed their required training.
- **Applicable NIH Guidelines**: Section III-D-1,4
- **Containment Conditions to be implemented**: BSL2
- **Risk assessment and Discussion**: The committee reviewed the proposed work involving recombinant DNA technologies to manipulate lipid-regulatory and signaling genes in cell culture and established animal models, including zebrafish and mice. Identified risks are consistent with the use of viral vectors and standard molecular biology techniques. Commercially obtained AAV vectors administered in vivo and lentiviral vectors used in vitro are replication-incompetent and handled using approved biosafety practices. Additional recombinant DNA activities, including plasmid propagation in bacterial systems and protein-based gene editing methods, present minimal risk when conducted under institutional containment requirements. The committee determined that the proposed activities are appropriate for the assigned biosafety containment levels and existing controls adequately mitigate potential risks.
- **Comments sent to the PI for clarification**:
    - **Section Staff Identification:** As written, no individual is identified as handling the materials listed in the protocol. If the PI will be responsible for handling these materials, this should be included under the ‘responsibilities’ section.

- **Section Summary of Proposed Research:** Plasmids encode multiple biologically active genes therefore please discuss the potential phenotypic risks (e.g., oncogenic signaling, pro-angiogenic effects).
- **Section Animals:** Both ABSL-1 and ABSL-2 are currently selected. If animals will be housed at ABSL-1, please select "Other housing" under the housing section and enter "ABSL-1" in the "Other animal room" text box.
- **Section Risk Assessment:** ***Question*** 'Does your proposed project include the use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems?' Change the answer to 'Yes' as lentivirus is used in 293 cells using packaging plasmids.
- **Section Exposure Management Laboratory:** Please mention AAV instead of adenovirus in the description. The spill and transport procedures are currently identical for RG1 and RG2 agents. Because these agents fall under different risk groups, the RG1 procedures should be revised to reflect the appropriate containment and response requirements for RG1 materials.

- **The motion to approve the study after designated member review was seconded and passed.**

Motion: Approvable by designated member review

- Yes Votes: 11
- No Votes: 0
- Abstained: 0
- Recused: 0
- Absent: 0

IBC AMENDMENTS

IBCA00001518
Title: Hazard Amendment 5 for IBC for Role of very Long-Chain fatty acids in neuroinflammation
Principal Investigator: Hyunglok Chung

Amendment Overview: This amendment includes major modifications to the research protocol, primarily involving the addition of lentiviral vectors for gene knockdown/overexpression and updates to experimental procedures. Lentiviral vectors are being introduced for stable gene delivery, including shRNA-based knockdown of ASAH1, ASAH2, ACER1, ACER2, and ACER3 and fluorescent reporter expression. No Risk Group 3 or 4 agents are used. All work remains within Risk Group 2. Experimental procedures have been updated to include lentiviral transduction of human cell lines (e.g., iPSC-derived astrocytes), in addition to existing electroporation-based gene editing approaches. Standard molecular biology techniques remain unchanged. No changes to laboratory location or containment level. All additional work is proposed to be conducted at BSL-2 containment.

- **Training**: All staff members have completed and are current with their required training
- **Applicable NIH Guidelines**: Section III-D-1
- **Containment Conditions to be implemented**: BSL2
- **Risk Assessment & Discussion:** The study utilizes a replication-incompetent, third-generation lentiviral vector engineered for stable gene delivery. The vector contains gene-specific shRNA or transgene expression cassettes, along with a fluorescent reporter and an antibiotic resistance marker to facilitate identification and selection of transduced cells. Pseudotyping with vesicular stomatitis virus glycoprotein (VSV-G) enables efficient transduction of mammalian cells while maintaining a favorable safety profile. All lentiviral vectors are commercially sourced and are handled exclusively under BSL-2 containment. The research team has submitted a laboratory-specific SOP detailing lentiviral handling practices, including the use of appropriate engineering controls, administrative controls, and PPE to mitigate potential exposure risks.
- **Comments sent to PI for clarification:** None
- **The motion to approve the PI amendment was seconded and passed.**

Motion: Approved

- Yes Votes: 11
- No Votes: 0
- Abstained: 0
- Recused: 0
- Absent: 0

IBC AMENDMENTS

IBCA00001494
Title: PI Amendment 1 for IBC for H-54673 TRAILBLASER
Principal Investigator: Natalie Chen

Amendment Overview: This amendment reflects a change in Principal Investigator (PI) from Dr. Valentina Hoyos Velez to Dr. Natalie Chen. The study is a Phase I clinical trial evaluating the safety and preliminary efficacy of CAR T-cell therapy in patients with HER2-expressing breast cancer. The investigational product consists of engineered HER2-targeted CAR T cells designed to eliminate tumor cells through HER2 recognition while also modulating the tumor microenvironment via a TR2.41BB co-receptor. The CAR construct additionally incorporates an inducible caspase 9 safety switch and interleukin-15 (IL-15) to enhance CAR T-cell expansion and persistence. Dr. Chen was mentored by Dr. Hoyos on this project during her tenure as a CPRIT Scholar and possesses the requisite training, experience, and qualifications to serve as PI for this study.

- **Training**: All staff members have completed and are current with their required training

- **Applicable NIH Guidelines**: Not applicable
- **Containment Conditions to be implemented**: Not applicable
- **Risk Assessment & Discussion:** Not applicable to the amendment
- **Comments sent to PI for clarification:** None
- **The motion to approve the PI amendment was seconded and passed.**

Motion: Approved

- Yes Votes: 11
- No Votes: 0
- Abstained: 0
- Recused: 0
- Absent: 0

IBCA00001493
Title: Hazard Amendment 3 for Research using Gasdermin C plasmid to facilitate other plasmid transfection efficiency in various mouse and human immortalized cell lines.
Principal Investigator: Yinan Gong

***Conflict of Interest: Voting members Biana Godin and Anjana Tiwari left the meeting prior to discussion of this amendment*

Amendment Overview: The protocol is being amended to include the use of synthetic RNA. Research-grade mRNA will be synthesized and purified in HMRI's RNA Core Facility or purchased from commercial vendors (e.g., luciferase, mCherry or GFP mRNA from GenScript). For both in vitro and in vivo studies, the mRNA (mCherry, luciferase, GFP, GSDMC, MFG-E8) will be encapsulated in lipid nanoparticles in Dr. Godin's laboratory in accordance with the SOP provided in the main protocol.

- **Training**: All staff members have completed and are current with their required training
- **Applicable NIH Guidelines**: Section III-D-4
- **Containment Conditions proposed**: BSL1
- **Risk Assessment & Discussion:** The proposed amendment introduces the use of encapsulated synthetic mRNA for administration in mice, resulting in a modification to the project's biosafety risk profile. A transport SOP has not been submitted and is required to address the transfer of materials between the originating laboratory, collaborator laboratory, and animal research areas. The committee also reviewed containment considerations and recommended Biosafety Level 2 (BSL-2) containment for work involving synthetic mRNA encoding GSDMC, unless additional information is provided to support handling under BSL-1 conditions.
- **Comments sent to PI for clarification:**

- **Section Hazard Identification:** The encapsulated mRNA encodes the N-terminal domain of Gasdermin C (GSDMC-N), a pore-forming domain that triggers pyroptosis, a lytic and pro-inflammatory form of cell death. Based on the hazardous nature of this gene product, please revise the containment level to BSL-2 or provide additional clarification for handling at BSL1.
- **Section Exposure Management:** Please submit a Biological Transport SOP covering the transport of mRNA to Dr. Godin's lab and subsequently to the animal facilities, as well as the transport of cell lines to the animal facilities. Use the CLO SOP template and modify it to include lab-specific details, removing any sections that do not apply. The SOP must be signed and dated. Please upload the finalized transport SOP in the "Summary of Proposed Research" section.
- **Staff Identification:** Have additional staff members joined the lab? At this time, the PI is the only individual listed on the protocol. Please also confirm that the PI has completed CMP training required for entry into the animal facilities.

- **The motion to approve the amendment after designated member review was seconded and passed.**

Motion: Approve after designated member review

- Yes Votes: 9
- No Votes: 0
- Abstained: 0
- Recused: 2, Biana Godin, Anjana Tiwari
- Absent: 0

ADJOURNMENT

The meeting adjourned at 11:50 am