Houston Methodist Research Institute IBC Meeting Minutes

5/7/2026

Meeting Time Records

Meeting start time: 10:00 am

Meeting end time: 11:05 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, Virtually
Vicente Zuno, BS, RBP	Member	Biosafety Officer, affiliated		Yes, Virtually
Joan E. Nichols, PhD	Member	Scientific, affiliated		Yes, Virtually
Chas Gray, RPh	Member	Scientific, affiliated		Yes, Virtually
Tanya Herzog, DVM	Member	Animal Expert, affiliated		No
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		Yes, Virtually
Jiangyong Shao, MS	Member	Scientific, Affiliated		Yes, Virtually
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		Yes, Virtually
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	No
Astrid Marcela Quiroga	Ex-officio, Employee Health Representative	Yes, Virtually
Leon Brown, MS	Ex officio, Radiation safety officer	Yes, Virtually
Wanda Quezada, CIP	Ex officio, Director Regulatory Oversight	Yes, Virtually
Don Sibley, PhD	Consultant, Expert Reviewer	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
Shehla Barlas, 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 May 7, 2026. The meeting was called to order at 10:00 a.m., with 15 members participating, exceeding the quorum requirement of 9 members.

REPORTS

BSO Report:

- The BSO connected HMRI RNA Core staff with Dr. Daniel Kirienko (Rice University), who has developed software to screen sequences of concern in support of compliance with applicable screening requirements.

ORP: Review of Approved Protocol

- A review of HSC and IBC protocols found only one compliance issue, involving a lapsed renewal for a PI who had left the organization, which has since been resolved. No other compliance concerns were identified; most apparent issues were due to a system error (around 2016–2017) that failed to auto-terminate outdated protocols after renewal, rather than actual lapses in approval.

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: Review process for the addition of mRNA derived from RG3 or RG4 agents to approved protocols

The committee discussed oversight and tracking of mRNA work involving mRNA encoding proteins related to RG3 and RG4 pathogens. Although this work is generally considered low risk, mRNA may function as an immunogen. The committee discussed if hazard protocol amendments related to production of mRNA encoding proteins from RG3 and RG4 pathogens should require full committee review even if the overall risk profile on the protocol remains unchanged. Current

SOP specify that if the risk is not increased, an amendment can be reviewed by designated two-member review (DMR). The committee noted the importance of maintaining awareness of its increasing use within the institution and potential future regulatory considerations.
Responsibility for tracking will remain with the Principal Investigator (PI), supported by existing laboratory inventory, audit, and oversight systems. The committee also reviewed standard institutional exposure reporting and evaluation processes and determined they are appropriate for managing potential exposures.

Motion: Require that all amendments involving mRNA constructs for RG3 and RG4 agents undergo Full Committee Review (FCR).

Votes

- Yes: 4
- No: 8
- Abstained: 3

The motion to require that all amendments involving mRNA constructs for RG3 and RG4 agents undergo Full Committee Review did not pass.

- 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 April 2, 2026, were reviewed. A motion to approve was made and seconded, and the minutes were subsequently approved.

Motion: Approved

- Yes votes: 15
- No votes: 0
- Abstained: 0

AGENDA ITEMS

IBC NEW APPLICATIONS

IBC00002649
Title: Randomized, Open-Label Study of the BRIA-IMT Regimen Using SV-BR-1-GM, an Allogeneic GM-CSF–Secreting, HER-2/neu-Positive Genetically Modified Breast Tumor Cell

Line, With Checkpoint Inhibitor in Metastatic Breast Cancer
Principal Investigator: Polly Niravath

Study Overview: This is a randomized, open-label clinical trial in metastatic breast cancer, stratified by HER2, ER/PR status, and triple-negative disease. Participants are randomized to receive the Bria-IMT regimen (SV-BR-1-GM) plus a checkpoint inhibitor (CPI) or treatment of physician's choice, with an additional monotherapy cohort evaluating Bria-IMT alone. An interim analysis is planned to assess overall survival.

SV-BR-1-GM is an irradiated, genetically modified HER2/neu-positive breast cancer cell line engineered to secrete GM-CSF to enhance immune activation. The dose is approximately 20 million cells administered intradermally, divided into four inoculations (two in the upper back and two in the thighs). Administration follows cyclophosphamide preconditioning, with local interferon given after inoculation; combination cohorts also receive anti-PD-1 therapy on a 3-week cycle. Patients in the monotherapy arm may transition to combination therapy upon disease progression.

The investigational product will be received and prepared by the KJCCT GMP facility, including thawing and syringe preparation, and transported to the outpatient clinic for administration within 4 hours.

- **Training**: All staff members have completed training.
- **Applicable NIH Guidelines**: Section III-C-1
- **Containment Conditions to be implemented**: BSL2
- **Risk Assessment & Discussion**: SV-BR-1-GM is an irradiated, non-proliferative, allogeneic human breast cancer cell line genetically modified to express HER2/neu and secrete GM-CSF (CSF2 gene). Irradiation renders the cells replication-incompetent, reducing the risk of engraftment or tumor formation. The material is best categorized as Risk Group 2 due to its human origin, genetic modification, and potential to elicit biological effects, though its replication incompetence reduces overall risk. The study presents a low to moderate risk to personnel and the environment when conducted under BSL-2 containment with standard clinical and biosafety practices. The genetic modification and human cell origin warrant oversight, but risks are mitigated by irradiation and controlled handling procedures.
- **Comments sent to the PI for clarification**:
    - **Exposure Management Section**: Minor clarifications needed correcting reference to " RG2 virus" to "RG2 biological material".
- **The motion to approve the study by administrative review was seconded and passed.**

Motion: Approvable by Administrative Review

- Yes Votes: 15
- No Votes: 0
- Abstained: 0
- Recused: 0

- Absent: 0

IBC00002688
Title: IBC for Evaluating the oncolytic virus ASP-9801 for anti-tumor activity in an mCRC xenograft murine model
Principal Investigator: Tanya Herzog

Study Overview: This is a 3-year resubmission evaluating the anti-tumor efficacy of ASP-9801, an engineered oncolytic vaccinia virus, in a murine colorectal cancer xenograft model. Mice will be implanted with colorectal tumor cells at two flank sites. Once tumors reach the target size, ASP-9801 or a control virus will be injected intratumorally into one tumor, and effects will be assessed on both the treated and untreated tumors to evaluate local and systemic responses. Tumors will be collected at study endpoint for analysis of treatment-induced changes in tumor and immune cell interactions.

ASP-9801 is a genetically modified vaccinia virus designed to selectively replicate in tumor cells and express immune-activating genes, resulting in tumor cell lysis and stimulation of anti-tumor immunity. The agent is classified as BSL-2 and is replication-competent in cancer cells but not in normal tissues. The study does not involve wild-type vaccinia virus or recombinant generation of the agent.

The investigational product was acquired from the sponsor, aliquoted, and stored frozen in the HMRI laboratory. It will be used as provided without further manipulation. All in vivo work will be conducted under ABSL-2 conditions. Animal carcasses and tissues will be handled in a biosafety cabinet, decontaminated, and disposed of in accordance with institutional ABSL-2 waste management procedures, including autoclaving and incineration.

Status/Progress Report: To date, ASP-9801 has been tested in a tumor mouse model. The resulting data were used to prepare a research manuscript. This renewal supports an increase in the number of animals per group to adequately test the current hypothesis and generate additional data in anticipation of potential reviewer requests for further experimentation.

- **Training**: All staff members have completed training.
- **Applicable NIH Guidelines**: Section III-D-1, 2, & 4
- **Containment Conditions to be implemented**: BSL2
- **Risk Assessment & Discussion**: While specific inhalation toxicity studies for ASP-9801 have not been conducted, the potential for respiratory exposure cannot be excluded. Therefore, all procedures involving the handling, preparation, or manipulation of the virus will be conducted within a certified biological safety cabinet to minimize the risk of aerosol generation and inhalation exposure. Following intratumoral injection, there are no known significant hazards associated with the treated animals beyond those typical of ABSL-2 agents. However, because ASP-9801 is a replication-competent oncolytic vaccinia virus (tumor-selective), animals will be handled under ABSL-2 containment practices for the duration of the study. With adherence to BSL-2/ABSL-2 containment, engineering controls, and standard biosafety practices, the risk of occupational exposure to ASP-9801

is considered low to moderate and manageable.

- **Comments sent to the PI for clarification**:
    - **Study Progress**: Some information needs to be provided related to the protocol progression with a description of the work that has been completed and any changes needed in the protocol related to Experiment 1 or 2.
    - **Summary of Proposed Research**: The euthanized animals will not be returned to EMPIRI; instead, they will be transferred to a laboratory at MD Anderson. The attached transport protocol appears to be a generic template and lacks study-specific details. It does not specify transport locations or describe packaging procedures. If laboratory personnel will retrieve euthanized animals directly from the animal facility, this must be clearly described in the transport protocol. Alternatively, if the animal facility is responsible for transport, detailed procedures outlining transport conditions and responsibilities must be provided. These materials require BSL-2 handling and contain live virus; therefore, all transport procedures must incorporate appropriate biosafety measures. An outdated manufacturer-provided safety data sheet (SDS) has been submitted. While this may be the only available documentation, the agent is investigational (live virus), and its handling is primarily governed by the associated study protocol rather than a standard commercial SDS.
- **The motion to approve the study after designated member review was seconded and passed.**

Motion: Approval after Designated Member Review

- Yes Votes: 15
- No Votes: 0
- Abstained: 0
- Recused: 0
- Absent: 0

IBC AMENDMENTS

IBCA00001530
Title: PI Amendment 5 for Phase 2 Study of Adjuvant V940 (mRNA-4157) + Pembrolizumab vs Placebo + Pembrolizumab in High-Risk Muscle-Invasive Urothelial Carcinoma Post-Radical Resection (Randomized, Double-Blind, Controlled
Principal Investigator: Dharam Kaushik

Amendment Overview: This amendment requests a PI change for an IBC protocol associated with a randomized, double-blind Phase 2 clinical study evaluating adjuvant V940 (mRNA-4157) in combination with pembrolizumab for high-risk muscle-invasive urothelial carcinoma. Dr. Kaushik meets the qualifications to serve as Principal Investigator for this study.

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

Motion: Approved

- Yes Votes: 15
- No Votes: 0
- Abstained: 0
- Recused: 0
- Absent: 0

ADJOURNMENT

The meeting adjourned at 11:05 am
