NIH Institutional Biosafety Committee Minutes
Location: National Cancer Institute at Frederick

January 8, 2026
12:00 PM – 2:00 PM
Virtual Meeting via WebEx

Members Present:

Voting Members (Quorum = 8)	Voting Members (continued)	*Ex officio* (non-voting)
☒ Sharon Altmann (Community member)	☒ Stephen Hughes	☐ Walter Hubert
☒ Theresa Bell	☒ Dan McVicar (Chair)	☐ Samuel Denny
☒ Stella Spears (Alternate for J. Gulani)	☒ Bradley St. Croix	☒ Krisztina Janosko
☒ Eric Freed	☒ Brandon Keele	☒ Michael Kujawa
☐ Jatinder Gulani	☐ Valentina Perepnikhatka	
☒ Effie Nomicos (Community member)	IBC Office (non-voting)	Other/Guests (non-voting)
☒ Sarah Hooper	☒ Wendy Kitta	
☒ Jason Yovandich		

Announcements & Call to Order

I. Meeting called to order by IBC Chair at 12:07 pm.

Review of Past IBC Meeting Minutes

I. December 4, 2025, Minutes
   a. Comments on minutes: None provided.
   b. The minutes were unanimously approved as written.

New Committee Business

I. BSO or IBC lead reviewer preliminary registration approvals since the previous meeting:

   a. Pathogen only Registration Numbers: Not applicable.

   b. rDNA Registration Numbers:
      - Dr. Yinling Hu- IBC 2025-74: Mouse Breeding to Study Role of IKKalpha in Cancer and Inflammation and Immunity (Renewal, Breeding-Only)
        Reviewers: St. Croix, Gulani
      - Dr. Thomas Zheng- IBC 2025-76: Breeding-Only IBC Registration Zheng Lab (Renewal, Breeding-Only)
        Reviewers: Gulani, Bell

c. Registration amendments (non-administrative) approved between September-December 2025:
   - ❖ Dr. Parirokh Awasthi: 2022-31-A1. *Description:* Add AAV vectors for the generation of genetically modified mice.
   - ❖ Dr. Yurong Song: 2025-56-A1. Description: To Add lentiviral-vector modified murine cell lines for administration in vivo.
   - ❖ Dr. Sanchez Hernandez: 2025-11-A3. Description: Add two new plasmid constructs to previously approved protein production activities.

d. Additional Committee Discussion: N/A

II. Registrations for Committee review

Ref# 200136 (Renewal), Dr. Jeffrey Gildersleeve:

i. *Reviewers:* Hughes, Perepnikhatka

ii. *Summary:* The goal of this project is to develop carbohydrate-binding antibodies for applications in cancer research and cancer therapy. One part of the project involves cloning, expressing, purifying, and characterizing existing anti-glycan antibodies as well as introduction of mutations and other variations to optimize binding properties.

iii. Committee Discussion:

-Section 5.15: Please indicate "N/A" as the response since other sections indicate that viral vectors are not used for experiments.

-Section 5.25 and 6.25: Please enter the risk group for the cell lines in use.

-Section 5.26.1.1:
1. Please list the non-viral vectors that are used to modify the cells.
2. Please describe the procedures used to modify the cells. Alternatively, a laboratory SOP that describes the procedures may be attached to the section and referenced in the text.

-Section 10, General Comment: Details pertaining to E. coli cells should not be listed in this section. They should instead be listed in section 8.

iv. Animal studies proposed: No

v. Committee discussion about Dual-Use Research of Concern (DURC) and enhanced Potential Pandemic Pathogen (ePPP) considerations: There were no DURC or ePPP concerns with the described experiments.

vi. *Work is approved at:* BSL2

vii. Training prescribed to staff in the roster: BBP

viii. *Relevant sections of the NIH Guidelines:* N/A-This registration only describes plasmid systems that are exempt.

ix. Public comment: None provided by the general public.

x. Votes: 10 approved, 0 abstained

xi. The committee unanimously voted to approve this registration pending minor clarifications.

Ref# 200225 (Renewal), Dr. Xiaolin Wu:

i. *Reviewers:* Perepnikhatka, Keele

ii. *Summary:* The laboratory receives whole blood, blood components, tumor biopsies from patients, or DNA/RNA extracted from human materials and cell lines. Some of the blood cells/DNA/RNA samples may have been transduced with lentiviral/retroviral vector or CRISPR non-vector by the sources of the materials. The Wu laboratory does not conduct any transductions/transfections.

iii. *Committee Discussion:*

-Section 2.6.1.1: Please attach the facility's intake form (the form which requesting investigators submit to NCI-CCR Genomics Core to request the processing of samples). Please ensure that the form includes the following items:

a. Material type received: Is it extracted nucleic acids? DNA/RNA from HIV+ samples? Human cell lines/animal cell lines? NHP samples? Primary human/animal materials? Any other infectious materials?

b. If single cell capture will occur to extract nucleic acids, please include a field in the form.

c. The form should include the services provided by Dr. Bao Tran's group, now that the group will merge with the core facility.

Note: The objective of the intake form is to inform staff who process the materials about the potential biological hazards that they may encounter on the job.

-Section 7.14: Please remove references from the text about the disposal of tips (even noncontaminated), in municipal waste. Laboratory materials need to be discarded in biomedical waste boxes/bags for incineration offsite. Please modify the text to reflect this. Suggestion: Pipette tips may be placed in a cardboard container (similar to an ice cream container) in the BSC, and then the container can be discarded in a biomedical waste bag/box for incineration.

-Section 10-General Comment: Please complete section 10 in its entirety to register purified genomic materials that are submitted to the laboratory for processing. Please make sure to clarify in the responses whether the laboratory could receive purified infectious genomes for sequencing. Note: In the past, the IBC did not require an IBC registration for the work that Dr. Bao Tran's group used to conduct in previous years. Now that scopes are expected to change due to collaborative endeavors, the sequencing activities need to be registered to afford the committee the opportunity to perform a comprehensive risk assessment

iv. *Animal studies proposed:* No

v. *Committee discussion about Dual-Use Research of Concern (DURC) and enhanced Potential Pandemic Pathogen (ePPP) considerations: There were no DURC or ePPP concerns with the described experiments.*

vi. *Work is proposed at:* BSL2

vii. Training prescribed to staff in the roster: BBP

viii. *Relevant sections of the NIH Guidelines:* Section III-D.

ix. Public comment: None provided by the general public.

x. Votes: 9 approved, 1 abstained.

xi. The committee voted to conditionally approve pending modifications and newly developed intake form. Dr Hughes abstained.

Ref# 200317 (Renewal), Dr. Jairaj Acharya:

i. *Reviewers:* Yovandich, Hughes

ii. *Summary:* Sphingolipids drive fundamental processes in biology ranging from cell division and differentiation to apoptosis. In order to understand the biological significance of individual enzymes/proteins in sphingolipid biology, the laboratory engages in studies addressing their role in vivo using Drosophila and mouse as model organisms and complementing these efforts using ex vivo and biochemical studies.

iii. Committee Discussion:

-Section 3.2.1.1:

1. The text in section 5.12 of the form currently indicates that "Lentiviral vectors will be used to label mouse tumor cells lines with luciferase or GFP. Viral particles produced by transfection of HEK 293 cells will be used to transduce the mouse cell lines. At least 10 days after transduction, cells will be injected intravenously, intraperitoneally, or intratumorally into tumor bearing mice". Currently the table in section 3 does not indicate that any of the transduced cells are administered in vivo (The response to the question "Transduced Cells Administered to Animals" is NO for all entries). Please correct the table to identify which transduced cells are injected into animals.

2. Regarding the use of Adeno-Cre: Under the column titled "Viral Vector Administered to Animals?", please clarify whether the viral vector will be injected directly into mice. Please make sure to enter a declarative statement that clearly indicates whether or not the Adeno Cre is administered in vivo. Note: If Adeno Cre is directly injected into mice, all pertinent details need to be described in Section 5.19.1.1 of the form.

-Section 4.13: There is a header at the bottom of the text (titled "Retroviral studies"). Was the remaining text omitted accidentally? If yes, please enter the information and update the rest of section 4 to reflect any procedures associated with retroviral vectors (Please make sure that the information is consistent with the viral vector summary table in section 3).

-Section 4.28.1.1: Please correct the minor typographical error: "mini-rep" to state "mini-prep".

-Section 4.35: The text in this section still references in vivo research activities in the animal facilities. Please remove those references, if they do not apply to the activities associated with human cell lines

-Section 4.36: Previous fields within section 4 indicate that human cell lines (modified or unmodified) are not injected into animals. However, the text in this section still references needles and sharps associated with animal research activities. If it is correct that in vivo work will not be conducted with the human cell lines, then the text in this section needs to reflect that. Also, if the human cell lines are only cultured for procedures/assays in vitro, the text should clarify that needles and sharps are not used for the in vitro/cell culture activities.

-Section 5.2: References to primary animal materials should be extracted from this section and then incorporated into section 6 of the form. This field is designed to only capture details about established animal cell lines.

-Section 5.19.1.1:
1. Please clarify in the text whether Adeno-Cre will be administered in vivo.
2. Section 5.12 indicates that viral vector modified animal cells are injected into animals. As currently presented, the responses in sections 5.12 and 5.19.1.1 are in direct conflict. Please correct. Note: If modified animal cells are injected, then the requested information in the field needs to be entered.

-Section 5.29: The response to this question needs to be changed to "No" if purified non-viral vectors and if transfected animal cell lines are not injected into animals.

-Section 5.36: In the first sentence, please clarify the text to indicate that the sharps container is inside the BSC and that upon reaching the 2/3 fill line, the sharps container is sealed with tape and placed into the biomedical waste box for incineration.

-Section 6.2:
1. Please describe the cells associated with the EAE model (described in section 8).
2. In the first paragraph, please remove the statement "We do not study diseases". It is understood from other sections of the form that the laboratory studies mechanisms and pathways that are relevant to diseases/health conditions that affect humans.
3. Please enter a statement that makes a connection between the studies described in this section and the relevant ASP document that supports the studies. The objective is to ensure that both documents are consistent.

-Section 6.3:
1. Please clarify what is the source of the described animal tissues (from a collaborator, from a commercial source, from a self-generated/maintained animal colony on site, etc.).
2. Will only animal tissues be received or should primary human tissues also be included? Please modify the text accordingly.
3. The text describes control and mutant animals. What is the nature of the mutant animals? Were they generated via viral or nonviral vector systems (via microinjections)? Were mutant mouse lines generated by the investigator or by a different source?

-Section 6.5: Please describe the cells associated with the EAE model (described in section 8).

-Section 6.6.1.1: The text in this field states that primary mouse cells are transduced with retroviral or lentiviral vectors. It is then inferred that these transduced cells could then be implanted into host mice (this point is not clear in the text). Please address the following:

a. Expand the text that briefly mentions purified and partially purified bone marrow cell populations that will be used for transductions. The names of the vectors used, and the cargoes involved (Along with the time that elapses between transduction and subsequent injection. Do the cells remain in culture for at least 10 days prior to injection in vivo?) need to be described to better assess the hazards associated with them. Furthermore, the text needs to describe the hazards associated with the tissues that are collected from recipient animals and how such risks are mitigated (for example, conducting all tissue dissections in a BSC, using safer sharp options such as blunt ended scissors in lieu of scalpels). Note:

Please make sure that the work with bone marrow that is described in this IBC registration is consistent with what is approved in the ASP document. Since the administration of virally transduced bone marrow cells into recipient animals is a new scope of work for the laboratory (not approved in the parental iteration of the registration), this work is not approved at this time. The IBC members need to first assess the hazards associated with the work scope before activities may commence.

b. Please update the table in section 3 of the form to reflect what viral vectors are used to transduce the primary bone marrow cells.

-Section 6.6.1.3: Please complete the table.

-Section 6.15: In the first sentence, please clarify the text to indicate that the sharps container is inside the BSC and that upon reaching the 2/3 fill line, the sharps container is sealed with tape and placed into the biomedical waste box for incineration.

-Section 7-General Comments:
1. Section 8 (Biological Toxins) currently describes the administration in vivo of Mycobacterium tuberculosis as an adjuvant. Section 7 needs to be completed in its entirety to describe work with this material. Note: Please make sure to make a strong connection between this material and how its use aligns with the overall scientific aims and objectives.

2. Sections 8.16 and 8.17 reference "viral particles". If those materials are actually worked with, they need to be clearly defined/described in section 7.

-Section 8.2: It is recommended to modify the text in a manner that clearly conveys the connection between the sphingolipid work with the overall scientific aims and objectives described in the IBC registration. Note: The work involving M. tuberculosis needs to be further defined in section 7 of the form.

-Section 8.9.1.1: Please refer to the label claim on the bottle of Cavicide to determine whether there is a statement indicating that the disinfectant is effective to inactivate pertussis toxin. Please also confirm the recommended contact time for inactivating the toxin. Please enter a statement in the text that confirms the efficacy of the disinfectant for this biological material and also state the contact time. Note: Please contact the Biosafety Officer, for inquiries pertaining to suitable disinfectants.

- Section 8.10: Please complete the table.

-Section 8.11.1.2: Please provide the requested information in this section.

-Section 8.17 and 8.18: Viral particles are referenced in these sections. Please remove the references from the text. If applicable, please describe all work associated with viral particles in section 7 of the form.

-Section 9.19: Please complete this section.

iv. *Animal studies proposed:* Yes, mice.
v. *Committee discussion about Dual-Use Research of Concern (DURC) and enhanced Potential Pandemic Pathogen (ePPP) considerations: There were no DURC or ePPP concerns with the described experiments.*
vi. *Work is described at:* BSL1, BSL2, ABSL2
xii. Training prescribed to staff in the roster: AEP, BBP, VVST
vii. *Relevant sections of the NIH Guidelines:* Section III-D-4, Section III-E-1, Section III-E-3.
viii. Public comment: None provided by the general public.
ix. Votes: 10 approved, 0 abstained.
x. The committee unanimously voted to defer the review of this registration.

III. Registration amendments for full committee review:
i. None
ii. Reviewers: N/A
iii. Review Summary: N/A
iv. Committee Discussion: N/A
v. Animal studies proposed: N/A
vi. *Committee discussion*
vii. Relevant sections of the NIH Guidelines: N/A
viii. Committee vote/recommendations: N/A

IV. Committee Review of Inactivation Procedures (if not reviewed under a registration)
a. None

V. Standard Operating Procedures/Plans
a. None

VI. Serious Adverse Events in Clinical Trials reviewed by the Committee
a. Not applicable

VII. Committee Training
a. None

Reports

I. Biosafety Officer Report –
a. None

II. Other reports
a. None

Around the Room/Committee Discussion

I. Enhancements to the experimental IBC registration form: Committee members discussed potential options to enhance the current form for users to easily document experiments involving purified viral vectors for administration in vivo. Suggestions included adding a new open field for users to enter descriptions or update an existing question to request additional information. Options will be discussed with developers.

II. Lab waste training tool: The committee was informed about a tool that was recently developed by EHS to provide guidance to research staff, regarding the proper mechanisms for disposing of laboratory waste. The IBC Chair recommended summarizing the information to make it more user friendly. The IBC Chair and the Biosafety Office will work on mechanisms to disseminate the tool to the research community.

Adjournment

I. Meeting adjourned by IBC Chair at 1:09 pm.

Next Meeting

I. February 5, 2026- Conference Room B, Building 549 (WebEx access available).