NIH Institutional Biosafety Committee Minutes
Location: National Cancer Institute at Frederick
April 2, 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	Other/Guests (non-voting)
☒ Effie Nomicos (Community member)	IBC Office (non-voting)	☒ Kaitlyn Connors
☒ Sarah Hooper	☒ Wendy Kitta	☒ Jocelyn Mendoza
☐ Jason Yovandich		

Announcements & Call to Order

I. Meeting called to order by IBC Chair at 12:03 pm.

Review of Past IBC Meeting Minutes

I. March 5, 2026, 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. Stanley Adoro- IBC 2026-22: Transgenic Rodents for Hematopoietic Cell Biology and Malignancy Research (Breeding-Only, Renewal)
        Reviewers: Gulani, Perepnikhatka

   c. Registration amendments (non-administrative)
      - Dr. Daniel McVicar 2025-18-A3. *Description:* Add human cell lines for administration in vivo.

- ❖ Dr. Shahanawaz Jiwani: 2024-02-A7. Description: Add human cell lines for in vitro procedures.

d. Additional Committee Discussion: N/A

II. Registrations for Committee review

Ref# 200179 (Renewal), Dr. William Bocik:

i. *Reviewers:* Keele, Yovandich

ii. *Summary:* The laboratory's work contributes to the ongoing development of highly-multiplexed assays capable of comprehensive analysis of heterogeneous tumor cell populations within solid or liquid tissue samples. The lab will include capabilities for single cell proteomics and morphology characterization of solid biopsy tissue, allowing characterization of drug responses in tumor tissues and mapping of biomarkers. The projects have been selected to address key scientific questions that require multiplex analysis.

iii. Committee Discussion:

-Section 2.6: Regarding the attached intake form-The committee requests additional fields on the form, which would serve to collect further information from the requesting investigators. The information would in turn provide clear information for the staff in the core facility, as to the risks associated with the samples received. The following items need to be incorporated into the form: Note: The IBC Coordinator will provide a sample intake form for reference, as to what items the committee is looking for in an intake form.

A. IBC registration number (if the requesting investigator is an NCI at Frederick investigator).

B. Cell/tissue type: Human or animal origin?

C. If the cells were modified with a viral vector, how long ago were the cells modified? Did the cells spend at least 10 days in culture?

-Section 7.2: Will the core facility conduct any tissue dissection/sectioning? If the answer is no, please provide a declarative statement indicating this in the text. Note: As currently written, the text is not clear as to whether only already prepared slides are received, or if the core facility would be producing slides from tissue blocks. Alternatively, if tissues will be sectioned/dissected by the core facility, please describe in section 7.5, how these activities are performed safely (i.e. if a microtome is used, does it have safety features? Are there special practices to prevent incidents? Is there a laboratory SOP that details safety provisions when conducting tissue sectioning? If an SOP is available, it should be attached to section 7.5)

-Section 7.5: Please specify in the text that all the work described in this section is conducted under BSL2 conditions, in a BSC.

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:* Section III-D.
ix. Public comment: None provided by the general public.
x. Votes: 10 approved, 0 abstained
xi. The committee unanimously voted to approve this registration.

Ref# 200183 (Renewal), Dr. Barbara Felber:

i. *Reviewers:* Altmann, Perepnikhatka
ii. *Summary:* The aim of this research is to develop nucleic-acid based vaccines targeting specific tumor antigens for cancer treatment, using different mouse models. For that purpose, the laboratory will also use a novel nanoparticle emulsion, which was also shown to induce robust immune responses in animal models and humans. These inorganic nanoparticles will be used as part of the therapeutic interventions in vivo. Moreover, the laboratory will develop immunotherapeutic interventions against cancer. Murine models will be used to test nucleic-based cancer vaccines able to induce efficient anti-tumor immunity resulting in tumor regression and increased survival. Several cytokines and chemokines will also be used, as plasmid DNA or purified proteins, to counteract the immunosuppressive microenvironment often associated with the tumor. The laboratory will use different mouse cancer models, including melanoma, breast cancer, pancreatic, lung and colon carcinoma.

iii. *Committee Discussion:*
-Section 5.8: Please include additional rows to declare the locations where animals are housed (currently only locations for procedures are identified on the table) and indicate the corresponding biological containment level. Please also state the duration of housing under such containment level (for example, for the duration of the study?).

-Section 9.13.1.1: Please include additional rows to declare the locations where animals are housed (currently only locations for procedures are identified on the table) and indicate the corresponding biological containment level. Please also state the duration of housing under such containment level (for example, for the duration of the study?).

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 proposed at:* BSL2, ABSL2
vii. Training prescribed to staff in the roster: AEP, BBP, VVST
viii. *Relevant sections of the NIH Guidelines:* Section III-D-2-a.
ix. Public comment: None provided by the general public.
x. Votes: 9 approved, 1 abstained.
xi. The committee voted to approve this registration. Dr. McVicar abstained.

Ref# 200240 (Renewal), Dr. Ligia Pinto:

i. *Reviewers:* Freed, Yovandich
ii. *Summary:* The HPV and GTIS Serology Laboratory will work in partnership with leaders in the field to standardize and harmonize serological assays for Human Papillomavirus (HPV) and Adeno-Associated Virus (AAV) antibody testing through development of a critical set of qualified reagents, standards and validated assays that will be made available to the scientific community.

iii. Committee Discussion:

-Section 4.2.1.1: Please add new line items to this table, to list HPV particles that carry a marker gene (as they are considered vectors.

-Section 7.2: Under the header "HIV+ Sample Studies", please add a statement that indicates whether the referenced samples are from patients who are currently suppressed/in therapy.

-Section 7.10: Will face masks actually be used? If yes, does the text refer to regular face masks or respirators (e.g. N95)? Note: If the reference to face masks was entered in error, please remove it from the text.

-Section 7.13: The text still references a link (in multiple occurrences) for disinfectants in EPA list N. Please replace the link with this one: https://www.epa.gov/pesticide-registration/epas-registered-antimicrobial-products-effective-againstclostridioides. Additionally, please reference EPA list K disinfectants.

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 described at:* BSL2

vii. Training prescribed to staff in the roster: BBP

viii. *Relevant sections of the NIH Guidelines:* Section III-D-1

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

x. Votes: 10 approved, 0 abstained.

xi. The committee unanimously voted to approve this registration.

Ref# 200282 (Renewal), Dr. Yousuke Takahama:

i. *Reviewers:* Gulani, St. Croix

ii. *Summary:* One of the most prominent characteristics of the immune system is the ability to distinguish foreign substances from self-components, so that the immune system attacks various pathogens while maintaining tolerance to the body. In the immune system, T cells play an essential role in distinguishing non-self from self. T cells acquire this ability by forming a functional repertoire of antigen recognition specificity during development in the thymus. The laboratory studies how the thymus microenvironments contribute to the selection of functionally competent T cells.

iii. Committee Discussion:

-The registration is detailed and well defined. Only minor administrative modifications pertaining to the locations section were requested.

iv. 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.

v. *Work is described at:* BSL1, ABSL1

vi. Training prescribed to staff in the roster: AEP

vii. *Relevant sections of the NIH Guidelines:* Section III-D-4

viii. Public comment: None provided by the general public.
ix. Votes: 10 approved, 0 abstained.
x. The committee unanimously voted to approve this registration.

Ref# 200499 (New), Dr. Jaime Rivera-Perez:

i. *Reviewers:* St. Croix, Keele
ii. *Summary:* The Standardized Organoid Modeling (SOM) Center will serve as a first-of-its-kind NIH-wide integrated platform dedicated to developing standardized organoid-based New Approach Methodologies (NAMs). It will serve as a neutral scientific hub for standardization, developing organoids that are reproducible, reliable, and accessible for medical research. By establishing validated, fit-for-purpose protocols for organoids that replicate key structural and functional characteristics of human organs, the center will support efforts to reduce reliance on animal testing, generate more precise human-based data, and minimize variability across laboratories.
iii. Committee Discussion:
-Section 2.2: For the first occurrence of the term, please write out i(PSC) as it is used throughout the document.

-Section 4.5-Regarding the attached safety manual:
1) Delete references to virus work (adeno/lenti/sendai) as this is not applicable at this time.
2) Replace "Protective Services" with "Security and Emergency Services".
3) In item 5.2, explicitly state that the human stem cells will only be manipulated inside of a BSC.
4) In item 5.2.1, please indicate to always avoid the use of sharps in a BSC and when working with biological hazards.
5) For waste disposal, please include a reference to the EHS procedures found here: https://ncifrederick.cancer.gov/ehs/procedures/default.aspx. This will help to keep document current if procedures change.

-Section 4.36: Is there an alternative way to conduct the described procedures without a needle? Is there a safer scoring device? Can a glass pipette tip or a plastic one be used instead? Please modify the text, as applicable.

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 described at:* BSL2
vii. Training prescribed to staff in the roster: BBP
viii. *Relevant sections of the NIH Guidelines:* Section III-D-1
ix. Public comment: None provided by the general public.
x. Votes: 10 approved, 0 abstained.
xi. The committee unanimously voted to approve this registration.

Ref# 200512 (New), Dr. Avinash Bhandoola:

i. *Reviewers:* Perepnikhatka, Gulani
ii. *Summary:* Plasma cells are a type of immune cell, and their job is to produce antibodies. Only plasma cells can synthesize and secrete antibodies. The factors that maintain plasma cell survival are not fully

understood. The laboratory is interested in extrinsic factors that mediate plasma cell survival since long-lived plasma cells cannot be fully depleted in humans, thus plasma-cell-mediated diseases are incurable. This includes life-threatening and chronic diseases such as certain autoimmune diseases (where antibodies target self), chronic transplant rejection (where antibodies target the transplant), and malignancies of plasma cells. The laboratory aims to better understand the extrinsic factors that mediate plasma cell survival, which will enhance the understanding of plasma cell biology and give new potential targets for human therapeutics in these diseases

iii. Committee Discussion:

-Section 6.5:

1. The lentiviral vector modified primary mouse cells could potentially be contaminated with replication competent viruses and there could also be unbound viruses in the cultures of those cells since they spend less than 10 days in culture. If possible, the cells should be washed prior to being shipped to Frederick to reduce the level of contamination. Please add a statement reflecting these points into the text.

2. Although the cargo encoded within the vectors does not appear to be dangerous, the vectors are insertional mutagens. Malignancies have been reported in patients receiving lentiviral vector therapies. It is particularly important that LASP technicians performing the injections into the mice and the blood draws follow these steps to mitigate the potential risk of exposure via accidental self-inoculation when performing the cell injections and the blood draws (please enter this information into the text): "Intravenous Injection All handling of lentiviral-modified cells and injections must occur inside a certified biological safety cabinet (BSC). An ACUC-approved mouse restrainer needs to be used during intravenous administration. A puncture-resistant glove will be worn under a disposable glove on the non-dominant hand used to hold the tail. Needles, syringes, and other sharps must be disposed of immediately after use in designated puncture-resistant sharps containers inside the BSC. Needles must not be recapped, bent, or removed from syringes prior to disposal to minimize injury risk. Sharps containers need to be closed when approximately three-quarters full and disposed of through EHS for incineration. Blood Collection (within 10 days post-injection with lentiviral-modified cell lines): Animals will be anesthetized using isoflurane inside a Class II B2 BSC. Blood will be collected via the submandibular vein. A puncture-resistant glove will be worn under a disposable glove on the non-dominant hand used to restrain the animal. All sharps must be handled and disposed of as described above". Please also reference the attached LASP SOPs (3049F and 3050F) in the text.

3. Please state in the text, whether any mice will be euthanized by LASP and samples analyzed, or if blood samples will be taken less than 10 days after the transduction in Bethesda. Please include the following safety provisions in the text, if LASP staff will be expected to conduct the procedures described above: "Animal Shipment (before 10 days post-injection, if necessary). If animals must be transferred to NIH during the hazardous period, LASP staff and drivers must be trained by EHS and must be current with DOT hazardous shipping requirements to manage transport. Animals will be packed in ACUC-approved hard plastic shipping containers (Taconic/Jax), secured with zip ties. A secondary EHS-approved shipping container will be used within the transport vehicle. The likelihood of shipment before completion of the 10-day biocontainment period is very low. Euthanasia and Tissue Collection (within 10 days post-injection). Euthanasia and tissue collection will be performed inside a BSC. Staff will wear double nitrile gloves and use blunt-ended scissors for dissection. Sharps handling and disposal will follow

the same procedures outlined above. Carcasses and tissues will be disposed of in accordance with the LASP ABSL-2 SOP".

-Section 6.6.1.1:
1. Please correct the text in this section, to indicate that lentiviral vectors will not recombine with endogenous murine viruses in a way that will produce replication competent progeny.

2. Will there be any likelihood of blood draws to be conducted on the animals within the 10-day window in ABSL-2 housing (post injection of the lentivirally modified cells)? If yes, what is the method of blood collection to be used? It is recommended to anesthetize the mice for the blood collection procedure to reduce the risk of exposure to the technical staff. If LASP staff will be expected to conduct these procedures, please incorporate the following language into the text: "Intravenous Injection. All handling of lentiviral-modified cells and injections will occur inside a certified biological safety cabinet (BSC). An ACUC-approved mouse restrainer will be used during intravenous administration. A puncture-resistant glove will be worn under a disposable glove on the non-dominant hand used to hold the tail. Needles, syringes, and other sharps will be disposed of immediately after use in designated puncture-resistant sharps containers inside the BSC. Sharps will not be recapped, bent, or removed from syringes prior to disposal to minimize injury risk. Sharps containers will be closed when approximately three-quarters full and disposed of through EHS for incineration. Blood Collection (within 10 days post-injection with lentiviral-modified cell lines). Animals will be anesthetized using isoflurane inside a Class II B2 BSC. Blood will be collected via the submandibular vein. A puncture-resistant glove will be worn under a disposable glove on the non-dominant hand used to restrain the animal. All sharps will be handled and disposed of as described above. Animal Shipment (before 10 days post-injection, if necessary). If animals must be transferred to NIH during the hazardous period, LASP staff and drivers must be trained by EHS and must be current with DOT hazardous shipping to manage transport. Animals will be packed in ACUC-approved hard plastic shipping containers (Taconic/Jax), secured with zip ties. A secondary EHS-approved shipping container will be used within the transport vehicle. The likelihood of shipment before completion of the 10-day biocontainment period is very low. Euthanasia and Tissue Collection (within 10 days post-injection). Euthanasia and tissue collection will be performed inside a BSC. Staff will wear double nitrile gloves and use blunt-ended scissors for dissection. Sharps handling and disposal will follow the same procedures outlined above. Carcasses and tissues will be disposed of in accordance with the LASP ABSL-2 SOP".

-Section 6.6.1.2:
1. Please state in the text, how long after transduction are the mice euthanized?
2. Is there a likelihood that LASP staff in Building 567 will have to euthanize and collect tissues from the animals inoculated with lentiviral modified cell lines? For example: If there is unexpected sickness or mortality in the mice (which would not allow for the normal workflow of the transfer of mice to Bethesda). If yes, please include a statement in the text to highlight the safety steps that LASP staff in Building 567 staff must follow. Text to incorporate into the text if LASP will be expected to conduct the procedures mentioned above:
"For tissue collections (within 10 days post-injection): Euthanasia and tissue collection will be performed inside a BSC. Staff will wear double nitrile gloves and use blunt-ended scissors for dissection. Sharps handling and disposal will follow the same procedures outlined above. Carcasses and tissues will be

disposed of in accordance with the LASP ABSL-2 SOP. For injections and blood collections: Intravenous Injection. All handling of lentiviral-modified cells and injections will occur inside a certified biological safety cabinet (BSC). An ACUC-approved mouse restrainer will be used during intravenous administration. A puncture-resistant glove will be worn under a disposable glove on the non-dominant hand used to hold the tail. Needles, syringes, and other sharps will be disposed of immediately after use in designated puncture-resistant sharps containers inside the BSC. Sharps will not be recapped, bent, or removed from syringes prior to disposal to minimize injury risk. Sharps containers will be closed when approximately three-quarters full and disposed of through EHS for incineration. Blood Collection (within 10 days post-injection with lentiviral-modified cell lines). Animals will be anesthetized using isoflurane inside a Class II B2 BSC. Blood will be collected via the submandibular vein. A puncture-resistant glove will be worn under a disposable glove on the non-dominant hand used to restrain the animal. All sharps will be handled and disposed of as described above".

-Section 6.13: Please correct the typographical error: "Do PPE" to state "Don PPE".

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 described at:* BSL2, ABSL2
vii. Training prescribed to staff in the roster: AEP, BBP, VVST
viii. *Relevant sections of the NIH Guidelines:* Section III-D-4
ix. Public comment: None provided by the general public.
x. Votes: 10 approved, 0 abstained.
xi. The committee unanimously voted to conditionally approve 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 about the dual-use and ePPP potential of these experiments:* N/A
  vii. Work is approved at Biosafety Level(s): N/A
  viii. Relevant sections of the NIH Guidelines: N/A
  ix. 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. The IBC Chair expressed gratitude to all the IBC members who provided feedback for the draft guidelines on SARS-CoV-2 research, which were developed by NIH.

Adjournment

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

Next Meeting: May 7, 2026- Executive Board Room, Building 549 (WebEx access available).