NIH Institutional Biosafety Committee Minutes
Location: National Cancer Institute at Frederick
February 5, 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)	☒ Grace Markley
☒ Sarah Hooper	☒ Wendy Kitta	☒ Jocelyn Mendoza
☒ Jason Yovandich		☒ Kaitlyn Connors

Announcements & Call to Order

I. Meeting called to order by IBC Chair at 12:05 pm.

Review of Past IBC Meeting Minutes

I. January 8, 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. Marielle Yohe- IBC 2026-05: Genetically Engineered Mouse Models of RASopathies and RAS-associated Malignancies (Breeding-Only, Renewal)
        Reviewers: Bell, Gulani
      - Dr. Douglas Kuhns- IBC 2026-06: Isolation of Blood Products from Vaccinia Vaccinated Volunteers and the Study of the Induction of Cytokines post Vaccinia Vaccine Inoculation, 03-I-0090. (Storage-Only, Renewal)
        Reviewers: Perepnikhatka, St. Croix

- ❖ Dr. Christopher Kanakry- IBC 2026-08: Breeding and Holding of Various Mouse Strains (Breeding-Only, Renewal)
  Reviewers: Gulani, Keele

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# 200179 (Renewal), Dr. William Bocik:

i. *Reviewers:* Yovandich, Keele

ii. *Summary:* This IBC registration describes activities conducted by the Imaging Mass Cytometry Program (IMC). The IMC laboratory is designated as a BSL2 lab, which will contribute 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:
Please check the "Yes" box as the response, since other sections of the document indicate that the laboratory functions as a facility that provides services to other investigators. Please also attach a PDF version of the intake form that investigators are required to complete prior to sending samples to the facility for processing. Items to address in the intake form:

a. Include questions that would clearly document whether the facility offers conjugation, fixation, fresh/frozen tissue sectioning, staining, and processing of materials in liquid form.

b. Include questions to clearly identify which samples are received fresh and need to be fixed. Also, the questions should clearly identify which samples have already arrived fixed. Recommendation: The form could include a field at the end, which is marked for "internal use only". This field could be used to document what is the required biological containment level for processing the request (BSL2); document whether any special handling (additional PPE?) is necessary for any particular sample based on the potential risk posed by the material; and to document what specific engineering controls are required to perform the requested procedures on the samples.

c. Add questions to clearly identify whether any of the cell lines to be processed have been modified via viral vector systems or non-viral vector systems. The type of system used for cell line modification also needs to be identified.

d. If the cells have been modified as mentioned above in point 3, the form should ask investigators to state when the cells were modified (Note: The committee is interested in learning whether the modified cells have remained in culture for at least 10 days prior to being submitted to the core facility for processing).

e. In some sections of the form, it is suggested that investigators requesting services may transport samples into the core facility and they subsequently transport processed samples back to their laboratory. The intake form needs to include statements indicating that the investigators requesting the processing of samples are responsible for ensuring that the samples are properly contained as follows: Biological samples are contained in a primary container that is properly sealed/capped and labeled to identify the biological material. The primary container is then placed into a secondary container that has sufficient absorbent material to capture any potential spills during transport. Investigators are required to transport materials back to their laboratory in the same safe manner that the samples were brought into the core facility.

-Section 5.2:
1. Please attach a general sample list of immortalized cell lines that the facility may accept from requesting investigators.

2. Please confirm the location of the material fixation activities (Section 7.9 references Building 434, room 12. Are there any other locations being used as part of the workflow?). Note: If samples are being transported from one location to another, this needs to be clearly stated in the text. Furthermore, the text needs to provide additional details as to how the transport of materials is conducted in a safe manner (see feedback in the biological safety questions below for additional guidance on requirements for transporting samples).

3. Please confirm whether the laboratory processes all incoming samples in the BSC. At what point are samples removed from the BSC (only after they are fixed and the material is no longer rendered viable and potential viruses/pathogens harbored inactivated?)?

-Section 5.5:
1. Does the laboratory have an SOP that describes how incoming samples are to be handled safely? If yes, this document needs to be attached to this section of the registration. Note: The SOP needs to describe how materials are neutralized/fixed and what engineering controls are used for those processes. The hazards associated with cells potentially modified with viral vector systems need to be acknowledged and clear mitigation strategies for working with them need to be described in the SOP.

2. The use of laser-containing equipment is referenced in the text. Are the lasers enclosed? Is the system closed?

3. Where is the laser-containing equipment located?

-Section 5.6:
1. Please identify the location (and corresponding biological containment level) for the fixation activities.

2. Please identify the location (and corresponding biological containment level) for the space housing the laser-based equipment.

-Section 5.31: Are face masks actually used? If yes, for what procedures? Please modify the text accordingly.

-Section 7.5:
1. Does the facility conduct fresh/frozen tissue sectioning and subsequent fixation/conjugation/staining? Note: If fresh/unfixed frozen tissues are processed, then the committee requires a pause on those activities until the risks associated with the operation may be comprehensively assessed by the committee.

2. Please confirm the location of the tissue processing activities (Section 7.9 references Building 434, room 12. Are there any other locations being used as part of the workflow?). Note: If samples are being transported from one location to another, this needs to be clearly stated in the text. Furthermore, the text needs to provide additional details as to how the transport of materials is conducted in a safe manner (see items in the biological safety questions for additional guidance on requirements for transporting samples).

3. Please confirm whether the laboratory processes all incoming samples in the BSC. At what point are samples removed from the BSC (only after they are fixed and the material is no longer rendered viable and potential viruses/pathogens harbored inactivated?)?

4. The use of laser-containing equipment is referenced in the text (as described in section 5). Are the lasers enclosed? Is the system closed?

5. Where is the laser-containing equipment located?

6. Does the laboratory have an SOP that describes how incoming samples are to be handled safely? If yes, this document needs to be attached to the IBC registration. Note: The document needs to describe how materials are neutralized/fixed and what engineering controls are used for those processes. TMAs also need to be described in detail. The hazards associated with fresh/frozen tissues need to be acknowledged and clear mitigation strategies for working with them need to be described in the SOP.

-Section 7.9:
1. Please create a new line item to identify the location (and corresponding biological containment level) for the fixation activities. Note: the objective is to have all locations and containment level easily identifiable on the table.

2. Please identify the location (and corresponding biological containment level) for the space housing the laser-based equipment.

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: 11 approved, 0 abstained
xi. The committee unanimously voted to defer this registration.

Ref# 200224 (Renewal), Dr. William Bocik:

i. *Reviewers:* Keele, Bell
ii. *Summary:* The laboratory provides core services to the research community and receives native cell lines (unmodified) for use as controls in standard runs and assay validation experiments in which peptides or nucleic acids are extracted from the cell lines. Additionally, the laboratory receives whole blood, blood components (plasma, serum, buffy coat, specific cell type isolates), blood in Paxgene tubes, saliva, fresh frozen tissue, hair, nail, buccal swabs, nasal swabs, and formalin fixed tissue sections for nucleic acid extraction and peptide capture.

iii. *Committee Discussion:*

-Section 2.6.1.1:

Please attach a PDF version of the intake form that researchers are required to complete prior to submitting samples to the core facility for processing. The form should include similar details as described in the feedback for IBC Ref# 200179. Note: The file that is currently attached to this section is a procedure for the use of the MD Wizard Request System. In addition to the items described in the feedback for IBC Ref# 200179, please ensure to address the following in the intake form:

1. Do the sources of the clinical specimens provide any human pathogen test results to the core facility, to identify any samples that may have been obtained from subjects that may harbor an infection (for example, HIV, HBV, HCV, HPV, etc.)? Note: It is recommended to add a field to the facility's intake form to identify whether such screening has occurred at the source and to identify any positive results (without including any PHI/PII).

2. Are any of the received cells modified via viral vector/non-viral vector systems? If yes, the intake form needs to have fields where investigators may declare this information (please reference the feedback for the intake form in IBC Ref# 200179 for additional information)

-Section 5.2: Are any of the received cells (from requesting investigators) modified via viral vector/non-viral vector systems? Please provide a declarative statement addressing this point in the text.

-Section 5.5:

1. Please confirm whether the laboratory processes all incoming samples in the BSC. At what point are samples removed from the BSC (only after they are fixed and the material is no longer rendered viable and potential viruses/pathogens harbored inactivated?)?

2. Does the laboratory have an SOP that describes how incoming samples are to be handled safely? If yes, this document needs to be attached to this section of the registration. Note: The document needs to describe how materials are neutralized/fixed and what engineering controls are used for those processes. The hazards associated with any cell lines that may arrive already transduced/transfected need to be acknowledged and clear mitigation strategies for working with them need to be described in the SOP.

-Section 7.3: Do the sources of the clinical specimens provide any human pathogen test results to the core facility, to identify any samples that may have been obtained from subjects that may harbor an infection (for example, HIV, HBV, HCV, HPV, etc.)? Please address this point in the text.

-Section 7.5: Section 7.2 indicates that the facility receives and processes fresh/frozen tissues. Are tissue sectioning and subsequent fixation/conjugation/staining occurring? Note: If the response is yes the committee requires a pause on those activities until the risks associated with the operation may be comprehensively assessed by the committee.

-Section 7.9: Please clarify which of the indicated locations will be used for tissue fixation/staining procedures.

-Section 7.10: Are specialized gloves used for tissue trimming procedures? Please address this point in the text.

-Section 7.15: The text currently describes the use of sharp razor blades to trim FFPE sections on slides. Can the use of a safer alternative to razor blades be implemented? Is any equipment used in conjunction with the blades? If yes, please describe it in the text.

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: 11 approved, 0 abstained.
xi. The committee voted to conditionally approve pending modifications and newly developed intake form.

Ref# 200241 (Renewal), Dr. Ligia Pinto:

i. *Reviewers:* Perepnikhatka, Altmann
ii. *Summary:* The objective of the described research is to test human specimens that include HIV+ samples to determine biomarker and antibody levels and associations with cancer, other diseases, and HPV vaccine responses by utilizing Luminex bead based technology. Testing will be performed according to the manufacture's procedure manual or internally developed standard operating procedures (SOP)s for each Luminex bead based assay.

iii. Committee Discussion:

-Section 1.2 and 7.2: Please remove all references to the research activities which are no longer active. The samples associated with the decommissioned scope of work need to be declared in a storage-only IBC registration. If the laboratory plans to resume such work in the future, an amendment needs to be submitted for the applicable experimental IBC registration(s). The amendment should be submitted in a timely manner to secure review by the IBC. Work with the materials may only proceed after the IBC has reviewed and approved the amendment. Note: Please also remove all references to the attachments that no longer apply to the research scope and remove the attachments from the registration.

-Section 7.3: The text in subsequent sections of the registration indicates that samples from cancer patients are processed. Could those samples harbor any infections? Does the source provide assurances that the samples from cancer patients/immunocompromised donors are free of human pathogens? Would the Pinto laboratory be informed if the samples are positive for any human pathogens? Please address in the text.

-Section 7.5:
1. Please remove all references to the research materials that are no longer going to be used, as they need to be declared in a storage-only IBC registration.

2. For the remaining paragraphs that detail the treatment of liquid waste: Please correct the text to indicate that undiluted bleach is added to a corresponding amount of liquid waste, as to create a solution of 10% bleach, which is then discarded down the drain (after 30-minute contact time) with copious amounts of water.

3. Please clarify in the text whether the heat inactivation procedures are equally applied to all the HPV, HIV, and AAV samples or only to some of the samples. As currently presented, it is not clear which ones of those samples will be heat inactivated.

4. The committee's concern is that the heat treatment (56 degrees) for 30-60 minutes is not sufficient to completely inactivate all the viruses in question. Additionally, the text references washing steps during assays, which would pose a hazard to staff (as live viruses would be in the samples), especially if those steps are not occurring inside the BSC. Note: The virus type and viral concentration are contributing factor in identifying the appropriate temperature and time to completely inactivate the viruses.

5. The file titled "30006 Sample Heat Inactivation Redacted" needs to be updated to reflect what is the appropriate temperature and time for the complete inactivation of HIV, HPV, and AAV samples. Considerations about virus type and viral concentration should also be included.

6. Potential alternative for the heat-treated samples: If the laboratory chooses to heat the samples at 56 degrees for 30-60 minutes, then those samples could be referred to as "attenuated" throughout the text (in the registration and in the attached protocol for heat inactivation), in lieu of "inactivated". Additionally, all the washing steps for assays would be required to be performed inside the BSC.

7. Will all the HPV, HIV, and AAV samples be gamma irradiated, or does this treatment only apply to the samples which are to be removed)?

8. If the HPV, HIV, and AAV samples are gamma irradiated, does the Pinto laboratory conduct the irradiation procedure on site, or does the source of the materials irradiate them prior to sending them to the Pinto laboratory? Please clarify in the text.

9. Please provide additional details as to what broad categories of biomarkers are being studied in the samples.

Section 7.12:

1. Please remove all references to the materials that are only going to be declared in a storage-only IBC registration.

2. For the remaining paragraphs that detail the treatment of liquid waste: Please correct the text to indicate that undiluted bleach is added to a corresponding amount of liquid waste, as to create a solution of 10% bleach, which is then discarded down the drain (after 30-minute contact time) with copious amounts of water.

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:* N/A, no recombinant DNA research is described in this registration.

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

x. Votes: 11 approved, 0 abstained.

xi. The committee unanimously voted to defer the review of this registration.

Ref# 200474 (New), Dr. Justin Quon:

i. *Reviewers:* Hughes, Bell

ii. Summary: The IBC document focuses on VCMP formulation and filling practices for biological materials that have already been produced under procedures described in other approved IBC registrations, which are linked to this IBC registration. In some cases, the biological materials are received from third-party VRC collaborators. As a result, this registration does not include bioreactor operations or traditional chromatography purification processes.

iii. *Committee discussion:* The registration is well defined and contains adequate information for the procedures to be conducted.

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

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

x. *Votes:* 11 approved, 0 abstained.

xi. The committee unanimously voted to approve this registration as written.

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. On January 9th, an employee sustained a laceration injury in the hand with a razor blade. The employee was conducting OCT tissue dissection. The tissue block was derived from PDX material. Remnant material on the blade involved in the incident was submitted for human pathogen testing. The results were negative for human pathogens. During the incident investigation, it was determined that the material had not reached the normal, appropriate level of thawing prior to initiating the dissection procedure. The employee involved in the incident will undergo retraining and the IBC recommended the use of safer sharps alternatives for this type of procedure.

II. Other reports
    a. None

Around the Room/Committee Discussion

I. IBC members were reminded to review the resources on the SharePoint site, regarding OSP's new initiative to modernize biosafety.

Adjournment

I. Meeting adjourned by IBC Chair at 1:26 pm.

Next Meeting

I. March 5, 2026- Executive Board Room, Building 549 (WebEx access available).