NIH Institutional Biosafety Committee Minutes
Location: National Cancer Institute at Frederick
May 7, 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)	☒ Paul Landon
☒ Sarah Hooper	☒ Wendy Kitta	
☒ 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. April 2, 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:
      - ❖ None

   c. Registration amendments (non-administrative)
      - ❖ Dr. Simone Difilippantonio: 2024-35-A8. *Description:* Add Adeno-Cre for instillations related to germ-free procedures.
      - ❖ Dr. Paul Roche: 2024-65-A1. Description: Add transduced murine cells for administration in vivo.

- ❖ Dr. Baktiar Karim: 2024-60-A4. Description: Add new microtome equipment as alternative.
- ❖ Dr. Eugene Valkov: 2025-19-A1. Description: Add primary murine cell lines for transduction.
- ❖ Dr. Esta Sterneck: 2026-26-A1. Description: Add primary human cell lines for transduction.
- ❖ Dr. Jeffrey Lifson: 2026-02-A1. Description: Add lipid nanoparticles containing mRNA.
- ❖ Dr. Yurong Song: 2025-56-A3. Description: Add transduced murine cell lines and updates to staff roster.
- ❖ Dr. Simone Difilippantonio: 2024-35-A10. Description: Add transduced cells, add locations and corresponding biological containment level.

d. Additional Committee Discussion: N/A

II. Registrations for Committee review

Ref# 200056 (Renewal), Dr. Daniel McVicar:

i. *Reviewers:* Yovandich, Bell

ii. *Summary:* The laboratory studies the innate immune response and the regulation of inflammation in the context of metabolism. Specifically, the metabolic basis for immune cell function in the response of innate immune cells to stimulation with proinflammatory stimuli is studied. In this protocol, the laboratory will challenge in-vitro macrophages with fungi, bacteria and parasites with and without drug treatment. These drugs are the well characterized inhibitors for various metabolic pathways.

iii. Committee Discussion:

-Section 8.7, 8.17.1.3, 8.24 and 8.26: Please update the text in this section to remove references to Building 571 for the pathogenic work. This work is now being conducted in Building 429, Room 23.

-Section 8.8: Under bullet point A (Source of larvae), please clarify that the prepared fecal cultures are from mice only and not from human subjects.

-Section 8.23: Do the referenced cardboard boxes have a plastic bag as a liner to prevent dissolving the cardboard boxes when wet pipettes and solid waste are discarded?

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 approved at:* BSL2, ABSL2

vii. Training prescribed to staff in the roster: AEP, BBP

viii. *Relevant sections of the NIH Guidelines:* N/A-No recombinant material is described.

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

x. Votes: 10 approved, 1 abstained

xi. The committee unanimously voted to approve this registration. Dr. McVicar abstained.

Ref# 200102 (Renewal), Dr. Denise Whitby:

i. *Reviewers:* Altmann, St. Croix

ii. *Summary:* The in vitro procedures performed by the laboratory are multiform and include viral and cellular transcriptional analysis, viral DNA sequencing, endpoint dilution assays for viral load testing in lieu of infectivity, and immune cell functional assays using cell lines as targets, etc. The experimental need which these procedures meet is similarly varied: The development and evaluation of in vitro infection methods, the investigation of the molecular mechanism of reactivation and persistence, including assessing the role of sequence variation and the effect of small molecules on virus lifecycle and replication, the study of the immune response to infected cells.

iii. *Committee Discussion:*
-Section5.28.1.1: Can sharps alternatives be used for band excision? Multiple non-sharp band cutting products are available. Please modify the text accordingly.

-Section 5.31: The text in section 5.6 (under the column Activities at Location) indicates that double gloves are worn as needed. That point is not communicated in section 5.31 or in the attached SOP. Please correct the text in this section and in the SOP (then re-attach the updated file to the registration).

-Section 7.5: Please clarify the text to indicate whether samples are fixed before assessment using FACS.

-Section 7.8.2.2: The text needs to include a disclaimer indicating that specimens that are not negative controls come from research participants who have a variety of risk factors, and are likely to be infected by bloodborne viruses, such as HIV, HCV, HBV etc.; therefore, multiple pathogens may be present in the samples.

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, VVST

viii. *Relevant sections of the NIH Guidelines:* Sections III-D-2-a and III-E-1.

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

x. Votes: 11 approved, 0 abstained.

xi. The committee voted to approve this registration pending clarification and Dr. Altmann's concurrence.

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

i. *Reviewers:* Altmann, Perepnikhatka

ii. *Summary:* The objective of this protocol is to test human specimens using Luminex bead-based technology to determine cytokines and antibody levels and evaluate the associations of the cytokines and antibody levels with age, gender, vaccination status, natural infection status, and other comorbidities. Testing will be performed according to manufacturer's procedure manual or internal developed standard operating procedures (SOP)s for each Luminex bead-based assay.

iii. Committee Discussion:

-Section 7.5 and Associated SOPs: The committee has expressed concern regarding the washing steps that take place on the bench, outside of containment. Currently, work involving HIV samples is described as being performed under BSL2* conditions, and the washing steps are conducted in the BSC. Note: HIV is not a concern from the aerosol perspective. Why are all other non-HIV samples (which could pose aerosol hazards) washed outside of containment on the bench? Is it feasible to conduct the washes for BSL2 work inside the BSC? What is the rationale for not washing the BSL2 samples inside the BSC? The committee has requested a visit to the laboratory to conduct a risk assessment. The Biosafety Officer and IBC Coordinator will work with the lab to schedule a suitable date and time for the visit. Once the visit is completed, the applicable modifications may be made to the registration and accompanying SOPs. The registration can be re-submitted at that point.

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 material is described.

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

x. Votes: 11 approved, 0 abstained.

xi. The committee unanimously voted to defer this registration pending clarifications and a visit to the laboratory by the Biosafety team.

Ref# 200247 (Renewal), Dr. Chengkai Dai:

i. *Reviewers:* Hughes, Gulani

ii. *Summary:* The main objective of this project is to understand how protein folding and degradation impact cancer development and further to explore the potential to target cancer proteome for anti-cancer therapy. In this project, two major types of experiments will be conducted: in vitro and in vivo. In vitro, proteins, peptides, cDNAs, siRNA/shRNAs, human and mouse cell lines will be utilized. For in vivo experiments, both immunocompetent and immunocompromised mice will be used.

iii. Committee Discussion:

Section 4.2.1.1-There are some discrepancies between the attached file "Viral Vector-gene combination" and the viral vector summary table of the registration form. Please address the following:
1. For the pLenti/V5-DEST line items (6th, 9th and 10th row) in the registration form: Note-It is recommended to have these three rows combined into one for clarity.

a. The 6th row indicates that oncogenes, tumor suppressor genes and reporter genes are encoded within the viral vector. Under column "Transduced Cells Administered to Animals?", the response indicates that cells which have been transduced with this vector system will not be administered in vivo. However, this information is not aligned with the text in line items 2 through 6 in the attached spreadsheet, which indicates that the transduced cells are in fact administered in vivo. Please correct to

ensure alignment between the registration and the attachment. Also, please make sure that the same cell lines are indicated in both portions.

b. Regarding the 9th and 10th row of the table on the registration: Only two cell lines are identified as being modified with the vector system, whereas 8 are identified on line items 2 through 6 of the attachment. Please correct.

2. Regarding the pLKO.1 vector system (Rows 1 and 8 on the summary table of the registration): Note-It is also recommended to combine these two rows for clarity.

a. In the first row of the table of the registration: The text in column "Transduced Cells Administered to Animals?" indicates that transduced cells are not administered in vivo. However, this is not aligned with the details provided in line items 30 and 31 of the attachment, which indicate that transduced A2058 cells are administered in vivo.

b. The column "Gene Type Encoded within Vector" in the registration's summary table (for row 1 and 8) does not identify the dangerous cargos in the shRNA, such as PTEN and other genes associated with carcinogenesis (as described in line items 24 through 31 of the attachment). Please include references to those genes under column "Gene Type Encoded within Vector" in the registration form. Please also include a statement similar to what is stated for pLX304 (indicating the hazard and to conduct all work in the BSC and avoiding the use of sharps because the materials can lead to carcinogenesis).

3. At the top of the attachment "Viral Vector-gene combination": Please include a strong statement indicating that shRNAs and cell
lines that have been transduced viral vector systems encoding such shRNAs are dangerous because they can cause carcinogenesis. For this reason, it is imperative to take precautions when working with the materials. All work needs to be performed in the BSC and sharps usage needs to be avoided to prevent exposure events.

4. Please attach an Excel spreadsheet listing the targets of the shRNAs under study.

-Section 5.20.1.3: Please clarify in the text, whether the tissue pulverization occurs in a BSC in the laboratory.

-Section 5.34: It is recommended to follow up the bleach disinfection procedure of corrodible surfaces with a wipe down using distilled water and then 70% ethanol or isopropanol solution. Please modify the text as applicable.

-Section 5.37: The autoclaving of carcasses in animal facilities is no longer applicable. Please modify the text to indicate that animal carcasses are bagged and placed in a facility dedicated freezer for eventual pick up by EHS Waste Management. The frozen animal carcasses are then sent out for incineration.

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:* BSL2, ABSL1, ABSL2
vii. Training prescribed to staff in the roster: AEP, BBP, VVST
viii. *Relevant sections of the NIH Guidelines:* Section III-D-1-a; III-D-3-a; and III-E-3-a
ix. Public comment: None provided by the general public.
x. Votes: 10 approved, 1 abstained.
xi. The committee unanimously voted to approve pending clarifications. Dr. St. Croix abstained.

Ref# 200259 (Renewal), Dr. Marina Dobrovolskaia:

i. *Reviewers:* Altmann, Yovandich
ii. *Summary:* The laboratory utilizes cell lines to evaluate nanoparticle cytotoxic properties and for mechanistic toxicology assays (e.g., autophagy, oxidative stress, lysosomal dysfunction) and mechanistic immunology assays (e.g., activation of toll-like receptors, nitric oxide induction). While the laboratory regularly does not conduct cancer efficacy studies, occasionally, cell lines are used for vivo studies when needed, to utilize tumor models to evaluate nanoparticles.

iii. Committee Discussion:
The procedures and materials in the registration have not changed significantly at the time of renewal. Simple modifications made to the document include the attachment of one updated file describing the targets under study and updates to the staff roster.

iv. *Animal studies proposed:* Yes, mice and rats.
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, BSL2*, ABSL2
vii. Training prescribed to staff in the roster: BBP, AEP
viii. *Relevant sections of the NIH Guidelines:* N/A-No recombinant material is described.
ix. Public comment: None provided by the general public.
x. Votes: 11 approved, 0 abstained.
xi. The committee unanimously voted to approve as written, pending Dr. Altmann's concurrence.

Ref# 200284 (New), Dr. Stanley Adoro:

i. *Reviewers:* Perepnikhatka, Gulani
ii. *Summary:* The laboratory uses human cell lines for in vitro assays quantifying the effects of various perturbations to the pathways that regulate proteostasis. Adoptive cell transfer models with oncogene-expressing human blood stem cells lacking key proteostasis sensors is utilized to investigate their role in leukemia development and leukemia resistance to standard and targeted therapies.

iii. Committee Discussion:
-Section 4.2.1.1:
1. Please address the following items on the table in the registration form:

A. Under column "Gene Type Encoded within Vector" for both rows: Please clarify if pseudotyped lentiviral vectors encoding oncogenes going to be used to transduce cells (primary human, primary animal, human cell lines, animal cell lines) that are then injected into mice?

B. Under column "Gene Type Encoded within Vector" for both rows: Please state what envelope is used in conjunction with the viral vectors.

C. Regarding the first row: MSCV is currently identified as amphotropic. This needs to be changed to ecotropic. Note: The same should apply to the lentiviral vectors, depending on the envelope being used. Also, please note that vectors are ecotropic at the time that they are introduced into the mice (via the cells); however, there is an inherent hazard in the viruses already present in the mice (especially in the case of immunocompromised animals, which can be permissive for recombination events taking place). Potential recombination events may result in the mice shedding replication competent viruses that are capable of infecting humans (due to their pantropic nature) and have a higher hazard profile especially because oncogenes are involved. The text needs to be enhanced to alert readers that caution must be exercised when isolating tissues from those animals (especially in immunocompromised animals) that were inoculated with the viral vector (encoding oncogenes)- transduced cells. For the case of the primary human cells and human cell lines, the pantropic viruses would be capable of infecting humans and leading to carcinogenesis.

2. Suggestion: The files currently attached in sections 6.12 and 5.14 should be attached to this section as well. Note: Please make sure to modify the attachment in 5.14 as advised in the comments within that section. Once the file is updated, please attach it to section 4.2.1.1.

-Section 5.2: Please correct the text to indicate that BSL-1 and BSL-2 cells should be RG1 and RG2 cells, respectively.

-Section 5.14: Please provide an Excel spreadsheet, which includes descriptions of the genes being encoded using viral vectors. The spreadsheet needs to clearly identify which vector/cell line combination are introduced in vivo (along with mitigation steps outlined). The current attachment in this section provides information about the viral vectors used, but it does not provide information about the genes encoded nor the transduced cells. Recommendation: The attachment that is currently included in section 6.12 of the form can be adapted to address the requirements for this section. Additionally, the attachment in section 5.2 can also be combined into the Excel spreadsheet to show a comprehensive landscape of the cell lines, vectors and encoded genes being administered in vivo.

iv. *Animal studies proposed:* Yes,

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, ABSL1, ABSL2

vii. Training prescribed to staff in the roster: BBP, AEP

viii. *Relevant sections of the NIH Guidelines:* Section III-D-2-a, Section III-E-1 Section III-F-8: Appendix C-VIII exemption
ix. Public comment: None provided by the general public.
x. Votes: 11 approved, 0 abstained.
xi. The committee unanimously voted to approve pending clarification.

Ref# 200507 (Renewal), Dr. Anna Maciag:

i. *Reviewers:* Freed, Keele
ii. *Summary:* The laboratory focuses on the development of small-molecule therapeutics for RAS-driven cancers. Cellular and biochemical assays suitable for high-throughput screening are developed and implemented to identify compounds that directly inhibit RAS and/or disrupt RAS interactions with effector proteins.

iii. Committee Discussion:
The document is described adequately, and the research only involves in vitro work.

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-a.
ix. Public comment: None provided by the general public.
x. Votes: 11 approved, 0 abstained.
xi. The committee unanimously voted to 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. *Incident report:* The Biosafety Officer provided a summary of the incident that occurred in Building 535, On April 15, 2026. A government employee working in a biological safety cabinet (BSC) within the Biosafety Level 2* laboratory in building 535 room 122, sustained a splash to the face with a pseudotyped, envelope-deficient lentivirus. The employee was using a 3 mL syringe and Luerlock .45 micron filter for virus supernatant filtration. While pushing the plunger to expel the virus supernatant into the tube, there was pressure detected and the continuous depression of the plunger lead to failure of the filter. The viral material sprayed outside of the BSC and onto the employee's face contacting the chin area, between the nose and upper lip, and inside the right nostril. The employee was not sitting at the BSC properly and was wearing personal protective equipment to include Tyvek suit, double gloves, and prescription eyewear but no safety glasses. The employee reported to OHS immediately and received first aid. This incident is reportable to NIH Office of Science Policy.

Please note the highlighted text above (derived from the original incident report that was sent to program leadership), indicating the employee received first aid. It was later determined that the employee was provided with one dose of the approved medication for post-exposure prophylaxis (PEP), in addition to first aid, as a result of a potential HIV exposure. The employee was provided with a baseline blood draw upon reporting to Occupational Health Services (OHS) immediately following the incident. Follow up blood draws will be offered to the employee by OHS per PEP guidelines. The incident report was submitted to the Office of Science Policy (OSP) with a notation indicating that the employee had received post-exposure prophylaxis.

Incident Causes:

• Improper position while working inside of BSC.Improper equipment while sitting at BSC.
• Failure to follow SOP for body position at BSC.
• Failure to follow SOP when filtering viral supernatant in BSC.

Follow-up Actions - What is Being Done & Lessons Learned:

•Three Findings and Actions have been generated:
1. Replace chair with one that has no arm rests, and a surface that is not slippery.
2. Face masks and disposable face shields are made available for use. Safety glasses will be required when working in the BSL2* lab. Face shields may be used in lieu of safety glasses. Face shields and face masks are required when performing virus filtration activities.
3. Update laboratory SOP and update virus filtration procedure and provide retraining to all staff performing this task.

IBC Discussion:

Initially, there were questions about the actual virus type that the employee was working with at the time of the incident (enveloped vs. non-enveloped virus). OHS, the Chair of the IBC, the PI and employee were involved in those discussions. As a confirmatory step, the PI's laboratory analyzed the samples involved in the incident, and it was determined that they contained enveloped virus.

The EHS director and other members of the committee shared their questions and feedback:

1. Is there a possibility for seroconversion? Baseline blood tests were conducted, as described in the post exposure prophylaxis (PEP) protocol and no issues were identified.
2. What part of the system used for the supernatant filtration failed (The gasket, luerlock, etc?)? It was discussed that exerting excessive pressure could lead to failure. In addition, if the filter was not placed properly, that could also result in failure of the system.
3. What behaviors could have contributed to this outcome? Complacency was suggested as a potential cause. In addition, confusion as to what samples were present in the BSC at the time of the incident.
4. Are there concerns with potential side effects of the treatment that the employee received? The administered drugs are innocuous and should not lead to severe effects.
5. Could the laboratory benefit from a similar system for labelling biological materials, as is done in animal facilities (for example, the use of cage cards with detailed information about what employees are working with)? This could be helpful for medical staff when employees report to OHS after an incident.

II. Other reports
    a. None

Around the Room/Committee Discussion

I. None

Adjournment

I. Meeting adjourned by IBC Chair at 1:31 pm.

Next Meeting: June 11, 2026- Executive Board Room, Building 549 (WebEx access available).