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

March 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		

Announcements & Call to Order

I. Meeting called to order by IBC Chair at 12:01 pm.

Review of Past IBC Meeting Minutes

I. February 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. Ramiro Iglesias Bartolome- IBC 2026-10: Animal Models of Skin Biology and Cancer (Breeding-Only, Renewal)
        Reviewers: Altmann, St. Croix
      - Dr. Yousuke Takahama- IBC 2026-12: Colony Maintenance for Thymus Biology (Breeding-Only, Renewal)
        Reviewers: Gulani, St. Croix

- ❖ Dr. Barbara Felber- IBC 2026-15: Storage Only-Felber Laboratory (Storage-Only, Renewal)
  Reviewers: Perepnikhatka, Bell

c. Registration amendments (non-administrative)
- ❖ Dr. Jose Sanchez Hernandez 2024-22-A3. *Description:* Add new plasmids and update the staff roster.
- ❖ Dr. Yurong Song: 2025-56-A2. Description: Add human platelets.

d. Additional Committee Discussion: N/A

II. Registrations for Committee review

Ref# 200192 (Renewal), Dr. Esta Sterneck:

i. *Reviewers:* Perepnikhatka, Yovandich

ii. *Summary:* The laboratory's aims and objectives involve the investigation of a gene of interest as a function of mammary tumor progression. The laboratory previously generated genetically modified mouse models to implant mammary tumor cells. It was subsequently found that tumor growth, tumor-induced splenomegaly and myeloid subtypes analyzed by surface marker expression were reduced in tumors from mutant mice compared to controls, and neutrophils clusters analyzed by single cell RNA sequencing were reduced in bone marrow from mutant mice compared to controls mice. These data suggest that the gene of interest is required to generate normal number of myeloid cells, which may directly or indirectly contribute to tumor growth and progression.

iii. Committee Discussion:

-Section 4.2.1.1:

1. Regarding the Viral Vector Summary Table and the file "Viral Vector List-200192 March 2026":

A. The information in the IBC registration and in the attached file are not in agreement with each other. Some vector families are listed in the registration, which are not mentioned in the attachment. Please correct and re-attach the file.

B. Please make sure that the modifications made to the attachment "Viral Vector List-200192…" (as requested below), are also adapted into the summary table of the registration form.

2. Regarding the file "Viral Vector List-200192 March 2026":

A. There is a nomenclature issue that needs to be corrected in the document. The pDEST construct is a standard E. coli expression vector. However, the name of the parental plasmid system is being used interchangeably to refer to the expressed lentiviral vector. Only the name of the expressed lentiviral vector should be used, for clarity. Note: While the source of the parental plasmid system may utilize the same nomenclature to refer to the derivative lentivirus and to the parental bacterial plasmid, this practice is discouraged because it leads to confusion when staff read the IBC registration and supporting documents. Please address these points in the registration and in the attachment.

B. The genes encoded within the viral vectors are not sufficiently described. Some of them are potentially oncogenic and this needs to be acknowledged in the table. In addition to stating the name

of the gene, please make sure to provide details about the nature of the gene (for example, identify it as an oncogene, proto-oncogene, tumor suppressor gene, etc.).

C. As currently presented, the table does not adequately demonstrate which vector/gene combinations will be used to modify cell lines that will be administered in vivo. It is recommended to use the template that has been attached to this section of the registration, for additional guidance as to what information the committee is seeking in the modified version of the table. The template may be adapted to the list of vectors. Once the document is updated, please re-attach it to the registration.

D. The committee is particularly concerned about MSCV-modified cell lines being injected in vivo (due to the potential for recombination events between the viral vector and endogenous elements within cells in the inoculated animals). This hazard needs to be clearly communicated in the table.

-Section 6.34: For consistency, the spill response in this section needs to indicate the use of an IBC approved EPA registered disinfectant and IBC approved contact time.

-Section 7.6.1.2: Please describe in the text, what type of homogenizer is used. Also, please clarify if the homogenizer is in a primary containment device and indicate what such device is.

-Section 7.12: Please clarify the text to indicate that an IBC approved EPA registered disinfectant at the approved contact time will be used.

-Section 7.13: For consistency, please modify the text to indicate that the spill response in this section requires the use of an IBC approved EPA registered disinfectant and contact time.

-Section 8.20: Please indicate the contact time for Cavicide disinfection (3-5 minutes) and describe how the soiled cleaning materials are to be discarded.

-Section 8.21: Please provide the requested information. The response cannot be N/A.

-Sections 8.22 through 8.25: Please make sure that the text in these sections is consistent with details provided in sections 7.10 through 7.17 of the document.

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, VVST
viii. *Relevant sections of the NIH Guidelines:* Section III-D-2-a.
ix. Public comment: None provided by the general public.
x. Votes: 10 approved, 1 abstained
xi. The committee unanimously voted to conditionally approve this registration. Dr. McVicar abstained.

Ref# 200237 (Renewal), Dr. Dwight Nissley:

i. *Reviewers:* Keele, Altmann

ii. *Summary:* The Cell Development Group (CDG) is tasked with supporting the cell culture needs of the Ras Initiative through 1) receiving, maintaining and distributing a repository of frozen cell line stocks; 2) development and production of cell based tools via replication incompetent lentivirus transduction or transient/stable DNA transfection to visualize and/or test the impact of RAS protein mutations as well as the effector proteins contained up or downstream relative to RAS within or outside of the MAPK signaling pathway on cellular growth or gene expression. This work also extends to other signaling pathways, which may or may not be affected by the presence or absence of RAS in the cells; 3) Perform quality control tests on all generated or received cell lines.

iii. *Committee Discussion:*
This registration is adequately described, and the SOP could serve as a reference for other investigators conducting viral vector 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 proposed at:* BSL2

vii. Training prescribed to staff in the roster: 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: 11 approved, 0 abstained.

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

Ref# 200510 (New), Dr. Raymond Fox:

i. *Reviewers:* Freed, St. Croix

ii. *Summary:* The Mechanism of Action Laboratory (MOAL) provides in-depth characterization of the molecular mechanism for combinations of FDA approved oncology agents. Specifically, the MOA lab is tasked with understanding the mechanism of action of approved cancer agents that have shown efficacy in the clinic when used in combination. This work will complement both preclinical research (in mouse models and human cell lines) and ongoing clinical trials. By understanding the mechanism of action of these drug combinations, the data generated by using human cell lines will help reduced toxicity through more selective patient selection for future clinical trials.

iii. Committee Discussion:

-Section 4.3: The text in section 4.3.2.1 currently indicates that all cell lines receive some form of screening prior to their use in assays. If this is correct, then the response to the question in section 4.3 needs to be changed to state "Yes" and the follow up questions need to be completed accordingly. Please address.

-Section 4.5:

1. Is the plate reader used for cell viability assays in the BSC? If not, how is plate reading performed safely? Are lids always kept on plates for plate reading? Please address in the text.

2. The text in this section must be clarified to indicate that the Fox laboratory will only generate the transduced cells which will then be transferred to the Alcoser group/other collaborators. Note: Per previous communications with the PI, it was indicated that the Alcoser group will subsequently conduct in vivo procedures with the transduced cells, per their approved IBC registration and corresponding ASP. Therefore, the Alcoser group will be required to amend their experimental IBC registration (and ASP) to include the new transduced cells obtained from the Fox laboratory, and the corresponding procedures in vivo. The work under Dr. Alcoser's IBC registration and ASP cannot proceed without first obtaining approvals from the IBC and ACUC, respectively. Please make the necessary modifications to the text to reflect these points.

3. The text in this section must clearly state how long the transduced cells remain in cell culture prior to the commencement of in vitro assays. There also needs to be a statement describing how long after transduction any viral vector-modified cells will be cultured before the cells are transferred to another lab.

4. The committee requires that the PI and laboratory staff complete the Viral Vector Safety training in Edge prior to initiating procedures with the vectors and transduced cells.

-Section 4.12: Regarding the attached SOP, titled "MOAL SOP Viral Vectors":

1. The PI must include strong declarative statements in the text, acknowledging the hazards associated with the viral vectors and the oncogenic inserts (pages 11-12 of the sample SOP described below could be referenced as examples for the type of information that needs to be entered). The statements need to be added to the introduction of the laboratory SOP. The objective of the statements is to inform laboratory staff about the dangers of working with the vectors and why it is important to always adhere to BSL2 practices and conducting all procedures with the vectors/transduced cells in the BSC. Suggestion: Language from the safety SOP that was attached to IBC registration Ref# 200237 (Dr. Dwight Nissley's IBC registration) could be used as an example for Dr. Fox to develop specific language for his SOP and registration. Pages 11, 12 and 21 through 42 of Dr. Nissley's SOP should be referenced for guidance as to what elements needs to be incorporated into the Fox lab SOP.

2. The SOP needs to be enhanced to include specific safety provisions for conducting the virus production and virus concentration in a safe manner. Recommendation: Language from the sample SOP (pages 21-42) could be referenced as an example.

3. The SOP must contain signature fields for laboratory staff to acknowledge that they have read and understood the contents of the SOP. The PI is required to provide laboratory-specific guidance to staff prior to initiating procedures. Administrative Note: The IBC Office may recommend tools to the PI to support these educational efforts.

-Section 4.23: Please remove the last sentence of the text. Details pertaining to liquid waste disinfection are already addressed in other sections of the form.

-Section 5.2: The text in this section must be clarified to indicate that the Fox laboratory will only generate the cells which will then be transferred to the Alcoser group/other collaborators. Note: Per previous communications with the PI, it was indicated that the Alcoser group will subsequently conduct in vivo procedures with the provided cells, per their approved IBC registration and corresponding ASP. Therefore, the Alcoser group will be required to amend their experimental IBC registration (and ASP) to include the new cells obtained from the Fox laboratory, and the corresponding procedures in vivo. The work under Dr. Alcoser's IBC registration and ASP cannot proceed without first obtaining approvals from the IBC and ACUC, respectively. Please make the necessary modifications to the text to reflect these points.

-Section 7.21: Regarding the first bullet point: The current text appears to be a copy/paste error (as it describes surface disinfection procedures and not liquid waste treatment). Please replace the statement with a description of how the liquid waste is disinfected prior to disposal (for example, indicating the use of an IBC approved EPA registered disinfectant and contact time).

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, VVST
viii. *Relevant sections of the NIH Guidelines:* Section III-D-3-a.
ix. Public comment: None provided by the general public.
x. Votes: 11 approved, 0 abstained.
xi. The committee unanimously voted to conditionally approve, pending modifications to the registration and SOP. The lead reviewers will assess the documentation once modifications are made.

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. None

Adjournment

I. Meeting adjourned by IBC Chair at 12:50 pm.

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