NIH Institutional Biosafety Committee Minutes
Location: National Cancer Institute at Frederick Facilities
September 17, 2026
12:00 PM – 2:00 PM
Virtual Meeting available via WebEx

Members Present:

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

Announcements & Call to Order

I. Meeting called to order by interim IBC Chair (Dr. Yovandich) at 12:02 pm.

Review of Past IBC Meeting Minutes

I. August 6, 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. Clifford Folmes- IBC 2026-51 (Ref# 200519): SOM Center Storage Protocol for Human Cell Lines (New, Storage-Only)

c. Registration amendments (non-administrative)
   - ❖ Dr. Robin Dewar: 2024-23-A3. *Description:* Add Dengue/Zika virus assays.
   - ❖ Dr. Shari Price: 2026-37-A2. Description: Add primary human cell lines, update locations, update responsibilities for staff in the roster.

d. Additional Committee Discussion: N/A

II. Registrations for Committee review

Ref# 100031 (Renewal), Dr. Thomas Zheng: To Determine the Mechanism of SARS-CoV-2 Replication, Subgenome Synthesis and Expression.

i. *Reviewers:* Keele, St. Croix

ii. *Summary:* The laboratory studies virus replication by monitoring cytopathic effects (CPE) induced by infection. At various points of infection, cell media will be collected to determine virus titer on uninfected cells. In addition, the infected cells will be harvested in TRIZOL reagent for determining the expression of viral genomic and subgenomic RNAs using RT-PCR, Northern blot, RNA-seq and Iso-seq analyses or in SDS-protein sample buffer or RIPA buffer for preparation of total cell proteins for Western blot or co-IP analyses.

iii. Committee Discussion:

-Section 5.5:

1. The attached SOP does not appear to contain the requested virus concentration and titration procedure/safety provisions. Please upload a modified version of the SOP to this section.

2. Regarding the text in the registration: It is recommended to modify the text to make it more safety focused, rather than being too focused on the technical details. Make sure to indicate that the work is done in the BSC and while following BSL2 practices the entire time.

3. Please explain in the text whether the viruses generated in the course of experiments can be made more pathogenic than wild type versions. Is the host range and the ability of virus to replicate being affected? If yes, how? Are these really "infectious" cDNA clones? Changes applied in this section also need to be applied to section 8.7. The focus needs to be placed on what affects the synthesis of subgenomic rna and whether a pathogen that is enhanced could be generated.

4. Please specify the names of the mutants, which are being generated (you may also attach an Excel spreadsheet listing them)

-Section 5.34: Please remove the word "immediately" from the phrase "The spills will be immediately covered..." as this is not done immediately after the spill, but after 30 min (after the affected area is evacuated for 30 minutes post-spill).

Section 6-General Comments:

1. The feedback that was previously provided by the committee was not addressed. The comments have been re-entered. Please complete all requirements in their entirety.

2. Section 8 of the form currently describes icSARS-CoV-2 being used in the infection assays. Will these viruses be used in conjunction with the animal cell lines? If yes, all fields within section 6 need to be updated to reflect their use.

-Section 6.5:
1. Please add a statement indicating whether only the hCoV-OC43 wild type and mutant viruses will be applied to the HCT-8 cell line. Alternatively, will the icSARS-CoV-2 clones also be applied? Please correct the text as applicable.

2. Please attach applicable laboratory SOP(s) that describe how the cell culture and infection procedures are performed safely, in addition to describing the rules of the laboratory. Note: The SOP also needs to provide detailed safety provisions for virus concentration and titration activities.

3. Please provide a declarative statement, indicating that the laboratory does not engage in cell line transductions (with viral vectors), and that only purified viral stocks will be used for infecting cells.

-Section 6.31: Section 8.19 indicates that face masks are required. If they are actually used, please ensure that the text is consistent throughout the document.

-Section 6.33:
1. Please correct the text to reflect IBC- approved concentration and contact time. Please also indicate in the text that after the contact time has elapsed, the decontaminated liquid waste will be discarded down the drain with copious amounts of water.

2. For waste that cannot be treated with bleach and discarded down the drain, such as waste containing Trizol: Because the lab works with Trizol this section needs to be updated to indicate how Trizol waste is safely discarded. Mixing bleach (sodium hypochlorite) with guanidine compounds produces highly hazardous and potentially fatal toxic gases, such as chlorine, chloramine, and hydrogen cyanide. Please indicate in the text that the waste is discarded into an approved, leak proof, properly labeled container and that the EHS Waste Management form will be completed to schedule a hazardous waste pick up.

-Section 6.34:
1. The second sentence needs to be made the first sentence. When a spill occurs outside of containment, the area needs to be evacuated for 30 minutes to allow aerosols to settle down. Signage is then placed on the door to alert other staff to avoid entry into the space. Please address these points in the text.

2. The current first sentence ("spills will be covered with paper towels...") needs to be entered after the sentence where staff don the appropriate PPE and initiate spill clean up activities. Please make sure to also indicate that the freshly prepared bleach solution will be gently poured over the paper towels and a contact time of 30 minutes will be allowed.

3. Regarding the last sentence: Waste that is soaked in bleach cannot be autoclaved, as doing so will cause corrosion inside the autoclave, and will cause the creation of hazardous gases inside the autoclave. Such waste needs to be discarded in biomedical waste boxes/bags destined for incineration. Please correct the text.

-Section 6.35:
1. Waste that is soaked in bleach cannot be autoclaved, as doing so will cause corrosion inside the autoclave, and will cause the creation of hazardous gases inside the autoclave. Such waste needs to be discarded in biomedical waste boxes/bags destined for incineration. Please correct the text.

2. In addition to plastics such as petri dishes, flasks, pipette tips, etc. please indicate in the text how soiled paper towels and other lab waste is discarded (non-bleached waste). Are non-bleach soaked materials placed in an autoclave bag and autoclaved prior to disposal into black bags? Please clarify in the text.

-Section 8.8:
1. Could any of the mutations being tested potentially make the virus more pathogenic? Are the viral products replication competent? Please explain why or why not in the text.

Items that were not addressed in the previous iteration. Please complete as requested:

2. Please describe in the text exactly what the referenced cDNA clones are (make sure to clarify that they are the actual virus/full viral genome and not viral vector systems used for transduction), along with how they are handled safely. Do they pose any potential risks to users?

3. Previous sections of the form describe MV1LU cells, but they are not described here. Please correct.

4. Please attach applicable laboratory SOPs that describe the rules of the laboratory and how the work with the viruses (to include cell culture, infection assays, titration, and viral concentration) are conducted safely.

-Sections 8.14 and 8.15: Please complete this section with the required details about each viral product.

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, VVST
viii. *Relevant sections of the NIH Guidelines:* Section III-D-2-a.
ix. Public comment: None provided by the general public.
x. Votes: 7 approved, 1 abstained
xi. The committee unanimously voted to defer review of this registration

Ref# 200082 (Renewal), Dr. Sanchez Hernandez: Assembly and Purification of a HA-Trimer/Pentamer Nanocage Flu Mosaic Vaccine

i. *Reviewers:* Yovandich, Hughes
ii. *Summary:* The biological materials used in this work are previously manufactured and purified recombinant protein components used to assemble investigational nanoparticle vaccine products, currently focused primarily on influenza using the Flu Mosaic nanoparticle platform. The purified recombinant protein components and assembled nanoparticle do not possess known risk properties associated with infectious agents. They are non-replicating, non-transmissible protein materials and

do not constitute live influenza virus. They do not produce spores or infectious virus and are not capable of propagating within or outside a host.

iii. *Committee Discussion:*
-Minor modifications were requested during the review process, to enter information from the attachments into the registration form. Additionally, details pertaining to projects described in other IBC registrations were removed.

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: 8 approved, 0 abstained.
xi. The committee voted to approve.

Ref# 200184 (Renewal), Dr. Barbara Felber: Expression of Cytokine, Viral, and Cellular Genes for the Development of Nucleic Acid Immunotherapies

i. *Reviewers:* Altmann, Perepnikhatka
ii. *Summary:* The objective of the research is to develop immunotherapeutic interventions for HIV and cancer. Plasmids are generated upon insertion of cDNAs that are isolated by the laboratory or are obtained from other investigators or from commercial sources and are cloned into standard eukaryotic expression vectors (providing a promoter, polyadenylation signal and a selection marker for growth in bacteria). cDNAs are obtained upon conducting RT-PCR or as synthetic restriction fragments from a plasmid generated by outside vendors. The sequence of the generated plasmid is confirmed by nucleotide sequencing. Human cell lines are utilized for transfection, and protein products are studied by Western blotting or ELISA. Stable cell lines to produce cytokines and HIV Env are produced to generate recombinant proteins.

iii. Committee Discussion:
- Section 3.2.1.1: Why is the virus restricted to a single round of infection? What specific engineering features allow the virus to only replicate once? The text states that the vector contains the HIV envelope of interest (from the plasmid DNA). With this in mind, it seems all the pieces are present to make replication competent HIV. If non-replication competent HIV is generated, how is that possible? It would seem likely that when the HIV vector is complemented with HIV env that all the sequences needed to produce a replication competent HIV would present. If this is not correct, please explain why. If this is correct, it would suggest that extra precautions should be taken with the HIV env assays because of the possibility that replication competent HIV could be produced. Please clarify the text in this section to address this.

-Section 4.5: The text indicates that the work is performed in a BSC within tissue culture room 226C. Transfected cells are fixed (presumably formalin fixed, thus rendering them non-infectious) and subjected to indirect immunofluorescence with anti-FLAG or anti-HA antibodies or antiserum to the protein. Alternatively, the protein of interest fused to GFP can be visualized in live cells (in this

scenario the cells remain potentially infectious, which the committee has concerns about). If the materials are infectious, movement of the samples should be minimized. Additionally, precautions must be taken when transporting samples (make sure to describe how the samples are transported safely).

-Section 4.10: The response needs to be changed to Yes. Please also address sections 4.11 through 4.18.

-Section 4.11: Check the box for "Lentiviral Vector" and respond to all the questions below (4.12 through 4.18) to provide details about the pHIV- 1NLEnv-NanoLuc produced in HeLa and HEK293 cell lines with VSV-G, HIV env.

-Section 4.12: The registration needs to clearly discuss the likelihood of recombination of vector and various env genes. The specific workflow that would need to be addressed is moving plates with infectious virus into a different lab and microscopically assess expression.

-Section 4.24: Regarding the attachment "IBC_HIVSIVmouse_GeneBFK1.pdf":
a. The formatting of this table needs to be fixed. Currently, all the columns are on different pages and the information cannot be assessed properly.

b. The column "Delivery in vivo" indicates that some of the materials are administered to animals; however, the information in section 4 of the form does not describe any in vivo work. If the referenced in vivo work is performed in Bethesda, this needs to be clearly stated on the table for the fields that indicate "Yes" under the column "Delivery in vivo".

c. COVID spike and nucleocapsid are listed on the table. They need to be removed, because the general descriptions within this registration indicate that only cancer and HIV work is being undertaken in this registration.

-Section 9.3:
Regarding the attachment "IBC_HIVSIVmouse_GeneBFK1.pdf":
a. The formatting of this table needs to be fixed. Currently, all the columns are on different pages and the information cannot be assessed properly.

b. The column "Delivery in vivo" indicates that some of the materials are administered to animals; however, the information in section 4 of the form does not describe any in vivo work. If the referenced in vivo work is performed in Bethesda, this needs to be clearly stated on the table for the fields that indicate "Yes" under the column "Delivery in vivo".

c. COVID spike and nucleocapsid are listed on the table. They need to be removed, because the general descriptions within this registration indicate that only cancer and HIV work is being undertaken in this registration.

-Section 9.5 (and 9.2): Aren’t alpha replicons described in another registration? They should be removed from all various sections within section 9 if another registration already describes them.

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, BSL2*, ABSL2
vii. Training prescribed to staff in the roster: AEP, BBP
viii. *Relevant sections of the NIH Guidelines:* III-D-2-a.
ix. Public comment: None provided by the general public.
x. Votes: 8 approved, 0 abstained.
xi. The committee unanimously voted to defer.

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

i. *Reviewers:* Yovandich, Perepnikhatka
ii. *Summary:* The laboratory serves as a core facility for the research community. Tissue culture at small scale is conducted to provide live cells for single cell analysis controls. DNA and RNA may also be extracted in the process.

iii. Committee Discussion:
The BSO and IBC Coordinator conducted a walkthrough of the spaces that the laboratory utilizes for the intake, processing and sequencing of samples. All contingencies from the previous review were addressed adequately.

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, BSL1
vii. Training prescribed to staff in the roster: BBP
viii. *Relevant sections of the NIH Guidelines:* N/A- No recombinant material identified.
ix. Public comment: None provided by the general public.
x. Votes: 8 approved, 0 abstained.
xi. The committee unanimously voted to approve.

Ref# 200281 (Renewal), Dr. Claudia Mani: Small Animal Imaging Program

i. *Reviewers:* St. Croix, Bell
ii. *Summary:* The FNLCR Small Animal Imaging Program provides Investigators with a state-of-the-art in vivo multimodality imaging facility to characterize animal models, perform drug efficacy studies, and characterize new imaging agents and drugs. In vivo imaging studies include magnetic resonance, nuclear (Positron Emission Tomography, Single Photon Emission Tomography, and X-ray Computed Tomography), optical (bioluminescence and fluorescence), and ultrasound imaging.

iii. Committee Discussion:

The committee's discussion indicated that there is a need for having SAIP SOPs which describe how intake forms are managed and reviewed to ensure that IBC requirements are met. When an intake form is submitted by an investigator, what is the workflow? Who confirms that the biological containment level is appropriate for the work scope? Are there any loopholes?
The currently presented intake form should be modified further, to include a field at the top where it is documented what the animal's housing status is (ABSL1 vs. ABSL2).

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. *Animal studies proposed:* Yes, mice and rats.

vi. *Work is described at:* BSL2
vii. Training prescribed to staff in the roster: BBP, AEP
viii. *Relevant sections of the NIH Guidelines:* N/A- No recombinant material described.
ix. Public comment: None provided by the general public.
x. Votes: 8 approved, 0 abstained.
xi. The committee unanimously voted to defer this registration.

Ref# 200307 (Renewal), Dr. Barry O'Keefe: Whole Cell Anti-HIV Screening Assay

i. *Reviewers:* Freed, Keele
ii. *Summary:* The Molecular Targets Program (MTP) is regularly engaged in screening complex natural products extracts for their activity against HIV. Replication-competent virus assays are particularly useful for the screening of natural product extracts where complex mixtures of compounds, with no pre-determined molecular targets, are allowed to access multiple virus lifecycles in a susceptible host cell system. This affords MTP the opportunity to engage previously undetermined targets and pathways with new chemical diversity and use the assay results to drive not only the discovery of new compounds but also the determination of new mechanisms of anti-HIV activity. This level of discovery is critical to deriving the maximum benefit from screening programs

iii. Committee Discussion:
The registration is properly described as written.

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- no recombinant material described.
ix. Public comment: None provided by the general public.
x. Votes: 8 approved, 0 abstained.
xi. The committee unanimously voted to approve.

Ref# 200309 (Renewal), Dr. Barbara Felber: Studies Using Infectious SIV/HIV Isolates and SIV/HIV Molecular Clones

i. *Reviewers:* Altmann, Perepnikhatka

ii. *Summary:* The laboratory works with complete molecular clones of either SIV or HIV, which are administered to human cell lines to produce complete viral particles. The supernatant of those cultures will be used to infect primary human cells or other cell lines. The objective is to assess the loss of infectivity and thus evaluate the success of the vaccination by incubating the supernatant with different concentrations of antibodies or plasma from vaccinated animals (containing neutralizing antibodies).

iii. Committee Discussion:

- Sections 3.2 and 4.10: Check "No" as the response. It appears this information on the table, is duplicative of what is already included in IBC registration 200184.

-Sections 4.11 through 4.16: Please clear the responses in these fields, since this information should only be described in IBC registration Ref# 200184. The details from this registration can be incorporated into 200184. This IBC registration only applies to wild type viruses being used. The lentiviral vector work is best suited for IBC 200184.

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:* BSL1, BSL2*

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

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

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

x. Votes: 8 approved, 0 abstained.

xi. The committee unanimously voted to defer this registration.

Ref# 200520 (New), Dr. Ligia Pinto: Sphingolipid and Phospholipid Signaling Section

i. *Reviewers:* Freed, Hughes

ii. *Summary:* The objective of this project is to evaluate the transfection efficiency and cellular effects upon use of a polymer of interest to transfect mammalian cell lines with siRNAs and anti-sense oligos targeting a gene of interest. The gene of interest is being evaluated as a therapeutic target for Neuropathic Pain and Oncology.

iii. Committee Discussion:

The registration is well written and no additional modifications are required.

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: 8 approved, 0 abstained.
xi. The committee unanimously voted to approve.

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. Reminder: The committee was reminded about the deadline for providing feedback to the NIH draft Biosafety Policy for Research Involving Biohazards (including Draft Incident Reporting Template and Draft IBC Meeting Minutes Template) is October 19th.
II. Reminder: All assignments for the October meeting are available in Topaz.

Adjournment

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

Next Meeting: October 8, 2026- Executive Board Room, Building 549 (WebEx access available).