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

August 7, 2025
12:00 PM – 2:00 PM
Virtual Meeting via WebEx

Members Present (Quorum = 8)

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

Announcements & Call to Order

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

Review of Past IBC Meeting Minutes

I. July 10, 2025, Minutes
   a. Comments on minutes: None.
   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. Eros Lazzerini- IBC 2025-49: Transgenic/Knockout Animal Generation and Breeding-Only (New, Breeding-Only)
        Reviewers: Kozlov, Gulani
      - ❖ Dr. Hyun Park- IBC 2025-54: Breeding and Maintenance of Mice (Renewal, Breeding-Only)

Reviewers: St. Croix, Bell

- ❖ Dr. Avinash Bhandoola- IBC 2025-55: Early T Cell Development (New, Breeding-Only) Reviewers: Gulani, Bell

c. Registration amendments (non-administrative) approved in August:
   - ❖ Dr. Sandra Wolin: 2024-07-A1. *Description:* Add new bacterial strains and permit information.
   - ❖ Dr. Scott Durum: 2024-32-A3. Description: Add human cell lines.

d. Additional Committee Discussion: N/A

II. Registrations for Committee review

Ref# 200150 (Renewal), Dr. Vinay Vyas:

i. *Reviewers:* Perepnikhatka, Keele

ii. *Summary:* The laboratory generates small lectin molecules in E. coli. The generated molecules' activity as broad-spectrum viral entry inhibitors and potentially as neutralizers of many emerging viruses make them ideal candidates for human therapeutics. There is a critical need for both therapeutic and preventive antivirals, as well as for broad-spectrum drugs that may improve preparedness against emerging viruses in the future.

iii. *Committee Discussion:*

Section 8.8: Please provide additional details in the text about the project's goals.

Section 8.11.1.1: In addition to attaching and referencing the combined SOPs, please enter a brief summary in the registration, which describes how the E. coli cells will be lysed and how the molecules of interest are purified. If any operations that involve pressurized systems are carried out, then that should be briefly described in the registration, along with mitigation strategies for protecting staff.

Section 8.11.1.2: Please clarify in the text what volumes of culture will be produced at one time. The current response in the registration does not clearly distinguish whether 1-10 g refers to the amount of E. coli culture, or the amount of purified material.

Section 10.5: Please clarify in the text what is the target under investigation.

Section 10.6.1.1:
1. Please define all acronyms mentioned in this section (for example, is IEX an acronym for ion exclusion chromatography?)
2. Please clarify in the text what type of sizing will be performed.

Section 8.19: Please correct the text to indicate the use of Nitrile gloves.

General feedback: The text in the registration includes some outdated language. Please remove.

iv. *Animal studies proposed:* No

v. *Committee discussion about the applicability of dual use research of concern (DURC) and ePPP's (enhanced potential pandemic pathogens) regulatory requirements: The Committee determined that DURC and ePPP requirements do not apply to 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:* Appendix B-I, Appendix K
ix. Public comment: None provided by the general public.
x. Votes: 12 approved, 1 abstained
xi. The committee unanimously voted to approve pending minor clarifications. Dr. Yovandich abstained.

Ref# 200399 (Renewal), Dr. Ping Zhang:

i. *Reviewers:* Freed, Perepnikhatka
ii. *Summary:* The laboratory focuses on the structural and mechanistic studies of kinase complexes involved in different cancers and Parkinson's disease. Mammalian cell lines and insect cell lines are used for the production of recombinant kinases and their complexes which are then used for biochemical and structural studies to understand their function and aid the development of potential therapeutic agents.
iii. *Committee Discussion:* The registration adequately describes safety procedures the culturing of human cell lines and insect cell lines. Baculoviral systems are used, which are not infectious to human cells.
iv. *Animal studies proposed:* No
v. Committee discussion about the applicability of dual use research of concern (DURC) and ePPP's (enhanced potential pandemic pathogens) regulatory requirements: The Committee determined that DURC and ePPP requirements do not apply to 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-2-a.
ix. Public comment: None provided by the general public.
x. Votes: 13 approved.
xi. The committee unanimously voted to approve this registration as written.

Ref# 200434 (Renewal), Dr. Jana Ognjenovic:

i. *Reviewers:* St. Croix, Yovandich
ii. *Summary:* The Advanced Cryo-EM Technology (ACT) team is dedicated to the development, implementation, and advancement of cryo-electron microscopy (cryo-EM) and cryo-electron tomography (cryo-ET) technologies. The laboratory's primary focus is employing these advanced imaging methodologies to elucidate detailed structural insights into cellular processes, mechanisms, and architectures directly associated with human diseases, with a particular emphasis on cancer development and progression. Cryo-ET technology allows for the visualization of cellular components in their native, near-physiological state with unprecedented detail, thus enhancing understanding of cancer cell biology, including alterations in cellular organization, signaling pathways, and interactions at the molecular level.
iii. Committee Discussion:
Section 7.8:
1. Regarding the attached Excel spreadsheet: Please add a column next to the name of the gene/protein being encoded. In the new column, please clarify what is the cellular function of each protein. Are some of them (or all) calcium-channel transport proteins, RNA transferases, etc.?

2. Please elaborate on the bacterial purification and affinity chromatography steps. Please also attach the applicable SOP.

iv. *Animal studies proposed:* No

v. *Committee discussion about the applicability of dual use research of concern (DURC) and ePPP's (enhanced potential pandemic pathogens) regulatory requirements: The Committee determined that DURC and* ePPP requirements do not apply to 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-1-a.
ix. Public comment: None provided by the general public.
x. Votes: 13 approved.
xi. The committee unanimously voted to approve pending minor clarifications.

Ref# 200465 (Renewal), Dr. Thomas Turbyville:

i. *Reviewers:* St. Croix, Freed
ii. *Summary:* This project entails developing imaging and protein-protein interaction (PPI)- based assays to study the localization of tagged proteins in mammalian cells. Cells are transiently and stably transfected with plasmid DNAs that contain the recombinant genes that encode fluorescent proteins and the protein of interest. Transduced cells are also worked with. These cells are then imaged on optical microscopes, or light production is quantified in plate readers. The data provide precise information about the location of the proteins of interest in cells or the amount of protein-protein interaction occurring in the cells.
iii. *Committee Discussion:*
All cell transductions are conducted by collaborators. The Turbyville laboratory receives those transduced cells (Modified with lentiviral 3rd generation vectors), after remaining in culture for 2 weeks prior to their use in the procedures in vitro. All questions regarding oncogenes had been addressed by the investigator in advance of the meeting.
iv. *Animal studies proposed:* No
v. Committee discussion about the applicability of dual use research of concern (DURC) and ePPP's (enhanced potential pandemic pathogens) regulatory requirements: The Committee determined that DURC and ePPP requirements do not apply to 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-1-a, Section III-D-3.
ix. Public comment: None provided by the general public.
x. Votes: 13 approved.
xi. The committee unanimously voted to approve this registration as written.

Ref# 200455 (New), Dr. Ven Natarajan:

i. *Reviewers:* Hughes, Yovandich
ii. *Summary:* The laboratory receives and processes samples from patients enrolled in clinical trials. The samples are collected, stored and transferred periodically to the laboratory by NIAID. Upon receipt, nucleic acids are isolated from the samples. The isolated nucleic acids are then amplified by polymerase chain reaction to detect infection status.
iii. *Committee Discussion:*
The discussion centered around systems in place to track clinical specimens upon receipt. Requirements pertaining to sample tracking and subject information protection are under the purview of the IRB. The laboratory's SOP for nucleic acid extraction and processing, steps 4 and 5, describe how samples are identified and stored. Materials are also declared in the laboratory's annual

biomaterial inventory, which is managed by EHS. The text describes the use of Lemon DC. The investigator has clarified that it will not be mixed with bleach.

iv. *Animal studies proposed:* No

v. Committee discussion about the applicability of dual use research of concern (DURC) and ePPP's (enhanced potential pandemic pathogens) regulatory requirements: The Committee determined that DURC and ePPP requirements do not apply to 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- Recombinant materials are not described in this registration.

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

x. Votes: 13 approved.

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

III. Registration amendments for full committee review:

i. Registration Number, PI: N/A

ii. Reviewers: N/A

iii. Review Summary: N/A

iv. Committee Discussion: N/A

v. Animal studies proposed: N/A

vi. Committee discussion of 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. LASP Presentation (see Appendix I)

Reports

I. Biosafety Officer Report –

a. Reminder regarding conflict-of-interest disclosures: Committee members were reminded to declare conflicts of interest prior to each registration's discussion.

b. Decommissioning of the Register My Research system: IBC members were informed that the Register My Research system was officially decommissioned, effective August 5th, 2025.

II. Other reports

a. None

Around the Room/Committee Discussion

I. None

Adjournment

I. Meeting adjourned by IBC Chair at 1:30 pm.

Next Meeting

I. September 4, 2025- Executive Board Room, Building 549 (WebEx access available)

Appendix I: LASP Presentation on Isolators

August 7, 2025

The purpose of the presentation was to discuss PPE requirements for working within isolators and for performing isolator disinfection activities. Topics of discussion included the following areas of interest:

- Features of isolators
- Activities performed within isolators
- General practices for working in isolators
- Maintenance and disinfection activities for isolators and spaces where isolators are located
- Steps for maintenance and disinfection
- Challenges and solutions
- Long-term planning discussions