Institutional Biosafety Committee
Meeting Minutes

The meeting was called to order on 7/22/2025 11:30AM. A quorum was present. The meeting was held via Zoom and in-person (Melville Library – 5th Floor, Room W5530). The meeting was open.

Attendance
Voting Members Present:
Hwan Kim
Rachel Brownlee
Jorge Escobar
Nicholas Carpino
Jeronimo Cello
Christopher Kuhlow

Non-Voting Attendees, Staff and Guests Present:
Rebecca Dahl
Lu-Ann Kozlowski
Aimee Minton

Recording:
Erin Augello

Items
1. Meeting called to order at 11:30AM

2. Next Meeting Date and General Announcements
The next meeting date is 8/26/2025. Dr. Carpino surveyed the assembled group to assess any conflict of interest or quorum issues. Members should recuse themselves and leave the room or Zoom meeting during the review of a study on which they have a conflict of interest.

3. Review of Minutes from Last Meeting
Review type: **Full Committee Review**
Action: **Approved**

Effective date: **6/24/2025**
Vote: **Total = 6 for = 6 Opposed = 0 Abstained = 0**

4. Report on Continuing Reviews Requiring Full IBC Review
This section was reviewed and noted by the committee.

5. Report on New Studies for Committee Review

a. Review of PROTO202500005 IBC Protocol SheikhBahaei Lab

PI:	Shahriar Sheikhbahaei
Submission Type:	Initial Protocol
Safety Review Type:	Biosafety
Funding:	Name: Stony Brook University, Grant Office ID: Award #1193614 Project #:102148, Funding Source ID: 951840
Training:	Training is not up to date. Study team member must take ELS003.
Applicable Section of the NIH Guidelines that the Research Falls Under:	IIID
Containment Conditions:	BSL-2

Determination: Modifications required
Modifications (If Applicable):
i. Training is not up to date. Shahriar Sheikhbahaei must take ELS003.
ii. In Section: Biosafety Summary
Item 1. Due to the stated use of cells/cell lines and viruses, the following sections must be selected from the drop-down menu on the 'Biosafety Summary' page and the requested information provided: 'Primary cells or Cell Lines' and 'Viruses or Prions'. In addition, please fill out requested information on the 'Biohazard' page.
iii. In Section: Recombinant or Synthetic Nucleic Acid Work Description
Item 12. The ADV vector is replication deficient; therefore, please clarify if "No" was intended instead of 'Yes'.
iv. In Section: Rodent Gene Transfer: Virus
Item 3. PI indicated in a previous section that no helper virus would be used but checked 'Yes' in this section. Please clarify.
v. In Section: Exposure Assessment and Protective Equipment
Item 1. Please include information related to potential risks/consequences of utilizing Adenovirus. In particular, focus specifically on describing the routes and consequences of potential exposure to infectious agents. (Note that the risk group (RG) of an agent refers to its inherent hazard to human health, while the biosafety level (BSL) refers to the containment practices required during laboratory work involving that agent). These terms are not interchangeable. While both are important for risk assessment, this section should emphasize potential exposure routes (e.g., injection, mucosal, aerosol) and biological consequences of exposure to the agents used. BSL assignments should be addressed in the

biosafety practices section.

Item 2. In addition, several important biosafety considerations are missing or conflated:

a. Lentivirus and adenovirus vectors should not be equated in risk. While the lentiviral vector is third-generation (lower RCL risk), the adenoviral vector is first-generation and has a higher likelihood of generating replication-competent adenovirus (RCA), particularly via recombination with endogenous adenovirus or HSV in human handlers. Please revise to reflect this distinction.

b. Lentiviral vectors, even third-generation, can integrate into the host genome and pose a risk of insertional mutagenesis. Additionally, if replication-competent lentivirus is generated (e.g., via recombination), there is a theoretical risk of HIV-related disease. These consequences should be noted, even if the probability is low.

c. Adenovirus does not integrate into the genome, but can cause productive infections in the respiratory tract, especially in immunocompromised individuals. Please clarify this point and distinguish it from lentivirus, which integrates.

d. AAV vectors, while generally low-risk, can infect human cells depending on the serotype used (e.g., AAV2, AAV9). Although wild-type AAV is non-pathogenic, recombinant AAV may integrate at low frequency, particularly if the ITRs remain intact. Please address this low but possible risk of insertional mutagenesis and clarify whether the AAV is pseudo typed and what serotype is used.

e. Finally, PI correctly notes that incomplete pseudo typing may allow for infection of a host cell, but that the virus cannot spread due to deletion of the rabies glycoprotein (G). However, even a single infected cell—whether in an animal or a human (e.g., due to accidental injection)—can still produce high levels of viral proteins and transgene products, which may result in cytotoxicity or localized inflammatory responses, including nervous system. Please revise this section to reflect the potential consequences of such localized expression, and address risks to both animals and laboratory personnel in the event of accidental exposure or inoculation.

f. PI mentions the use of diphtheria toxin. However, there is not description of experimental work with this toxin and consequence of exposure to the toxin. PIease provide this information. In addition, toxin information should be provided on the ‘Biohazards’ page.

Item 4. Please provide information on location and certification of a BSC, due to use of human cell lines and AAV. (Is this part of vi?)

vi. In Section: Waste Management

Item 1. "BSL-2 waste containers" should be replaced with "regulated medical waste containers" or "RMW containers".

Item 2. "BSL-2 waste containers" should be replaced with "regulated medical waste containers" or "RMW containers".

Effective Date: 7/22/2025
Project Expiration: 7/8/2026
Votes:

For:	6
Against:	0
Recused:	0
Absent:	2
Abstained:	0

6. Report on Amendments Requiring full IBC review

a. Review of AMEND202500068 ZIKV Continuing Review

PI:	Erich Mackow
Submission Type:	Amendment
Safety Review Type:	Biosafety
Funding:	None
Training:	PI and all laboratory staff have received appropriate training.
Applicable Section of the NIH Guidelines that the Research Falls Under:	IIID
Containment Conditions:	BSL-2

Determination: Approved

Modifications (If Applicable):

i. In Section: Funding Resources
Item 1. No funding information is provided. Please clarify.

ii. In Section: Primary Cells or Cell Lines
Item 3. Remove bacterial cells from here, select the "Bacteria, Yeast, Fungi, or Parasites" option on the Biosafety Summary page and list bacterial cells in Table 1.

iii. In Section: Viruses or Prions
Item 2. PI describes the lentiviral system as "non-HIV derived." However, the packaging system (pCgpV, pRev) and vector backbone (pLenti) appears to be based on HIV-1 sequences, consistent with a third-generation HIV-based lentiviral vector system. Please clarify. (If pLenti is non-HIV derived, complete Item 14 on the rsNAM Work Description page).
Item 2. The CDC or NIH do not use"BSL-2H" as a defined category of containment. "BSL2H" should be clarified or replaced with "BSL-2 with enhanced precautions" if that is what is meant. If the work will be conducted under BSL-2 with enhanced precautions (often referred to as BSL-2+), please clearly describe the specific procedures and practices that constitute these enhanced conditions (e.g., use of sealed centrifuge rotors, respiratory protection, restricted access, etc.). This clarification is important for accurately assessing biosafety measures. Otherwise, indicate "BSL-2" throughout protocol submission.
*Risk Groups define risk level associated with a particular biological agent and not the type of containment or facility that is required. This wording should be corrected throughout the submitted protocol.

iv. In Section: Biohazards
Item 2. The only content in this section that directly addresses the required description of the agents is the first paragraph describing Zika virus strains and their intended use, and the final paragraph regarding lentiviral vectors. The intervening text primarily discusses biosafety practices, transmission risks, inactivation methods, and PPE, which are already addressed under Exposure Assessment and Protective Equipment. Please remove those sections from here to avoid redundancy and to keep this section focused on agent descriptions, as requested.

v. In Section: Exposure Assessment and Protective Equipment
Item 1. The statement that "no laboratory-acquired infections have been documented to date" is incorrect. Several laboratory-acquired Zika virus infections have been reported, including cases resulting from needle stick, aerosol exposure, or unknown routes. Please revise this statement to reflect current evidence. It is accurate to note, however, that no deaths or serious long-term sequelae from laboratory-acquired Zika infections have been reported to date.
Item 1. The sentence referring to "Standard Risk Group 2 facilities, safety precautions and cabinets, PPE…" is vague and overly broad. The term "Standard RG2 facilities" is not a defined containment designation.

Effective Date: 7/22/2025
Project Expiration: 7/21/2026
Votes:

For:	6
Against:	0
Recused:	0
Absent:	2
Abstained:	0

b. Review of AMEND202500072 2025 0709 amendment

PI:	Yue Zhang
Submission Type:	Amendment
Safety Review Type:	Biosafety
Funding:	None
Training:	Training is not up to date. Study team member requires ELS 003, EOS 004, ENV 001.
Applicable Section of the NIH Guidelines that the Research Falls Under:	IIID
Containment Conditions:	BSL-2

Determination: Approved
Modifications (If Applicable):
i. Training is not up to date. Study team member requires ELS 003, EOS 004, ENV 001.
ii. In Section: Biohazards
Item 2. Retrovirus is listed in point 1 however, it is not described here. Please provide requested description.
iii. In Section: Recombinant or Synthetic Nucleic Acid Work Usage
Item 1. Only 3 D applies. 3F does not. Please remove the latter.
iv. In Section: Recombinant or Synthetic Nucleic Acid Work Description
Item 1. Is retrovirus to be used? If so, describe any work involving e retrovirus
Item 11. If retrovirus is used in this protocol, complete information here
v. In Section: Exposure Assessment and Protective Equipment
Item 1. PI indicates the use of A549 human lung cancer cells ('Primary Cells and Cell Lines', Item 2). Therefore, please include information related to the consequences potential

exposure to bloodborne pathogens.
Item 1. If retrovirus is used in this protocol, describe potential consequence of exposure, such as the potential for insertional mutagenesis, and oncogenesis, leading to unintended infection and the potential for the virus to spread, disrupt, or activate genes, resulting in oncogenesis or other genetic effects.
Item 4. Please note: BSC recertification will be due 8/12/2025.

Effective Date: 7/24/2025
Project Expiration: 7/23/2026
Votes:

For:	6
Against:	0
Recused:	0
Absent:	2
Abstained:	0

c. Review of AMEND202500074 Stem Cells, Epidermal Differentiation, and Retinol Metabolism in mammalian cells and EPM in bacteria

PI:	Marcia Simon
Submission Type:	Amendment
Safety Review Type:	Biosafety
Funding:	None
Training:	Training is not up to date. Study team member requires ELS 002, ELS 003, EOS 004, ENV 001, ENV 005. Study team member requires ENV 001, ENV 005.
Applicable Section of the NIH Guidelines that the Research Falls Under:	IIID
Containment Conditions:	BSL-2

Determination: Approved
Modifications (If Applicable):

i. Training is not up to date. Study team members requires ELS 002, ELS 003, EOS 004, ENV 001, ENV 005. Study team member requires ENV 001, ENV 005. Training must be completed prior to protocol approval.
ii. In Section: Primary Cells or Cell Lines
Item 1. Remove E. coli and Rhizobium tropici
iii In Section: Exposure Assessment and Protective Equipment
Item 1. The second-generation lentiviral system carries a risk of generating replication-competent lentivirus due to the arrangement of packaging components, and the vectors retain the ability to integrate into the genome and potentially cause long-term effects. PI should also address the fact that pseudotyped MMLV vectors, especially when using VSV-G, can infect human cells and pose a risk of insertional mutagenesis. PI should revise this section to reflect these risks.
Item 4. Please provide room number of BSC location. Also, please note that annual certification is coming due soon.

Effective Date: 9/3/2025
Project Expiration: 9/2/2026
Votes:

For:	6
Against:	0
Recused:	**0**
Absent:	**2**
Abstained:	**0**

7. Review Of Incidents
None

8. Review of Other Agenda Items
None

9. Inspection Results
None

10. Discussion Items/Readings (major and minor points of order)
None

11. Meeting Adjourned at 12:07PM