Institutional Biosafety Committee
Meeting Minutes

The meeting was called to order on 9/22/2026 at 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:
Nicholas Carpino
Jeronimo Cello
Jorge Escobar
Hwan Kim
Christopher Kuhlow
Natalie Osorio
Alyssa Tuthill

Non-Voting Attendees, Staff and Guests Present:
Lu-Ann Kozlowski

Recording:
Erin Augello

Items
1. **Meeting called to order at 11:34AM**

2. **Next meeting date and general announcements**

The next meeting date is 10/27/2026. Dr. Kim 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: 9/22/2026

Vote: Total 7 For 7 Opposed 0; Abstained 0

4. Continuing reviews requiring IBC review

This section was reviewed and noted by the committee.

5. New studies for committee review

a. PROTO202600022 Therapies for kidney injury

PI:	Navjotsingh Pabla
Submission Type:	Initial Protocol
Safety Review Type:	Biosafety
Funding:	Name: Stony Brook Foundation, Grant Office ID: , Funding Source ID:
Training:	PI and all laboratory staff have received appropriate training.
Applicable Section of the NIH Guidelines that the Research Falls Under	III-D
Containment Conditions:	BSL-2

Determination: Modifications Required

Modifications (If Applicable):

i. BASIC INFORMATION

4. Please include a brief description of the rsNAM work.

ii. FUNDING SOURCES

1. Please complete and attach a document illustrating relevant research activities (if from grant applications, attach the research strategy portion).

iii. TISSUES, BLOOD OR BODILY FLUIDS

1. Mouse tissues can be used at BSL-1 and do not require BSL-2 containment unless they contain pathogens.

iv. BACTERIA, YEASTS, FUNGI OR PARASITES

1. The biocontainment level for E. coli is BSL-1, unless pathogenic organisms are used.

v. BIOHAZARDS

1. Mouse tissues and E. coli are BSL-1.

2. Please describe how the listed agents will be used for the proposed rsNAM work.

vi. RECOMBINANT AND SYNTHETIC NUCLEIC ACIDS USAGE

1. Please review and clarify if the proposed activities belong to III-D.

vii. RECOMBINANT AND SYNTHETIC NUCLEIC ACIDS WORK DESCRIPTION

2. Please edit the incomplete sentence.

The protocol indicates that a lentiviral vector is used. However, the PI answered "No" to Question 13, indicating that no HIV-derived lentiviral vector will be used. Please verify this response. If an HIV-derived lentiviral vector is used, Question 13 should be answered "Yes" and the corresponding section completed. If the lentiviral vector is derived from a source other than HIV, please answer Question 17 accordingly and complete the required information.

viii. ANIMALS

4. Please provide IACUC protocol information.

ix. GENETICALLY MODIFIED ANIMALS: DNA SOURCE

5. Change to "Yes" for use with lentivirus.

6. Change to "Yes".
Please clarify if lentiviruses are used in animals.
x. RISK GROUP AND CONTAINMENT PRACTICES
1. The response to the question regarding the highest Risk Group should be reviewed. Human cell lines are generally considered Risk Group 2 materials for institutional biosafety purposes. If the study uses an HIV-derived lentiviral vector, the highest Risk Group is RG3. If only a non-HIV lentiviral vector is used, the highest Risk Group is RG2. Please revise the response accordingly after clarifying the type of lentiviral vector used.
Effective Date: 7/31/2026
Project Expiration: 7/30/2027
Votes:

For:	7
Against:	0
Recused:	0
Absent:	3
Abstained:	0

b. SPROTO202600000005 Cancer and Intestinal Fibrosis Biosafety Protocol

PI:	Minguk Jo
Submission Type:	Initial Protocol
Safety Review Type:	Biosafety
Funding:	Name: National Institutes of Health, Grant Office ID: FP00016338, Funding Source ID: 1K22CA303691-01 • Name: Crohns and Colitis Foundation, Grant Office ID: FP00016415, Funding Source ID: 1287804
Training:	PI and all laboratory staff have been trained
Applicable Section of the NIH Guidelines that the Research Falls Under	III-D, III-E, III-F
Containment Conditions:	BSL-2

Determination: Modifications Required
Modifications (If Applicable):
i. GENE TRANSFER: VIRUS
2. Please change to "Yes".
ii. EXPOSURE ASSESSMENT AND PROTECTIVE EQUIPMENT
1. Pl should expand the consequences of potential RCL exposure to describe the possible clinical manifestations of an acute and/or persistent systemic lentiviral infection.
4. Please update the BSC certification date.
Effective Date: 9/3/2026
Project Expiration: 9/2/2027
Votes:

For:	7
Against:	0

Recused:	0
Absent:	3
Abstained:	0

c. SPROTO202600000008 68284528MMY4006

PI:	Michael Schuster
Submission Type:	Initial Protocol
Safety Review Type:	Biosafety
Funding:	• Name: Janssen Research and Development Limited Liability Company, Grant Office ID: , Funding Source ID:
Training:	PI and all laboratory staff have been trained
Applicable Section of the NIH Guidelines that the Research Falls Under	III-C
Containment Conditions:	BSL-2

Determination: Modifications Required

Modifications (If Applicable):

i. BASIC INFORMATION

4. Please revise and briefly describe how the patient's T cells are genetically modified, including the use of a lentiviral vector to introduce the CAR construct. The summary should clearly identify the genetically modified cells and the role of the lentiviral vector in generating the investigational product.

ii. FUNDING SOURCES

1. Please provide additional funding information.

iii. RECOMBINANT AND SYNTHETIC NUCLEIC ACIDS WORK DESCRIPTION

The protocol states that the BCMA-directed CAR transgene is introduced using a lentiviral vector; however, the specific lentiviral vector system is not identified, and the question regarding use of HIV-derived lentiviral vectors is marked “No.”

Please specify the lentiviral vector used to introduce the BCMA-directed CAR transgene and complete Point 13 if the lentiviral vector is HIV-derived, or Point 17 if a non-HIV-derived lentiviral vector is used.

4. Location is missing. If the Cell Therapy Lab is involved in making the CAR-T products and shipping them to SBU, please list the room where the samples will be stored and administered to patients.

iv. RISK GROUP AND CONTAINMENT PRACTICES

1. The committee cannot determine the origin of the lentivirus (whether it is HIV-derived or not). Please specify whether the lentivirus is HIV-derived.

v. EXPOSURE ASSESSMENT AND PROTECTIVE EQUIPMENT

1. The occupational exposure assessment currently addresses exposure to genetically modified T cells but does not address the theoretical risk of replication-competent lentivirus (RCL). Please address this risk.

vi. WASTE MANAGEMENT

1. & 4. Please list specific disinfectants and their contact times.

Effective Date: 9/27/2026

Project Expiration: 9/26/2027
Votes:

For:	7
Against:	0
Recused:	0
Absent:	3
Abstained:	0

d. SPROTO202600000012 Study of CC-97540 (BMS-986353), CD19-CAR T Cells, in Participants with Active SLE Despite Immunosuppressants (Breakfree-SLE)

PI:	Qing Ping Yao
Submission Type:	Initial Protocol
Safety Review Type:	Biosafety
Funding:	Name: Juno Therapeutics, Grant Office ID: , Funding Source ID:
Training:	PI and all laboratory staff have been trained
Applicable Section of the NIH Guidelines that the Research Falls Under	III-D
Containment Conditions:	BSL-2

Determination: Approved
Modifications (If Applicable):
i. BASIC INFORMATION
4. The research summary does not adequately describe the recombinant/synthetic nucleic acid molecule (rsNAM) component of the study. Please revise the summary to indicate that CC-97540 (BMS-986353) is an autologous CAR T-cell therapy and briefly describe how the patient's T cells are genetically modified, including the use of a lentiviral vector to introduce the CAR construct. Also, clearly identify the genetically modified cells and the role of the lentiviral vector in generating the investigational product.
ii. FUNDING SOURCES
1. Funding sources information is missing.
iii. PRIMARY CELLS OR CELL LINES
2. Information related to the patient's own T cells does not belong in "Other Mammalian Species Cell Lines".
Please add the following sections and complete the required information.
i) Recombinant or synthetic nucleic acid usage, ii) Recombinant or synthetic nucleic acid work description, and iii) Human Gene Transfer/Human Clinical Trial
iv. RISK GROUP AND CONTAINMENT PRACTICES
1. Cannot determine the source of the lentiviral vector (whether it is HIV-derived or not). If the lentivirus used to manufacture the CAR-T cell is HIV-derived, the RG is 3.
v. EXPOSURE ASSESSMENT AND PROTECTIVE EQUIPMENT
1. The response “Minimal” does not adequately address the question. Please describe the potential consequences of exposure irrespective of the likelihood of such exposure. Because the study involves human-derived cells, the response should acknowledge the potential consequences of exposure to bloodborne pathogens. In addition, because the CAR T cells are genetically modified using a lentiviral vector, please address the potential consequences

associated with exposure to the genetically modified cells/vector, including the potential for replication-competent lentivirus (RCL), even if the likelihood of such an event is considered very low.
vi. WASTE MANAGEMENT
3. Please indicate the specific disinfectant and the contact time.
Effective Date: 9/27/2026
Project Expiration: 9/26/2027
Votes:

For:	7
Against:	0
Recused:	0
Absent:	3
Abstained:	0

e. SPROTO202600000015 The carcinogenicity of 1,4-Dioxane

PI:	Fei Chen
Submission Type:	Initial Protocol
Safety Review Type:	Biosafety
Funding:	Name: National Institutes of Health, Grant Office ID: , Funding Source ID: 1R01ES038941-01
Training:	PI and all laboratory staff have been trained
Applicable Section of the NIH Guidelines that the Research Falls Under	III-D
Containment Conditions:	BSL-2

Determination: Modifications Required
Modifications (If Applicable):
i. FUNDING SOURCES
1. Please provide a specific aims page (or any relevant research strategy) of the application related to the protocol.
ii. BIOHAZARDS
1. List E. coli.
iii. RECOMBINANT AND SYNTHETIC NUCLEIC ACIDS USAGE
1. Please include Section III-D-4.
iv. RISK GROUP AND CONTAINMENT PRACTICES
1. Use RG3 if the lentivirus is derived from HIV.
v. WASTE MANAGEMENT
1 & 3. Please specifically list disinfectants, their concentrations, and contact times. We do not have an institutionally approved disinfectant.
Effective Date: 9/27/2026
Project Expiration: 9/26/2027
Votes:

For:	7

Against:	0
Recused:	0
Absent:	3
Abstained:	0

f. SPROTO202600000017 RNAi in symbiotic cnidarians

PI:	Aki Ohdera
Submission Type:	Initial Protocol
Safety Review Type:	Biosafety
Funding:	• Name: Stony Brook University, Grant Office ID: , Funding Source ID:
Training:	PI and all laboratory staff have been trained
Applicable Section of the NIH Guidelines that the Research Falls Under	III-D, III-F
Containment Conditions:	BSL-1

Determination: Modifications Required
Modifications (If Applicable):
i. BASIC INFORMATION
4. Please include a description of rsNAM work that will be done in this protocol.
ii. FUNDING SOURCES
1. Please include funding sources information.
ii. RECOMBINANT AND SYNTHETIC NUCLEIC ACIDS WORK DESCRIPTION
1. While the committee appreciates the experimental details listed in this protocol, additional details on the proposed rsNAM work are required for this section.
2. Please list the gene(s) to be genetically manipulated
iii. EXPOSURE ASSESSMENT AND PROTECTIVE EQUIPMENT
1.The response focuses primarily on the very low likelihood of accidental release and the measures used to prevent it. However, this section asks for the consequences of exposure or release irrespective of the probability of such an event. PI briefly describe the potential consequences of exposure to the dsRNA constructs and/or release of the treated organisms for humans, animals, and plants/environment, as applicable. If no adverse consequences are reasonably anticipated for a particular category, please state that explicitly and briefly explain why.
Effective Date: 9/27/2026
Project Expiration: 9/26/2027
Votes:

For:	7
Against:	0
Recused:	0
Absent:	3
Abstained:	0

6. Amendments requiring IBC review

None

7. Review of incidents
None

8. Review of other agenda items
None

9. Inspection results
All inspections and responses were summarized by Mr. Kuhlow and reviewed and noted by the committee.

10. Discussion items/readings (major and minor points of order)
None

11. Meeting adjourned at **12:02PM**