Institutional Biosafety Committee
Meeting Minutes

The meeting was called to order on 3/24/2026 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:
Rachel Brownlee
Nicholas Carpino
Jeronimo Cello
Jorge Escobar
Hwan Kim
Christopher Kuhlow
Natalie Osorio
Dafang Wang

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

Recording:
Erin Augello

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

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

The next meeting date is 4/26/2026. 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: 3/24/2026
Vote: **Total = 8; For = 8; 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. PROTO202500044 Krystal Biotech KB801 Neurotrophic Keratitis

PI:	Robert Honkanen
Submission Type:	Initial Protocol
Safety Review Type:	Biosafety
Funding:	Name: Krystal Biotech Incorporated
Training:	PI and all laboratory staff have been trained
Applicable Section of the NIH Guidelines that the Research Falls Under	Section IIID
Containment Conditions:	BSL-2

Determination: Modifications Required
Modifications (If Applicable):
i. In Section: Biosafety Summary
Although the HSV-1 vector is produced by a commercial entity, it is a recombinant viral vector. Therefore, Pl should select the "Recombinant and Synthetic Nucleic Acid Molecules" option from the dropdown menu and complete the new sections by providing a description of the genetic modifications (e.g., deletions rendering the virus replication-deficient, insertion of the nerve growth factor gene, and key regulatory elements), or reference manufacturer documentation that describes these features. This information is required for appropriate biosafety review.
ii. In Section: Tissues, Blood, or Body Fluids
Item 1. 'Human Derived Blood and Blood Types' should be handled at BSL2, not BSL1.
iii. In Section: Viruses and Prions
Item 1. HSV-1 should be handled in BSL2.
iv. In Section: Biohazards
Item 1. Should be BSL-2 for both items in this section.
v. In Section: Risk Group and Containment Practices
Item 1. Both items in the table should be handled at BSL-2.
vi. In Section: Exposure Assessment and Protective Equipment
Item 1. The description of consequences of exposure is incomplete and includes overly absolute statements (e.g., "no risk"). Please revise to describe the potential consequences of exposure, including mucosal exposure and accidental inoculation, and the possibility of local infection or inflammation. Although the HSV-1 vector is replication-defective and largely episomal, it can still enter cells and express residual viral genes, which may lead to cellular stress, cytotoxicity, or local inflammatory responses, particularly at mucosal surfaces. The response should focus on the possible outcomes following exposure, rather than statements minimizing risk.
Item 2. Please include lab coat and protective eyewear.

Item 4. If a Biosafety Cabinet is used in preparation of the study drug, please indicate location and certification date.
vii. In Section: Waste Management
Item 1. Please include contact time for the different disinfectants. Further, it is unclear the "site policy" that is referenced. Please clarify.
viii. In Section: Supporting Documents
Item 1. Please attach documentation from Krystal Biotech Inc describing the relevant technology/therapeutic approach.

Effective Date: 3/26/2026
Project Expiration: 3/25/2027

Votes:

For:	8
Against:	0
Recused:	0
Absent:	1
Abstained:	0

b. PROTO202500047 VWF in Thrombocytopenia During Systemic Candidiasis

PI:	Thomas Diacovo
Submission Type:	Initial Protocol
Safety Review Type:	Biosafety
Funding:	Name: Cellphire Therapeutics Incorporated, Grant Office ID: 1199919
Training:	PI and all laboratory staff have been trained
Applicable Section of the NIH Guidelines that the Research Falls Under	Section IIID
Containment Conditions:	BSL-2

Determination: Approved
Modifications (If Applicable):
i.In Section: Basic Information
Item 4. The summary refers to a Candida albicans strain with a "disrupted INT1 variant," but it is unclear whether this strain was generated using recombinant or synthetic nucleic acid methods. Please clarify whether rsNAM techniques were used to create this variant, or if it is an existing strain obtained from an external source.
ii. In Section: Biosafety Summary
If the "disrupted variant of wt C. albicans" will be generated using rsNAM method, PI should include and complete the Recombinant & Synthetic Nucleic Acids section
iii. In Section: Bacteria, Yeasts, Fungi, or Parasites
Item 1. Candida albicans should be handled following BSL2 practices and procedures.
iv. In Section: Biohazards
Item 1. Candida albicans should be handled following BSL2 practices and procedures.
v. In Section: Genetically Modified animals, DNA Source
Item 2. Please mark 'Yes' as animals will be bred internally.
vi. In Section: Risk Group and Containment Practices

Item 1. C. albicans is RG2. Change to RG2.
Item 2. NIH Guidelines physical containment should be BSL-2.
vii. In Section: Waste Management
Item 1. Please include contact time for disinfectants.

Effective Date: 3/26/2026
Project Expiration: 3/25/2027

Votes:

For:	8
Against:	0
Recused:	0
Absent:	1
Abstained:	0

c. PROTO202600008 Gut Virome and FMT Response and Ulcerative Colitis

PI:	Lasha Gogokhia
Submission Type:	Initial Protocol
Safety Review Type:	Biosafety
Funding:	Stony Brook University, Grant Office ID: 910226-08
Training:	PI and all laboratory staff have been trained
Applicable Section of the NIH Guidelines that the Research Falls Under	Section IIID
Containment Conditions:	BSL-2

Determination: Modifications Required
Modifications (If Applicable):
i. In Section: Basic Information
Item 4. The summary provides a clear description of the scientific objectives; however, it does not indicate whether the proposed work involves manipulation of recombinant or synthetic nucleic acid molecules (rsNAM). Please revise the summary to briefly describe any rsNAM work (e.g., genetic manipulation of bacteriophages, bacteria, or host systems), or explicitly state if no such work is involved.
ii. In Section: Funding Sources
Item 1. Please include funding sources information.
iii. In Section: Biosafety Summary
Item 1. Include rsNAM in this protocol and complete all information in relevant sections.
iv. In Section: Primary cells or cell lines
Item 1. The information is inconsistent and unclear. “Primary cells or cell lines from non-human primates” is listed, but the source provided is C57BL/6 mice, which are murine. Please clarify the species of origin. If both murine and non-human primate cells are used, they should be listed separately with accurate categorization, source, and use. If non-human primate cells are utilized, please identify the non-human primate.
v. In Section: Exposure Assessment and Protective Equipment
Item 1. Non-human primate cells may harbor zoonotic agents transmissible to humans. For primary materials, this may include agents such as Herpes B virus and enteric pathogens (e.g.,

Shigella, Salmonella, Campylobacter). Even for established cell lines, the potential for latent or adventitious agents exists. Therefore, if non-human primate cells are used, please describe the consequences of exposure to bloodborne pathogens.
vi. Item 4. A BSC is applicable for work with RG-2 strains of bacteria and human cells that require BSL-2 containment. Please include BSC certification information.
vii. In Section: Waste Management
Item 1. Liquid biological waste that is bleached and had the appropriate contact time can be flushed down a sink drain and is not collected by EH&S. Please revise.

Effective Date: 3/26/2026
Project Expiration: 3/25/2027

Votes:

For:	8
Against:	0
Recused:	0
Absent:	1
Abstained:	0

d. PROTO202600011 CKD Mechanisms

PI:	Shipra Agrawal
Submission Type:	Initial Protocol
Safety Review Type:	Biosafety
Funding:	Name: Dialysis Clinic Incorporated, Grant Office ID: 1195615-1-102945, Funding Source ID: C-4225 Name: National Institutes of Health, Grant Office ID: 1182891-1-97604, Funding Source ID: DK133440
Training:	PI and all laboratory staff have been trained
Applicable Section of the NIH Guidelines that the Research Falls Under	Section IIID
Containment Conditions:	BSL-2

Determination: Approved
Modifications (If Applicable):
i. In Section: Viruses and Prions
Item 1. Oligodeoxynucleotides (asODNs) are synthetic nucleic acids, not biological agents. They are neither viruses nor prions, and should not be listed in that category.
ii. In Section: Biohazards
Item 1. The AAV is being used as a delivery vector for oligonucleotides (asODNs). However, these should not be grouped together in the biohazards section. AAV is a viral vector and should be listed as the biohazard, while the asODNs represent the nucleic acid cargo and should be described under rsNAM.
Item 2. PI states that podocytes are free of any BBP. This statement should be removed unless it can be documented that the cells have been tested for and clear of every potential BBP.
iii. In Section: Recombinant or Synthetic Nucleic Acid Work Description

Item 10. Due to use of lentivirus, check YES and complete.
iv. In Section: Risk Group and Containment Practices
Item 1. Change to RG3, due to use of lentivirus.
v. In Section: Exposure Assessment and Protective Equipment
Item 1. The statement that the cell lines “do not contain any blood-borne pathogens” is not appropriate. All human-derived cell lines should be considered potentially infectious, as they may harbor latent or undetected bloodborne pathogens or become contaminated during handling. Please revise the description accordingly and ensure that the consequences of potential exposure are appropriately addressed.
vi. In Section: Waste Management
Item 3. Please provide more detail in the event of a biological accident or spill (i.e. what will be done with solid biological waste?, what PPE will be used, etc.).

Effective Date: 3/26/2026
Project Expiration: 3/25/2027

Votes:

For:	8
Against:	0
Recused:	0
Absent:	1
Abstained:	0

6. Amendments requiring IBC review

a. AMEND202600022 Add Personnel and Funding

PI:	Sian Piret
Submission Type:	Amendment
Safety Review Type:	Biosafety
Funding:	None
Training:	PI and all laboratory staff have been trained
Applicable Section of the NIH Guidelines that the Research Falls Under	Section IIID
Containment Conditions:	BSL-2

Determination: Approved
Modifications (If Applicable):
i. In Section: Funding Sources
Item 1. Please include sponsor's Funding ID/Grants Office ID information for two sources missing information.
ii. In Section: Primary cells or cell lines
Item 1. Do HK2 cells refer to HEK293T cells? If not, need to add the latter, as they mentioned in the rsNAM Work Description section.
iii. In Section: Exposure Assessment and Protective Equipment
Item 1. The statement that the cell lines “do not contain any blood-borne pathogens” is not appropriate. All human-derived cell lines should be considered potentially infectious, as they may harbor latent or undetected bloodborne pathogens or become contaminated during handling.

Please revise the description accordingly and ensure that the consequences of potential exposure are appropriately addressed.
iv. In Section: Waste Management
Item 1. Include incubation time of the bleach with the contaminant.
Item 3. Please provide additional details how a biological accident or spill will be handled (i.e. how will solid biological waste be handled?, use of PPE?, etc. etc.).

Effective Date: 3/25/2026
Project Expiration: 3/24/2027

Votes:

For:	8
Against:	0
Recused:	0
Absent:	1
Abstained:	0

b. AMEND202600026 Change in Personnel and Materials

PI:	Hwan Kim
Submission Type:	Amendment
Safety Review Type:	Biosafety
Funding:	None
Training:	PI and all laboratory staff have been trained
Applicable Section of the NIH Guidelines that the Research Falls Under	Section IIID
Containment Conditions:	BSL-2

Determination: Approved
Modifications (If Applicable):
i. In Section: Biohazards
Item 2. The response describes the clinical symptoms of COVID-19 but does not provide a description of the agent as requested. Please revise to include a brief description of SARS-CoV-2 as a biological agent (e.g., virus type, Risk Group classification, relevant transmission routes, and key biosafety considerations), rather than clinical manifestations of disease.
ii. In Section: Exposure Assessment and Protective Equipment
Item 1. Human cell lines may harbor latent or undetected bloodborne pathogens (e.g., HBV, HCV, HIV). Please include information related to potential exposure to BBP.

Effective Date: 4/23/2026
Project Expiration: 4/22/2027

Votes:

For:	7
Against:	0
Recused:	1
Absent:	1
Abstained:	0

c. AMEND202600033 260313 Host Interactions with Bacterial Pathogens

PI:	Adrianus van der Velden
Submission Type:	Amendment
Safety Review Type:	Biosafety
Funding:	None
Training:	Protocol team member needs to complete EHS training ELS003 and EOS004
Applicable Section of the NIH Guidelines that the Research Falls Under	Section 3III
Containment Conditions:	BSL-2

Determination: Approved

Modifications (If Applicable):

i. Training is not up to date. Van der Velden, Chen and Mathur require ELS 003 and EOS 004. Please ensure training is accomplished.

ii. In Section: Basic Information

Item 4. Please provide more detail in the summary, specifically describe the work that will be conducted with rsNAM.

iii. In Section: Funding Sources

Item 1. Include missing funding information (Grants office IDs, etc.).

iv. In Section: Bacteria, Yeasts, Fungi, or Parasites

Item 1. The designation of E. coli as BSL-2 is not appropriate for standard laboratory strains (e.g., DH5α), which are RG1 and handled at BSL-1 under routine conditions.

v. In Section: Biosafety Hazards

Item 1. E. coli should be designated BSL-1.

vi. Section: Recombinant or Synthetic Nucleic Acid Work Description

Item 2. The description is too broad and does not adequately answer the question. Please provide a complete and specific list of the genes/inserts to be cloned, their expected gene products, and the relevant regulatory elements. Terms such as “such as,” “virulence genes,” “antigens,” and “murine genes involved in immunity” are too vague for biosafety review, and the status of any transposable elements (active vs. inactive fragments) should also be clarified. The term “non-mammalian eukaryotic sequences” is too broad. Please specify the source organism(s) (e.g., yeast, insect, plant, or other) and the genes involved, as different sources may have different biosafety considerations.

Item 3. The response does not adequately address the question. Please provide a specific description of each gene/insert, including its biological activity/function and species of origin. General statements (e.g., “See above,” “may encode a potential toxin”) are insufficient for biosafety review, particularly when RG2-derived sequences are involved.

Effective Date: 3/26/2026

Project Expiration: 3/25/2027

Votes:

For:	8
Against:	0
Recused:	0
Absent:	1

Abstained:	0

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 **12:21PM**