

NIH Institutional Biosafety Committee Minutes
Location: Rocky Mountain Laboratories

December 18, 2025

1:00 PM – 3:00 PM

Virtual via Microsoft Teams/In person at Building A Room 322

Members Present:

Quorum Met: Yes

☐	Sue Priola	Chair	☐	Alida Merritt	Local Non-Affiliated
☒	Andrea Marzi	Vice Chair	☐	Alexandra Scranton	Member
☒	Rebecca Anderson	Biosafety Officer	☐	Clayton Winkler	Lab Representative
☒	Paul Beare	Lab Representative	☒	Todd Wohlman	Member
☒	Chris Bosio	Lab Representative	☐	Sonja Best	Ex officio
☒	Megan Brose	Member	☐	Marshall Bloom	Ex officio
☐	Larry Brouwer	Local Non-Affiliated	☐	Marcie Caldwell	Ex officio
☒	Chad Clancy	Animal Expert	☐	Frank DeLeo	Ex officio
☐	Erik Hoover	Local Non-Affiliated	☐	Heinz Feldmann	Ex officio
☒	Scott Kobayashi	Lab Representative	☐	Josh Kellar	Ex officio
☐	Jamie Lovaglio	Animal Expert	☐	Brian Vickrey	Ex officio

Guests Present:

Michael Kujawa, Grace Markley, Shanda Sarchette, Richard Baumann, Jocelyn Mendoza, Kaitlyn Connors, Madison Cahill, Jared Montana

Announcements & Call to Order

- I. Meeting called to order by Andrea Marzi at 1:02 pm.
- II. The IBC Chair reminded all members present to identify any conflicts of interest as each registration is reviewed.

Review of Past IBC Meeting Minutes

- I. November 20th, 2025 Minutes
 - a. Comments on minutes
 - i. 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 – None
 - b. rDNA and rDNA/pathogen Registration Numbers: None
 - c. Registration amendments summary: None
 - d. Committee Discussion: None

II. Registrations for Committee review

a. Registrations for committee review:

Ashley Groshong, 25-RML-015

- i. Reviewers: Scott Kobayashi, Paul Beare
- ii. Review Summary and risk assessment: This registration combines RD-21-134 & PRD-21-233 and includes two items of new material: 1) Added a signature tagged mutagenesis transposon library for *Borrelia burgdorferi* (added to pathogen section) and 2) a new *Borrelia hermsii* transposon vector (added in recombinant section). The reviewer noted that in the new transposon library section, the PI did not list the antibiotic resistance elements planned, this also occurs in other sections as well and needs to be updated. The PI also needs to clarify what proteins they are expressing in the section describing protein expression. Also, the DURC questionnaire could include antibiotic resistance explanation. Finally, the *Pichia* is a eukaryote, not prokaryote, this needs to be corrected in one section.
- iii. Committee Discussion: The committee agreed with the reviewer comments and had no further discussion.
- iv. Minimum PPE required, special practices, and recommended OMS consult if applicable: Lab coat and gloves.
- v. Training:
 1. Laboratory safety training (includes BBP training)
- vi. Animal studies proposed: No.
- vii. The committee discussed the dual-use and ePPP potential of these experiments. The committee agreed that there were no dual-use or ePPP concerns with the proposal.
- viii. Work is approved at BSL-2/ABSL-2
- ix. Relevant sections of the NIH Guidelines: III-D-1-a, III-D-2-a
- x. A motion was made to approve the registration pending the following changes or conditions.
- xi. The committee unanimously approved with minor modifications.
 1. Conflicts of Interest: None
 2. Votes for: 8 Votes against: 0 Abstained: 0

b. Registration amendments for committee review:

Marshall Bloom, PRD-19-75 Amend

- i. Reviewers: Not applicable; No recombinant DNA work
- ii. Review Summary and risk assessment: The registration amendment is to add another Flavivirus, Tick-borne encephalitis virus (TBEV) western subtype, Neudorfl. Neudorfl virus is transmitted naturally by ticks and causes neurological illness, including encephalitis in humans. It is known as a lower pathogenic strain compared to other TBEV viruses.
- iii. Committee Discussion: The committee noted that in the TBEV and Powassan virus sections, the PI needs to check the box for primary human cells. In the Powassan virus section, need to add the animal biosafety level is 3.
- iv. Minimum PPE required, special practices, and recommended OMS consult if applicable: Disposable gown, double gloves, N95 or PAPR, and shoe covers. Eye protection if potential for splashes.
- v. Training:

1. Laboratory safety training (includes BBP training)
2. BSL-3 laboratory biosafety training
3. Select Agent Training
- vi. Animal studies proposed: No.
- vii. The committee discussed the dual-use and ePPP potential of these experiments. The committee agreed that there were no dual-use or ePPP concerns with the proposal. The committee agreed that the registration meets the criteria for review by the DURC-IRE.
- viii. Work is approved at BSL-3
- ix. Relevant sections of the NIH Guidelines: Not applicable; no recombinant work
- x. A motion was made to approve the registration pending the following changes or conditions.
 1. In the TBEV and Powassan virus sections, the PI needs to check the box for primary human cells.
 2. In the Powassan virus section, need to add that the animal biosafety level is 3.
- xi. The committee unanimously approved with minor modifications.
 1. Conflicts of Interest: None
 2. Votes for: 8 Votes against: 0 Abstained: 0

Carrie Long, 24-RML-001 Amend

- i. Reviewers: Not applicable; No recombinant DNA work
- ii. Review Summary and risk assessment: The amendment is to add work with non-pathogenic amoeba and *Balamuthia mandrillaris*. *Balamuthia mandrillaris* causes Granulomatous Amebic Encephalitis. The amoeba is a “free-living” amoeba found in soil and warm, often stagnant water. It is a facultative parasite, causing infection and disease when entering the body through cuts, inhalation, or mucus membranes and generally infects individuals with compromised immune systems. Symptoms include: mental status changes, loss of coordination, fever, muscular weakness or partial paralysis affecting one side of the body, double vision, sensitivity to light, and other neurologic problems. Anti-fungal treatments are available and effective.
- iii. Committee Discussion: The committee had no comments or concerns with the amendment.
- iv. Minimum PPE required, special practices, and recommended OMS consult if applicable: Dr. Long has agreed to work with non-pathogenic amoeba in BSL-2 with BSL-3 practices. Work with *Balamuthia mandrillaris* & non-pathogenic amoeba is approved at BSL-2, with Biosafety Level 3 practices (BSL-2/3). BSL-2/3 includes enhanced practices in a BSL-2 facility: (1) fastidious adherence to proper microbiological techniques, (2) decontaminating all potentially infectious waste prior to removal from BSC, (3) working in a BSC wearing proper PPE- double gloves, full eye protection and mucus membrane protection, tie-back gown, (4) use of gasketed safety cups for centrifugation procedures, and (5) minimizing the use of sharps, among other considerations to minimize worker exposure to aerosols, such as only working in a certified Class II BSC for any procedures that may generate aerosols.
- v. Training:
 1. Laboratory safety training (includes BBP training)
- vi. Animal studies proposed: No.

- vii. The committee discussed the dual-use and ePPP potential of these experiments. The committee agreed that there were no dual-use or ePPP concerns with the proposal.
- viii. Work is approved at BSL-2 with BSL-3 practices
- ix. Relevant sections of the NIH Guidelines: Not applicable; no recombinant work
- x. A motion was made to approve the registration as written.
- xi. The committee unanimously approved with the registration as written.
 - 1. Conflicts of Interest: None
 - 2. Votes for: 8 Votes against: 0 Abstained: 0

Sonja Best, 24-RML-007 Amend

- iv. Reviewers: Andrea Marzi, Chris Bosio
- v. Review Summary and risk assessment: The amendment is to add experiments using reverse genetics to mutate Powassan, Langat, Yellow Fever, and Dengue virus. The amendment describes the rationale clearly and outlines the proposed modifications to each virus. Each recombinant DNA section of the registration was updated to include the proposed studies, however some of the sections include description of other viruses than what the specific section covers. This should be cleaned up to only state what is proposed for the specific virus in each section.
- vi. Committee Discussion: The committee discussed the proposed experiments and had no concerns with the amendment.
- vii. Minimum PPE required, special practices, and recommended OMS consult if applicable: Disposable gown, double gloves, N95 or PAPR, and shoe covers. Eye protection if potential for splashes.
- viii. Training:
 - 1. Laboratory safety training (includes BBP training)
 - 2. BSL-3 laboratory biosafety training
 - 3. Select Agent Training
- ix. Animal studies proposed: No.
- x. The committee discussed the dual-use and ePPP potential of these experiments. The committee agreed that there were no dual-use or ePPP concerns with the proposal. The committee agreed that the registration meets the criteria for review by the DURC-IRE.
- xi. Work is approved at BSL-3
- xii. Relevant sections of the NIH Guidelines: III-D, III-E-1
- xiii. A motion was made to approve the registration pending the following changes or conditions.
 - 1. In each recombinant DNA section, remove language about other viruses not relevant to the section.
- xiv. The committee unanimously approved with minor modifications.
 - 1. Conflicts of Interest: None
 - 2. Votes for: 8 Votes against: 0 Abstained: 0

III. Committee Review of Inactivation Procedures (if not reviewed under a registration)
 a. None.

IV. Standard Operating Procedures/Plans

- a. BSL-3 Suite A SOP
 - i. SOP Summary: The update was to add communication of when Burkholderia pseudomallei work is planned or in progress.
 - ii. Committee Discussion: The committee had no questions or comments.
 - iii. A motion was made to approve the SOP as written.
 - iv. The committee unanimously approved as written.
 - 1. Conflicts of Interest: None
 - 2. Votes for: 8 Votes against: 0 Abstained: 0
- b. BSL-4 SOP#4-28-17 Nonhuman primate procedures in Level 4 biocontainment
 - i. SOP Summary: The update adds more detail to the restraint procedures for handling of NHPs. This is a follow-up item related to the recent incident reported to the IBC.
 - ii. Committee Discussion: A committee member noted that in D.3.b., a sentence should be added to indicate an animal may be re-dosed with injectable anesthetic. As written it, it does not include the ability to re-dose when necessary.
 - iii. A motion was made to approve the registration pending the following changes or conditions.
 - 1. In section D.3.b., add a sentence to indicate an animal may be re-dosed with injectable anesthetic.
 - iv. The committee unanimously approved with minor modifications.
 - 1. Conflicts of Interest: None
 - 2. Votes for: 8 Votes against: 0 Abstained: 0
- c. Maximum Containment Laboratory Operations and Safety Procedures (MCL OSP)-Annual Review
 - i. SOP Summary: The update to the plan includes a description requiring research staff departing RML to either destroy inventory samples or to ensure that the PI assigns a responsible party for the remaining samples. The updates also include language to state the frequency that the Division of Safety collects breathing air samples for testing. The last update to the document includes new language to describe tagging cages of animals that are in an advanced disease state.
 - ii. Committee Discussion: The committee noted that there is no language to indicate an animal may be re-dosed with injectable anesthetic, this should be included.
 - iii. A motion was made to approve the registration pending the following changes or conditions.
 - 1. In section D.3.b., add a sentence to indicate an animal may be re-dosed with injectable anesthetic.
 - iv. The committee unanimously approved with minor modifications.
 - 1. Conflicts of Interest: None
 - 2. Votes for: 8 Votes against: 0 Abstained: 0

- V. Serious Adverse Events in Clinical Trials reviewed by the Committee
 - a. None

Reports

- I. Biosafety Officer Report – See attached

Around the Room/Committee Discussion

- I. None

Adjournment

- I. Meeting adjourned by Andrea Marzi at 01:55 pm

Next Meeting

- I. Scheduled January 15th, 2026.

NIH RML Institutional Biosafety Committee Meeting

Biosafety Officer (BSO) Report

December 18, 2025

Business Conducted since the last IBC Meeting

- A. BSO approvals
 - a. None
- B. Electronic business
 - a. Inactivation testing for MCL of Orthopoxviridae with SDS, Trizol, and RLT
 - b. SOP#4-28-31 Removal for Protein Analysis
 - i. Add inactivation methods for Orthopox viruses
 - c. SOP#4-28-32 Removal for Nucleic Acid Extraction
 - i. Add inactivation methods for Orthopox viruses

New business for IBC meeting

- A. See agenda.

Division of Safety activities since the last IBC Meeting

- A. Animal Study Protocols Review- Performed by Division of Safety staff
 - a. 4 ASPs reviewed since the last IBC meeting.
- B. Biosafety Training- Performed by Division of Safety staff

Type of Training	Number of Sessions	Number of Employees Trained
New Employee		
Annual Refresher Lab Biosafety	2	247
Select Agent-Initial	1	2
Select Agent- Refresher	3	87
Select Agent- Visitor	N/A	N/A
BSL-3 Laboratory Biosafety-Initial	1	2
Practical Training	1	2
BSL-4 Laboratory Biosafety-Initial	N/A	N/A
Suit Training	N/A	N/A
Checklist Training	3	3
BSL-4 Laboratory Biosafety-Refresher & SA Refresher	2	8
Laboratory Biosafety Support Staff-Initial	N/A	N/A
Laboratory Biosafety Support Staff-Refresher & SA Refresher	1	18
BSL-4 Medical Emergency Egress Training	N/A	N/A

- C. Biological Incidents to Report
 - a. None
- D. Other Updates
 - a. None