NIH Institutional Biosafety Committee Minutes
Location: Rocky Mountain Laboratories

November 20, 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:

Rachel Feldman, Michael Kujawa, Richard Baumann, Grace Markley, Jocelyn Mendoza, Heike Bailin, Kaitlyn Conners, Katherine Houghton, Shanda Sarchette,

Announcements & Call to Order

I. Meeting called to order by Sue Priola at 1:01 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. September 18th, 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:
    i. None

b. Registration amendments for committee review:
Vinod Nair, PRD-18-151 Amend
    i. Reviewers: Not applicable; No recombinant DNA work
    ii. Review Summary and risk assessment: This is an amendment to add influenza A virus to registration, the lab already has approval for influenza B strains. The microscopy group will perform imaging studies with influenza B. Handling of live virus is very minimal. Virus will be frozen on grids on their vitrobot, the SOP for that work is attached. Samples are either imaged or subsequently stained. The straining will take place in a BSC when using live virus. This detail is not included in the registration or SOP but should be added.
    iii. Committee Discussion: A committee member noted that there was reference to an attached strain list, but no list was attached. PI should make sure the list and sections throughout the document are consistent for strains of influenza. When "Inf" is used, it should spell out influenza.
    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
    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. Update SOP and registration to clarify that staining of live virus will be in a BSC.
        2. PI should make sure the list and sections throughout the registration are consistent for strains of influenza.
        3. "Inf" should be changed to spell out influenza.
    xi. The committee unanimously approved with minor modifications.
        1. Conflicts of Interest: None
        2. Votes for: _10____ Votes against: _0_____Abstained: __0_____

Carrie Long, 24-RML-002 Amend
    i. Reviewers: Not applicable; No recombinant DNA work
    ii. Review Summary and risk assessment: The Long lab is proposing to perform standard antimicrobial susceptibility testing against the following compounds: Cepfazidime (CAZ), Imipenem (IPM), Meropenem (MEM), Amoxicillin-clavulanic acid (AMC), Trimethoprim-sulfamethoxazole (SXT), Chloramphenicol (CAT), Doxycycline (DOX), and Tetracycline (TET). Samples to be tested include *Burkholderia pseudomallei* strains isolated from patients with melioidosis that are present in the environment and circulating in endemic areas. This work does not change the biosafety level, training, or PPE, but will need to be reviewed by the DURC-IRE.

iii. Committee Discussion: The committee discussed some items that need to be updated to clarify the registration: list the non-human primate cell lines that will be used. Uncheck the animal biosafety level boxes in the Eukaryote Cell section if no animal work is proposed and remove animal rooms from the locations section. There is one researcher that does not have an email address showing in the system so that should be corrected. For the location of *Burkholderia psuedomallei*, there is reference to a BSL-2 lab room number, this should be deleted. In the Assertions section, respirator training should be checked. In the Eukaryote cell section, change cells will be "inoculated" with to "infected" with.

iv. Minimum PPE required, special practices, and recommended OMS consult if applicable: Disposable gown, double gloves, N95 or PAPR, and shoe covers.

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 will need to be reviewed by the DURC-IRE.

viii. Relevant sections of the NIH Guidelines: Not applicable; no recombinant work

ix. A motion was made to approve the registration pending the following changes or conditions and DURC-IRE review.
   1. List the non-human primate cell lines that will be used.
   2. Uncheck the animal biosafety level boxes in the Eukaryote Cell section if no animal work is proposed and remove animal rooms from the locations section.
   3. Update the registration for the individual with an email address not showing in the system.
   4. Remove reference to a BSL-2 lab room number for the location of *Burkholderia psuedomallei*.
   5. In the Assertions section, respirator training should be checked.
   6. In the Eukaryote cell section, change cells that will be "inoculated" with to "infected" with.

x. The committee unanimously approved with minor modifications pending DURC-IRE review.
   1. Conflicts of Interest: None
   2. Votes for: _10____ Votes against: _0_____Abstained: __0_____

Rahul Suryawanshi, 24-RML-014 Amend

i. Reviewers: Not applicable; No recombinant DNA work

ii. Review Summary and risk assessment: The Suryawanshi lab is proposing to use tonsil organoids to investigate the effect of glucose concentration on antiviral immune response. They are already registered for human blood and body fluids and cell lines, but they had added another section to describe the proposed work with tonsil organoids and viral infections of those organoids.

iii. Committee Discussion: The committee members noted some items that need to be clarified/updated in the registration submission: in the new human blood and

body fluid section, where tissues are checked, they should write in the comment box, “tonsils”. The names of strains of influenza should be listed consistently throughout the document. In the Influenza eukaryote cell section, include human airway, brain, and tonsil organoids. The PI should spell out AAV at least once in the registration. In the AAV recombinant details section, the biological origin of the sequences should have human and bacterium also checked. In the AAV recombinant material handling section for what the expression product will be exposed to, the whole organism box should be checked. There were no other concerns with the amendment.

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

ix. Relevant sections of the NIH Guidelines: III-D-2, III-E-1

x. A motion was made to approve the registration pending the following changes or conditions.
   1. In the new human blood and body fluid section, where tissues are checked, they should write in the comment, “tonsils”.
   2. The strains of influenza should be listed consistently throughout the document.
   3. In the Influenza eukaryote cell section, include human airway, brain, and tonsil organoids.
   4. The PI should spell out AAV at least once in the registration.
   5. In the AAV recombinant details section, the biological origin of the sequences should have human and bacterium checked.
   6. In the AAV recombinant material handling section for what the expression product will be exposed to, the whole organism box should be checked.

xi. The committee unanimously approved with minor modifications.
   1. Conflicts of Interest: None
   2. Votes for: _10____ Votes against: _0_____Abstained: __0_____

III. Committee Review of Inactivation Procedures (if not reviewed under a registration)

a. Orthopoxviridae inactivation validation with SDS, Trizol, and RLT buffer for the MCL.

i. Inactivation procedure summary: The lab validated an inactivation protocol using either 2x SDS buffer, Trizol or RLT buffer plus ethanol. The appropriate controls were included and yielded the expected results. All test samples were negative by plaque assay.

ii. Committee Discussion: The committee discussed a few items that were not clear in the write-up. In the submission for 2x SDS, the $1x10^6$ PFU/mL was not clear if this was the amount of virus tested on the column or in the entire assay. A committee member also noted that SOP#4-28-31 listed a higher number of cells in the assay than what was tested. The committee determined that these questions need to be addressed before a complete review can occur. The

committee agreed to review the inactivation validation testing and associated SOPs electronically once the noted items were clarified. The committee stated that it was critical for the tested validation procedures to match the SOP.

iii. The committee tabled the review.

IV. Standard Operating Procedures/Plans

a. BSL-3 Suite D SOP

i. SOP Summary: The update was to add an agent summary section for another Flavivirus strain, Tick-borne encephalitis Western subtype.

ii. Committee Discussion: A committee member noted that "virus" should be added after Tick-borne encephalitis. A couple typos with the degree symbol were noted and should be corrected. It was also stated that the SOP on page 20 does not include the detail that we now require for our inactivation SOPs, this should be updated but can be done after this month. It was noted that this SOP was for non-select agent viruses.

iii. A motion was made to approve the plans pending the following changes or conditions

1. Insert "virus" after Tick-borne encephalitis.
2. Correct a couple typos with the degree symbol.
3. SOP on page 20 does not include the detail that we now require for our inactivation SOPs, this should be updated but can be done after this month.

iv. The committee unanimously approved with minor modifications.

1. Conflicts of Interest: None
2. Votes for: _10____ Votes against: __0____Abstained: __0_____

b. BSL-4 SOP#4-28-31 Removal for Protein Analysis

i. SOP Summary: The update is to add the new inactivation methods to the table of approved methods. This includes 2x SDS for cells infected with Orthopoxviridae.

ii. Committee Discussion: The committee agreed to review the inactivation validation testing and associated SOPs electronically once the noted items were clarified.

iii. The committee tabled the review.

c. BSL-4 SOP#4-28-31 Removal for Nucleic Acid Extraction

i. SOP Summary: The update is to add the new inactivation methods to the table of approved methods. This includes Trizol and RLT for cells infected with Orthopoxviridae.

ii. Committee Discussion: The committee agreed to review the inactivation validation testing and associated SOPs electronically once the noted items were clarified.

iii. The committee tabled the review.

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 Sue Priola at 02:00 pm

Next Meeting

I. Scheduled December 18th, 2025.

NIH RML Institutional Biosafety Committee Meeting

Biosafety Officer (BSO) Report

November 20, 2025

Business Conducted since the last IBC Meeting

A. BSO approvals
   a. None
B. Electronic business
   a. None

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. 7 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	1	4
Annual Refresher Lab Biosafety	n/a	n/a
Select Agent-Initial	1	1
Select Agent- Refresher	n/a	n/a
Select Agent- Visitor	1	1
BSL-3 Laboratory Biosafety-Initial	n/a	n/a
Practical Training	n/a	n/a
BSL-4 Laboratory Biosafety-Initial	n/a	n/a
Suit Training	n/a	n/a
Checklist Training	n/a	n/a
BSL-4 Laboratory Biosafety-Refresher & SA Refresher	n/a	n/a
Laboratory Biosafety Support Staff-Initial	1	1
Laboratory Biosafety Support Staff-Refresher & SA Refresher	1	33
BSL-4 Medical Emergency Egress Training	n/a	n/a

C. Biological Incidents to Report
   a. Form 3 reported to Federal Select Agent Program on 11/13/2025.

D. Other Updates
   a. None