NIH Institutional Biosafety Committee Minutes
Location: Rocky Mountain Laboratories
May 21, 2026
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
☒	Andrea Marzi	Vice Chair
☒	Rebecca Anderson	Biosafety Officer
☒	Paul Beare	Lab Representative
☒	Chris Bosio	Lab Representative
☐	Megan Brose	Member
☐	Larry Brouwer	Local Non-Affiliated
☐	Chad Clancy	Animal Expert
☒	Erik Hoover	Local Non-Affiliated
☒	Scott Kobayashi	Lab Representative
☐	Jamie Lovaglio	Animal Expert
☐	Alida Merritt	Local Non-Affiliated
☐	Alexandra Scranton	Member
☒	Clayton Winkler	Lab Representative
☐	Todd Wohlman	Member
☐	Sonja Best	Ex officio
☐	Marshall Bloom	Ex officio
☐	Marcie Caldwell	Ex officio
☐	Frank DeLeo	Ex officio
☐	Heinz Feldmann	Ex officio
☐	Josh Kellar	Ex officio
☐	Brian Vickrey	Ex officio

Guests Present:

Michael Kujawa, Richard Baumann, Chris McGee, Rachel Feldman, Kaitlyn Conner, Jocelyn Mendoza

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. March 19th, 2026 Minutes
    a. Comments on minutes
        i. Add Rachel Feldman to the list of guests
    b. The minutes were unanimously approved with minor modifications.

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:

Marshall Bloom, 26-RML-005

i. Reviewers: Not applicable; No recombinant DNA work
ii. Review Summary and risk assessment: This is a new registration for work with West Nile virus (WNV). The purpose of this study is to examine and characterize changes caused by acute or persistent WNV infection in vertebrates or arthropod cells. WNV will be used as a positive control for *in vitro* assays looking at cellular responses to flavivirus infection. WNV will be obtained from another RML lab that already has strains in BSL-2. Most individuals infected with WNV remain asymptomatic. West Nile fever is typically a mild illness lasting 3 to 6 days. The main symptoms are sudden onset of fever with chills, rash, malaise, headache, backache, arthralgia, myalgia and eye pain. Meningitis, encephalitis, and/or acute flaccid paralysis develop in less than 1% of WNV-infected individuals. Patients with neurological disease typically have a febrile prodrome of 1 to 7 days, which may be biphasic, before they develop neurological symptoms. Typically, neurological patients will present with a fever, stiff neck, headache, weak muscles, gastrointestinal symptoms, disorientation, tremors, convulsions, and paralysis. The natural route of transmission is through the bite of an infected mosquito, although human to human transmission can occur through organ transplantation or vertical transmission. There are no specific treatments or vaccines, support care is given. The primary lab hazards are accidental parenteral inoculation, contact with broken skin or mucous membranes, accidental needle stick.
iii. Committee Discussion: The committee had no comments or concerns.
iv. Minimum PPE required, special practices, and recommended OMS consult if applicable: Lab coat and gloves, eye protection if potential for splashes.
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 as written.
xi. The committee unanimously approved the registration.
    1. Conflicts of Interest: None
    2. Votes for: _8____ Votes against: _0_____Abstained: __0_____

a. Registration amendments for committee review:

Heinz Feldmann, PRD-18-92 Amend

i. Reviewers: Not applicable; No recombinant DNA work
ii. Review Summary and risk assessment: The amendment is to add an attenuated strain of Rift Valley Fever virus (RVFV), MP-12 to the registration. This strain will be used as a positive control vaccine for immunogenicity and protection from RVFV in mice. The MP-12 strain, a live-attenuated candidate vaccine, is attenuated in the M- and L-segments, but the S-segment retains the virulent phenotype. MP-12 vaccine was generated by 12 serial plaque-passages in human diploid MRC-5 cells in the presence of the chemical mutagen 5-fluorouracil. MP-12 is highly

immunogenic in ruminants and can also induce sufficient immune response in humans. MP 12 is not known to cause disease in humans but can infect human cells *in vitro*. This strain is exempted from the Select Agent regulations due to its attenuation.

iii. Committee Discussion: The committee discussed the registration and wanted the source of the virus added and confirmation that the lab will receive MP-12 (not virulent RVFV) from the collaborator. In the MP-12 section for types of human or nonhuman primate body fluids or tissues, "cells" should be checked.

iv. Minimum PPE required special practices, and recommended OMS consult if applicable: Lab coat and gloves, eye protection if potential for splashes.

v. Training:
    1. Laboratory safety training (includes BBP training)

vi. Animal studies proposed: Yes, mice.

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: Not applicable; no recombinant work

x. A motion was made to approve the registration pending the following changes or conditions.
    1. Add source of the virus and confirmation that the lab will receive MP-12 (not virulent RVFV) from the collaborator
    2. In the MP-12 section for types of human or nonhuman primate body fluids or tissues, "cells" should be checked

xi. The committee unanimously approved with minor modifications.
    3. Conflicts of Interest: None
    4. Votes for: _8____ Votes against: _0_____Abstained: __0_____

Heinz Feldmann, 24-RML-003 Amend

i. Reviewers: Not applicable; No recombinant DNA work

ii. Review summary and risk assessment: The amendment to the Dengue virus registration is to add a project with mini pigs that includes a second Dengue virus challenge. The PI recently finished the first part of the project where mini pigs were infected with Dengue virus serotype 2. The lab did not observe any clinical signs of disease or evidence of viral replication. All exposed mini pigs seroconverted indicating exposure or infection. The proposed follow-up study is designed to better understand what happens when an animal has undergone a second infection with a different Dengue virus serotype (in this cage serotype 3). In humans, a second Dengue virus infection with a different serotype can be more severe than the first. It is thought a phenomenon described as antibody-dependent enhancement (ADE) is responsible. ADE is still not fully understood, and this study is focused on assessing that response. The amendment with the attached animal study protocol was submitted for dual use review since there will be two sequential infections of the same animals. The DURC-IRE met the day prior to the IBC meeting and determined that there were no DURC concerns.

iii. Committee Discussion: The committee discussed that the summary should be updated to make it more clear that the same pigs are being infected a second time and that the mini pigs already tested negative for virus replication from the

first round of infection. The committee also requested that the co-infection language be more specific to the proposed study and more clear that it is not a statement of Dengue virus infection in general. The committee discussed the biosafety level and agreed there did not need to be a change in level over that of what was already approved.

iv. Minimum PPE required special practices, and recommended OMS consult if applicable: Lab coat and gloves, eye protection if potential for splashes.

v. Training:
    1. Laboratory safety training (includes BBP training)

vi. Animal studies proposed: Yes, mini pigs.

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: Not applicable; no recombinant work

x. A motion was made to approve the registration pending the following changes or conditions.
    1. The summary should be updated to make it more clear that the same pigs are being infected and that the mini pigs have already tested negative for virus replication from the first round of infection.
    2. The co-infection language should be more specific to the proposed study and made clear that it is not a statement of Dengue virus infection in general.

xi. 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. *Francisella tularensis* inactivation validation with 4% PFA for Katy Bosio.

i. Inactivation procedure summary: The lab validated an inactivation protocol using 4% PFA on *Francisella tularensis* infected lungs and spleens. Positive and negative controls were included and yielded the expected results. All test samples were negative by growth on Mueller Hinton (MMH) plates after 72 hours.

ii. Committee Discussion: The committee discussed the experimental design. The committee questioned the max titer that was inactivated. Katy Bosio used historical controls for the max titer in the experiment as her model is very reproducible. The committee would have liked to see a positive control go through the homogenization process and plate on the MMH plates. The committee also expressed concern that only spleen and lung were tested, but the lab would like liver approved as well. The committee also noted that the SOP lists the same time that was tested and did not allow a safety margin. The IBC wants the PI to know that the IBC will double the inactivation time in the SOP that was tested. The committee requests the PI to repeat the experiment and include a control for the homogenization process and include liver in the testing.

iii. The committee tabled the inactivation validation.
    1. PI is requested to repeat the experiment including liver and a control that is homogenized and plated along with the experimental samples.

b. *Orthomyxoviridae* inactivation validation with 10% formalin for the MCL.
    i. Inactivation procedure summary: The lab validated an inactivation protocol using 10% formalin on H5N1 infected tissues. This was a retest to increase the approved titer in the SOP. The lab is finding that the bovine H5N1 is getting higher titers in the tissues than what was tested with a different H5N1. The appropriate controls were included and yielded the expected results. All test samples were negative by hemagglutination test.
    ii. Committee Discussion: The committee agreed that the results show effective inactivation of the virus but asked for more clarification in the way the data was presented. Specifically, the sensitivity of the HA test should be clarified, label the wells on the results of the HA test, and specify what was done with the positive control during the 7-day fixation of test samples.
    iii. The committee unanimously approved with minor modifications.
        1. Conflicts of Interest: None
        2. Votes for: _8____ Votes against: _0_____Abstained: __0_____

IV. Standard Operating Procedures/Plans
a. Draft ABSL-3 Animal SOP *F. tularensis*, *Y. pestis*, *C. burnetii*
    i. SOP Summary: The update is to add the new SOP for 4% PFA inactivation of tissues.
    ii. Committee Discussion: The committee tabled the SOP since the PI will need to repeat the inactivation testing.
    iii. The committee tabled the inactivation validation.
        1. PI will repeat inactivation testing.
b. Draft SOP#4-28-33 Removal of Samples via Fixation
    i. SOP Summary: The update is to increase the approved titer for 10% formalin fixation of small tissues infected with Orthomyxoviridae.
    ii. Committee Discussion: The committee had no concerns with the updates to the SOP.
    iii. A motion was made to approve the increase in titer for 10% formalin of small tissue infected with Orthomyxoviridae.
    iv. The committee unanimously approved as written.
        1. Conflicts of Interest: None
        2. Votes for: _8____ Votes against: _0_____Abstained: __0_____
c. Draft ABSL-3 Animal SOP *C. burnetii*
    i. SOP Summary: The updates were to clean up some minor language changes and add new routes of inoculation. The routes of inoculation will require select agent approval, but the first step is to update the SOP so it can be submitted with the amendment to Carrie Long's select agent registration.
    ii. Committee Discussion: The committee noted an error in the intranasal inoculation section that referenced syringes. Syringes should be removed from this section since they are not used for this type of inoculation
    iii. A motion was made to approve the updates.
    iv. The committee unanimously approved with minor modifications.
        1. Conflicts of Interest: None
        2. Votes for: _8____ Votes against: _0_____Abstained: __0_____
d. Draft Animal SOP Orthoflaviviruses

i. SOP Summary: The update was to add Tick borne encephalitis virus (TBEV) to the existing West Nile virus SOP for PI Best. The procedures did not change, TBEV was added to the agent summary section and the title was changed to Orthoflaviviruses instead of West Nile virus.
ii. Committee Discussion: The committee had no comments or concerns with the updates.
iii. A motion was made to approve the updated SOP.
iv. The committee unanimously approved as written.
    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. Not applicable.

Reports

I. Biosafety Officer Report – See attached

Around the Room/Committee Discussion

I. None

Adjournment

I. Meeting adjourned by Sue Priola at 01:55 pm

Next Meeting

I. Scheduled June 18th, 2026.

NIH RML Institutional Biosafety Committee Meeting

Biosafety Officer (BSO) Report

May 21, 2026

Business Conducted since the last IBC Meeting

A. BSO approvals
   a. Long 24-RML-001
      i. Add Naegleria australiensis and Naegleria italica (previously in PRD-23-253, now inactivated to consolidate registrations)
   b. Long 24-RML-002
      i. Add HBBF (previously in PRD-18-153, now inactivated to consolidate registrations)
   c. Long RD-23-500
      i. Add HBBF and animal inoculation routes (previously in PRD-23-253 and PRD-18-70, now inactivated to consolidate registrations)
   d. Bloom 25-RML-004
      i. No pathogen hazard, only chemical hazard. Reviewed with NIH Chemical Hygiene Officer.
   e. Van Doremalen 24-RML-013
      i. Updated viral family nomenclature
   f. Feldmann PRD-22-143
      i. Add CDC permit

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	2	5
Annual Refresher Lab Biosafety	n/a	n/a
Select Agent-Initial	1	1
Select Agent- Refresher	n/a	n/a
Select Agent- Visitor	n/a	n/a
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	4	3
Checklist Training	8	5
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	n/a	n/a
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 3/19/2026. Form 3 closed out.

i. The risk assessment determined that the risk was negligible; however, the incident met reporting requirements for the Federal Select Agent Program.

b. Incident reported to NIH OSP on 5/8/2026. No response from OSP to date.
    i. The risk assessment determined that the risk was negligible; however, the incident met reporting requirements for the NIH Office of Science Policy.

D. Other Updates
    a. Unannounced FSAP Inspection was April 14-16th, 2026. There were no findings from this inspection.