NIH Institutional Biosafety Committee Minutes
Location: Rocky Mountain Laboratories
August 21, 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	Local Non-Affiliated
☒	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:

Shanda Sarchette, Michael Kujawa, Jayme Angelo, Kaitlyn Conners, Grace Markley, Katherine Houghton, Richard Baumann, Shane Gansebom, Jared Montana, Rachel Feldman

Announcements & Call to Order

I. Meeting called to order by Sue Priola at 1:00 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. July 17, 2025 Minutes
    a. Comments on minutes
        - Previous minutes comments had a typo of where “committee” should have been “committees”
    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:

i. None.

b. Registration amendments for committee review:

Heinz Feldmann, PRD-22-132 Amend

i. Reviewers: Not applicable; no recombinant DNA work

ii. Review Summary and risk assessment: The amendment to the registration is to add animal work with bats and add two strains of influenza, H17N10 and H18N11. Technically, the two strains were already covered in the registration, the PI wanted to ensure they were clearly listed on the registration. The proposed bat studies will be performed in the BSL-4 according to IBC approved bat SOPs. Bites and scratches are the hazards associated with this work and staff will wear leather gloves for handling bats.

iii. Committee Discussion: The routes of inoculation should be spelled out instead of abbreviated.

iv. Minimum PPE required, special practices, and recommended OMS consult if applicable: Lab coat or disposable gown, gloves, and surgical mask. When handling bats, leather gloves will be worn.

v. Training:

1. Laboratory safety training (includes BBP training)
2. BSL-3 laboratory biosafety training
3. BSL-4 laboratory biosafety training (for bat studies performed at BSL-4)

vi. Animal studies proposed: Yes. Bats.

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: H17N10 and H18N11 is approved at BSL-2/ABSL-2. Bat studies where other influenza viruses requiring a higher biosafety level are approved at ABSL-4.

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. Spell out routes of inoculation.

xi. The committee unanimously approved with minor modifications.

1. Conflicts of Interest: None
2. Votes for: Unanimous Votes against: None Abstained: None

Heinz Feldmann, 24-RML-003 Amend

i. Reviewers: Not applicable; no recombinant DNA work

ii. Review Summary and risk assessment: The amendment to the registration is to add animal work with minipigs and ferrets. The hazards associated with working with these animals include bites and scratches. Leather gloves with gauntlets or other forearm protection will be worn when handling the ferrets.

iii. Committee Discussion: The PI should clarify if they want esophageal or oral inoculation listed as the route of inoculation.

iv. Minimum PPE required, special practices, and recommended OMS consult if applicable: Lab coat or disposable gown, gloves, and surgical mask. When handling ferrets, leather gloves with forearm protection will be worn.

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

vi. Animal studies proposed: Yes. Ferrets and minipigs.

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: Work with ferrets and minipigs with Dengue virus is approved at 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. Clarify esophageal or oral gavage for route of inoculation.

xi. The committee unanimously approved with minor modifications.
    1. Conflicts of Interest: None
    2. Votes for: Unanimous Votes against: None Abstained: None

Heinz Feldmann, PRD-23-202 Amend

i. Reviewers: Scott Kobayashi, Paul Beare

ii. Review Summary and risk assessment: The amendment to the registration is to add animal work with bats. The proposed bat studies will be performed in the BSL-4 according to IBC approved bat SOPs. Bites and scratches are the hazards associated with this work and staff will wear leather gloves for handling bats.

iii. Committee Discussion: The routes of inoculation should be spelled out instead of abbreviated. Also, the in the bat section, check "other" and write in oral gavage.

iv. Minimum PPE required, special practices, and recommended OMS consult if applicable: Positive pressure BSL-4 suit. When handling bats, leather gloves will be worn over suit gloves.

v. Training:
    1. Laboratory safety training (includes BBP training)
    2. BSL-4 laboratory biosafety training

vi. Animal studies proposed: Yes. Bats.

vii. The committee was informed by the BSO that the DURC-IRE reviewed the registration amendment prior to the IBC meeting and approved the proposed studies. 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: Work with H5N1 in bats is approved at ABSL-4.

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. Spell out routes of inoculation.
    2. Update the bat section to check "other" and write in oral gavage.

xi. The committee unanimously approved with minor modifications.
    1. Conflicts of Interest: None
    2. Votes for: Unanimous Votes against: None Abstained: None

Lucas Tirloni, PRD-20-227 Amend

i. Reviewers: Sue Priola, Chris Bosio

ii. Review Summary and risk assessment: The amendment to the registration is to add *Anaplasma phagocytophilum* to the registration. *A. phagocytophilium* is the causative agent of human granulocytic anaplasmosis (HGA), is a tick-borne intracellular bacterium primarily transmitted by Ixodes ticks. Symptoms including fever, chills, headache, muscle aches, nausea, and diarrhea typically begin within 1-2 weeks after infection. As of now, no vaccines or immunization strategies are licensed for use in humans or animals. There is no approved pre-exposure chemoprophylaxis for HGA in humans. Post-exposure treatment is not routinely recommended after a tick bite unless the patient becomes symptomatic. Doxycycline is the treatment of choice.

iii. Committee Discussion: It was noted that animal work is included in the registration but the ASP was not attached, it should be included. In the first Recombinant Material Details section, check "plant" and "other" in the biological origin of the sequences that will be modified or expressed. Clarify with the PI whether the expression is stable or transient. In the animal overview, a description of Anaplasma animal work should be included.

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: 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: Work with *Anaplasma phagocytophilum* is approved at BSL-2/ABSL-2.

ix. Relevant sections of the NIH Guidelines: Not applicable; no recombinant work in proposed amendment.

x. A motion was made to approve the registration pending the following changes or conditions.
    1. Attach ASP for *Anaplasma phagocytophilum* study.
    2. In the first Recombinant Material Details section, check "plant" and "other" in the biological origin of the sequences that will be modified or expressed.
    3. Clarify with the PI whether the expression is stable or transient.
    4. In the animal overview, a description of Anaplasma animal work should be included.

xi. The committee unanimously approved with minor modifications.
    1. Conflicts of Interest: None
    2. Votes for: 8 Votes against: None Abstained: 1

Rahul Suryawanshi, 24-RML-014 Amend

i. Reviewers: Andrea Marzi, Sue Priola

ii. Review Summary and risk assessment: The amendment to the registration is to add work with AAV vectors, new strains of Influenza and HSV, as well as animal work with mice. The proposed experiments were summarized for the committee. The AAV will be obtained from commercial sources, there are two types, ER-TurboID and DREADD. The ER-TurboID allows for tracking of peptides and proteins. DREADDs are modified muscarinic receptors that are only responsive to otherwise inert compounds like clozapine-N-oxide (CNO). By delivering these receptors into neurons, they can

artificially activate or repress their activity by providing exogenous CNO. This enables the lab to validate the function of neuronal species in the absence of the original stimulus. The addition of the Influenza and HSV viruses does not change the biosafety level.

iii. Committee Discussion: In the Recombinant Material Details section, they need to indicate if the duration of expression is transient or stable. In the animal work section for mice, the box for recombinant material needs to be checked now that they are adding AAV studies.

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: 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: Work with AAV, HSV, and Influenza is approved at BSL-2/ABSL-2.

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

x. A motion was made to approve the registration pending the following changes or conditions.

   1. In the Recombinant Material Details section, they need to indicate if the duration of expression is transient or stable.
   2. In the animal work section for mice, the box for recombinant material needs to be checked now that they are adding AAV studies.

xi. The committee unanimously approved with minor modifications.
   1. Conflicts of Interest: None
   2. Votes for: Unanimous Votes against: None Abstained: None

Carrie Long, RD-23-500 Amend

i. Reviewers: Paul Beare, Chris Bosio

ii. Review Summary and risk assessment: The amendment to the registration consolidates multiple registrations into one. This includes adding RD-20-107, PRD-23-246, PRD-22-238, PRD-22-239, and PRD-18-70 to RD-23-500. No new recombinant work is proposed in the registration amendment, the recombinant DNA section was updated to include detail for all ERS questions and other RDs into the current registration. The new work outlined is to perform animal studies in mice with *Coxiella burnetii* to evaluate the potential for LPS elongation *in vivo*. The lab has already identified that LPS elongation can occur in guinea pigs and in vitro with specific media and now are interested in looking at the same LPS elongation potential in mice. Previous work evaluating LPS elongation was reviewed and approved by the DURC-IRE. This amendment for mouse work will be reviewed by the DURC-IRE at the September meeting.

iii. Committee Discussion: “RSSA439” should be corrected in a couple of places to “RSA439”. In the Pathogen section for *Coxiella burnetii*, indicate that the inventory is in an electronic database. In the *Coxiella burnetii* exempt section, correct Clone 2 to Clone 4. In the DURC questionnaire, in question 1, correct 32 kb to 26 kb. Also, clarify in the amendment reason that proposed mouse experiments will be performed in the

ABSL-3 and treated as select agents. Also, more detail should be included to clarify use of *E. coli* in the Recombinant Prokaryotic Cell Work section.

iv. Minimum PPE required, special practices, and recommended OMS consult if applicable: Lab coat and gloves for BSL-2. Disposable gown, double gloves, shoe covers, respiratory protection for BSL-3. Eye protection when splash potential.

v. Training:
   1. Laboratory safety training (includes BBP training)
   2. BSL-3 laboratory biosafety training

vi. Animal studies proposed: Yes. Mice.

vii. The committee discussed the dual-use and ePPP potential of these experiments. The committee deferred review of the dual use and ePPP potential to the DURC-IRE.

viii. Work is approved at: Work with *Coxiella burnetii* exempt strains (including recombinant) is approved at BSL-2/ABSL-2. Work with *Coxiella burnetii* select agent strains is approved at BSL-3/ABSL-3. Work with BCG is BSL-2/ABSL-2. Work with *Candida albicans* is approved at BSL-2/ABSL-2.

ix. Relevant sections of the NIH Guidelines: Not applicable; no new recombinant work in amendment

x. A motion was made to approve the registration pending the following changes or conditions and DURC-IRE review.
   a. "RSSA439" should be correct in a couple of places to "RSA439".
   b. In the Pathogen section for *Coxiella burnetii*, indicate that the inventory is in an electronic database.
   c. In the *Coxiella burnetii* exempt section, correct Clone 2 to Clone 4.
   d. In the DURC questionnaire, in question 1, correct 32 kb to 26 kb. Also, clarify in the amendment reason that proposed mouse experiments will be performed in the ABSL-3 and treated as select agents.
   e. More detail should be included to clarify use of *E. coli* in the Recombinant Prokaryotic Cell Work section.

xi. The committee unanimously approved with minor modifications pending DURC-IRE review.
   3. Conflicts of Interest: None
   4. Votes for: Unanimous Votes against: None Abstained: None

III. Committee Review of Inactivation Procedures

a. ***Coxiella burnetii* inactivation validation with DNeasy Ultra Clean Microbial Kit, Dr. Carrie Long**

i. Inactivation procedure summary: The lab validated an inactivation protocol combining DNeasy Ultra Clean Microbial kit with a boiling step. Infected cells were resuspended in a Powerbead solution and boiled for 30 minutes. All test samples were negative either by qPCR or by microscopy. The appropriate controls were included and yielded the expected results. The results confirm that the Powerbead solution with 30 minutes of boiling is sufficient to inactivate *Coxiella burnetii* infected cells. The written procedure in the SOP matches what was validated.

ii. Committee Discussion: There were no comments from the committee.

iii. A motion was made to approve the procedure as is.

iv. The committee unanimously approved as written.
   1. Conflicts of Interest: None

2. Votes for: Unanimous Votes against: None Abstained: None

b. ***Burkholderia pseudomallei* inactivation validation by boiling for PCR, Dr. Carrie Long**
   i. Inactivation procedure summary: The lab validated an inactivation protocol using boiling for the inactivation of *Burkholderia pseudomallei*. Cultures of *Burkholderia thailandensis (surrogate for pseudomallei)* were boiled for 5, 10, 20, or 30 minutes and then plated on TSB plates. The committee discussed that the surrogate was appropriate for use in these experiments. Plates were evaluated for growth. The appropriate controls were included and yielded the appropriate results. The minimum time to inactivate *Burkholderia thailandensis* was 10 minutes. The PI proposes to use 20 minutes in their SOPs. The PI noted that they will confirm the boiling with *Burkholderia pseudmallei* as well.
   ii. Committee Discussion: The committee discussed that the measure of bacteria was listed as an OD reading and that the bacterial numbers need to be listed as well. This should be included in the inactivation summary and the SOP. The plate size should be clarified in the write-up and SOP.
   iii. A motion was made to approve the procedure pending the following changes or conditions
      1. Include the bacterial numbers in SOP and inactivation summary.
      2. The plate size should be clarified in the write-up and SOP.
   iv. The committee unanimously approved with minor modifications.
      1. Conflicts of Interest: None
      2. Votes for: Unanimous Votes against: None Abstained: None

c. ***Burkholderia pseudomallei* inactivation with disinfectants, Dr. Carrie Long**
   i. Inactivation procedure summary: The lab validated the appropriate contact time for inactivation of *Burkholderia pseudomallei* (surrogate *Burkholderia thailandensis)* with 10% bleach, 70% ethanol, and 2% EarthSense for various times. Cultures of *Burkholderia thailandensis* were pelleted and resuspend in each of the three disinfectants for 2, 5, 10, 15, or 30 minutes. After the allotted time, the samples were centrifuged for 5 minutes and then plated on TSB plates and monitored for growth. The appropriate positive and negative controls were included and yielded the expected results. The PI proposes to use all three disinfectants at the appropriate contact time.
   ii. Committee Discussion: The committee discussed that similar to the previous testing, the measure of bacteria was listed as an OD reading and that the bacterial numbers need to be listed as well. This should be included in the inactivation summary and the SOP. Additionally, the committee discussed that the disinfectant was remaining in the tubes (not diluted) for the 5 minutes that it was centrifuged and should have been washed out. The committee agreed that 5 minutes should be added to each of the testing times to account for the full time that disinfectant was in contact with the bacteria. The approved inactivation times are as follows: 15 minutes with 10% bleach, 15 minutes with 70% ethanol, and 20 minutes with 2% EarthSense.
   iii. A motion was made to approve the procedure pending the following changes or conditions.
      1. Include the bacterial numbers in SOP and inactivation summary.
      2. Update the approved inactivation times in the inactivation summary and SOP.
   iv. The committee unanimously approved with minor modifications.
      1. Conflicts of Interest: None

2. Votes for: Unanimous Votes against: None Abstained: None

IV. Standard Operating Procedures/Plans
   a. **BSL-3 Suite A SOP** (Updates)
      i. SOP Summary: The SOP was updated to include the three new inactivation procedures presented for IBC approval at this meeting, *Coxiella burnetii* inactivation with DNeasy, *Burkholderia pseudomallei* inactivation by boiling, and *Burkholderia pseudomallei* inactivation with disinfectants 10% bleach, 70% ethanol, and 2% EarthSense. There was some additional cleanup to SOPs to clarify either add Burkholderia or change titles to a generic, "bacteria".
      ii. Committee Discussion: None.
      iii. A motion was made to approve the SOP as is.
      iv. The committee unanimously approved as written.
         1. Conflicts of Interest: None
         2. Votes for: Unanimous Votes against: None Abstained: None

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 2:05 pm

Next Meeting

I. September 18, 2025 virtual via Microsoft Teams/Building A Room 322

NIH RML Institutional Biosafety Committee Meeting

Biosafety Officer (BSO) Report

August 21, 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. 8 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	N/A	N/A
Annual Refresher Lab Biosafety	N/A	N/A
Select Agent-Initial	1	5
Select Agent- Refresher	N/A	N/A
Select Agent- Visitor	N/A	N/A
BSL-3 Laboratory Biosafety-Initial	1	3
Practical Training	3	4
BSL-4 Laboratory Biosafety-Initial	N/A	N/A
Suit Training	2	1
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	N/A	N/A
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. None

D. Other Updates
   a. None