NIH Institutional Biosafety Committee Minutes
Location: Rocky Mountain Laboratories
June 18, 2025
1:00 PM – 3:00 PM
Virtual via Microsoft Teams, Bldg A Room 322

Members Present:

Quorum Met: Yes/No

☒	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

Jayme Angelo
Richard Baumann
Ishveen Chopra
Shane Gansebom
Katherine Houghton
Michael Kujawa
Grace Markley
Andrew Martin
Jocelyn Mendoza
Jared Montana
Shanda Sarchette

Announcements & Call to Order

The meeting was called to order by Sue Priola at 1:00 PM.

Review of the Past IBC Meeting Minutes

15 May 2025 Minutes

a. Comments on minutes
   - Page numbers to be added for all future meeting minutes.
   - Regarding the committee discussion for 24-RML-14, "Remove the SARS-CoV-2 reference from the rationale", the committee suggested clarifying that the virus is not part of the registration.

b. The minutes were unanimously approved with minor modifications.

New Committee Business

I. BSO preliminary registration approvals since the previous meeting
   a. Pathogen registrations: None
   b. rDNA and rDNA/pathogen registrations: None
   c. Registration amendments: None
   d. Committee discussion: None

II. Registrations for Committee Review

a. Registrations for committee review: None

b. Registration amendments for committee review

PRD-22-138, Dr. Heinrich Feldmann

i. Reviewers: Not applicable; no recombinant DNA work

ii. Review Summary: The investigators proposed an amendment to introduce bats as a new animal model for studies focusing on Arenaviruses. The investigators will characterize the course of infection in Jamaican fruit bats using Tacaribe virus, a Risk Group 2 Arenaviridae. The study aims to identify the kinetics of viral shedding, clinical features, and immune responses following different routes of inoculation, including aerosolization, subcutaneous injection, and intranasal administration. The ASP was provided.

Safety measures will include conducting studies in BSL-4 and ABSL-4 facilities according to IBC-approved SOP husbandry procedures for bats in level 4 biocontainment. Potential risks include bites and scratches from bats due to teeth and nails, respiratory transmission from the aerosolization route, and needle stick injuries from subcutaneous injections. To mitigate risks, positive pressure suits will be worn, and additional protective gloves, such as leather or sheepskin gloves, will be worn over the suit gloves when manually restraining bats to protect against bites and scratches.

iii. Committee Discussion:

- Specify the specimens being collected via swabs under "other organism specimens."

iv. Animal studies proposed: Yes. Bats

v. 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.

vi. Work is approved at: Bat studies with the aerosol route of inoculation are approved at ABSL-4. Bat studies with arenaviridae Risk Group 2 are approved at ABSL-2. Bat Studies with arenaviridae Risk Group 3 are approved at ABSL-3.

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

viii. The committee unanimously approved with minor modifications.

ix. Conflicts of Interest: None

x. Votes for: _8____ Votes against: __0____Abstained: ___0_____

PRD-22-240, Dr. Vincent Munster

i. Reviewers: Not applicable; no recombinant DNA work

ii. Review Summary: The investigators proposed an amendment to obtain two recombinant Monkeypox (MPox) strains, both of Clade I, Zaire 79, one tagged with GFP and the other with luciferase. The work will focus on the functional characterization and sequencing of MPox samples to develop new assays and medical countermeasures. The strains will be obtained from BEI Resources, and no recombinant work is proposed. Monkeypox, an Orthopoxvirus, is characterized by early onset symptoms like fever, headache, backache, swollen lymph nodes, and fatigue, followed by a rash. The smallpox vaccine is effective against it, though the infectious dose remains unknown. Transmission can occur via respiratory routes, direct contact with bodily fluids, and fomites, and disinfectants like a 1:10 dilution of bleach and 5% MicroChem are effective. Personnel involved must undergo specific training, including on bloodborne pathogens and exposure control, and will be offered the Hepatitis B and smallpox vaccines.

iii. Committee Discussion:

- On page 5, "biological origin" entries list "arthropod" for the luciferase construct and "aquatic species" for GFP. The biological origin of the virus used for the recombinant system should be added.

- The committee recommended omitting the generic "synthetic biology" dual-use designation for the amendment. Bethesda IBC flags dual-use only when recombinant work results in novel or enhanced pathogens, not for using synthetic biology techniques. This will ensure both committees are consistent in answering the question.

iv. Animal studies proposed: Yes. Mice, Dormice, non-human primates

v. 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.

vi. Work is approved at: Eukaryotic work at BSL-3, animal work at ABSL-3 containment and practices

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

viii. The committee approved with minor modifications.

ix. Conflicts of Interest: None

x. Votes for: _8____ Votes against: __0____Abstained: ___0_____

RD-22-410, Dr. Heinrich Feldmann

i. Reviewers: Sue Priola, Scott Kobayashi

ii. Review Summary: The investigators proposed an amendment to include ChAdOx2 as the fourth replication-deficient adenoviral vaccine vector, alongside the existing AdV systems. ChAdOx2 is built on a chimpanzee adenovirus 68 backbone rendered replication-incompetent by deleting the E1 and E3 regions and replacing native E4 Orf4/6/7 with HAd5 sequences to boost vector yields in E1-complementing cell lines; codon-optimized antigen cassettes under a CMV promoter are inserted into the deleted E1 locus via homologous assembly The vector map also incorporates the DogTag peptide into permissive capsid hexon sites, enabling post-translational Tag-Catcher coupling of protein antigens (e.g., SARS-CoV-2 RBD) to mask vector epitopes, reduce anti-vector immunity, and enhance booster responses. All ChAdOx2 vectors will be obtained from the University of Oxford, UK, and the vector maps were provided.

iii. Committee Discussion:

- The committee requested clarifying the meaning of "0–<38% of recombinant AdV," specifying which portions of the adenovirus genome are being cloned and confirming that this limit prevents reconstitution of a replication-competent virus.
- "Bacterium" and "aquatic species" should also be checked under the biological origin of the sequences.

iv. Animal studies proposed: Yes. Mice, hamsters, guinea pigs, ferrets, non-human primates

v. 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.

vi. Work is approved at: Prokaryotic work at BSL-2, eukaryotic work at BSL-2, animal work at ABSL-2 practices and containment

vii. Relevant sections of the NIH Guidelines: Prokaryotic work at III-D-2-a, eukaryotic work at III-E-1, III-D-3-a animal work at III-D-4-a

viii. The committee approved with minor modifications.

ix. Conflicts of Interest: None

x. Votes for: _8____ Votes against: __0____Abstained: ___0_____

24-RML-012, Dr. Sonja Best

i. Reviewers: Andrea Marzi, Paul Beare

ii. Review Summary: The investigators proposed an amendment to add *in vivo* influenza A (strain H1N1 A/PR/8/34) studies alongside their existing SARS-CoV-2 work, incorporating an intranasal infection of wild-type mice with A/PR/8/34 and experiments in HNF4α-conditional knockout mice generated via tamoxifen induction (intraperitoneal, 75 mg/kg for 5 days). A draft, stand-alone ASP for the influenza

project is being prepared in parallel. The routes of administration include intranasal for virus challenge and intraperitoneal for tamoxifen or morpholino-PPMO delivery.

iii. Committee Discussion:
- Remove intraperitoneal administration for influenza since no virus or recombinant material is proposed to be delivered intraperitoneally.
- Explicitly specify routes for each "biologic" entry—virus under intranasal and tamoxifen/PPMO under intraperitoneal.
- Blood & serum sampling for serology will potentially be performed and must be checked under "organisms and specimens to be collected."
- Recommended selecting "No" for the question regarding synthetic biology, per the updated guideline that only *de novo* synthesis of novel organisms warrants dual-use designation.

iv. Animal studies proposed: Yes. Mice

v. 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.

vi. Work is approved at: Prokaryotic work at BSL-2, eukaryotic work at BSL-2, animal work at ABSL-2 practices and containment

vii. Relevant sections of the NIH Guidelines: Prokaryotic work at III-D-2-a, eukaryotic work at III-D-3-a, animal work at III-D-4-a

viii. The committee unanimously approved with minor modifications.

ix. Conflicts of Interest: None

x. Votes for: _8____ Votes against: __0____Abstained: ___0_____

III. Committee Review of Inactivation Procedures

***F.* tularensis inactivation validation of infected cells with Cell Signaling Buffer, Dr. Catharine Bosio**

i. Inactivation procedure summary: The investigators validated an inactivation protocol combining Cell Signaling lysis buffer and heat treatment for intracellular bacterial pathogens in macrophages. Murine macrophages were infected (MOI 50) for 24 hours, washed with PBS, and then lysed in 550 µL of Cell Signaling buffer. The lysate was boiled at 99 °C for 5 minutes (with a parallel 10-minute boil). Lysates were clarified using spin columns and serially diluted (10^2 to 10^5), alongside a positive control (unheated lysate in water) and a negative control (buffer only). Triplicate plates from three independent experiments were incubated for 72 h on MMH agar. All boiled samples showed zero CFU, positive controls yielded $5x10^5$ to $7x10^5$ CFU, and negative controls remained sterile. These results confirm that a 5-minute boil in Cell Signaling buffer is sufficient for complete inactivation, in alignment with SOP Sections 7.6.1-7.6.3.

ii. Committee discussion:
- Clarification is needed since the same Cell Signaling lysis buffer is used for both test samples and the negative control (instead of RIPA buffer) to ensure identical inactivation conditions.

iii. The committee unanimously approved with minor modifications.

iv. Conflicts of Interest: None

v. Votes for: _8____ Votes against: __0____Abstained: ___0_____

IV. Standard Operating Procedures/Plans

BSL-3 Suite C SOP- update to add inactivation procedure

i. SOP summary: Lysis and inactivation of F. tularensis has been added to the previously approved BSL-3 Facility, Room 159/Suite C SOP.

ii. Committee discussion:
- The investigator needs to specify the infectious titer in the SOP

- The SOP needs to explicitly define the bacterial input per inactivation reaction (i.e., 7 x 10^5 CFU per well from an MOI 50 infection of 1 x 10^5 macrophages in 100 µL) to standardize the challenge dose and prevent variability when scaled-up.

iii. The committee unanimously approved as with minor modifications.

iv. Conflicts of Interest: None

v. Votes for: _8____ Votes against: __0____Abstained: ___0_____

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

Reports

I. Biosafety Officer Report

a. See attached report

b. Public availability of meeting minutes: Beginning July 2025, the NIH will publish finalized minutes for meetings held on or after 01 June 2025, on the ORS website (https://ors.od.nih.gov/sr/dohs/biosafety-committee-minutes/Pages/default.aspx), consolidating records for all four IBCs.

c. Executive Order for Improving Safety and Security of Biological Research: The NIH is implementing the recent Presidential Executive Order, which rescinds the May 2025 policy and instead defines "potentially pandemic pathogens" by specific experimental effects rather than by the agent itself. Experimental effects include experiments with potential dual-use concerns or a negative societal impact. The IBC Biosafety Officers have reviewed all IBC registrations flagged for "yes" on any DURC question and have curated a list for the DURC-IRE review next week. Investigators with projects under review have been asked to submit justifications by 20 June 2025 explaining whether their work constitutes "dangerous gain-of-function" according to the new criteria. The committee will convene on 24 June 2025 to finalize recommendations and report the findings to the HHS on 30 June 2025. In the interim, some investigators have voluntarily paused or deactivated registrations to simplify compliance, and updates will be provided following the DURC-IRE meeting.

II. Other reports

Around the Room/Committee Discussion

None

Adjournment

The meeting was adjourned by Sue Priola at 1:48 PM.

Next meeting

July 17, 2025 virtual via Microsoft Teams/Building A Room 322

NIH RML Institutional Biosafety Committee Meeting

Biosafety Officer (BSO) Report

June 18, 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	3
Select Agent- Refresher	n/a	n/a
Select Agent- Visitor	n/a	n/a
BSL-3 Laboratory Biosafety-Initial	3	5
Practical Training	1	2
BSL-4 Laboratory Biosafety-Initial	3	5
Suit Training	3	2
Checklist Training	5	2
BSL-4 Laboratory Biosafety-Refresher & SA Refresher	n/a	n/a
Laboratory Biosafety Support Staff-Initial	n/a	n/a
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. Incident reported to NIH OSP on 6/4/2025. No response from OSP to date.

D. Other Updates
   a. IBC Minutes will be posted on the DOHS website: https://ors.od.nih.gov/sr/dohs/biosafety-committee-minutes/Pages/default.aspx.
   b. Update on implementation of the recent presidential Executive Order for Improving Safety and Security of Biological Research.