NIH Institutional Biosafety Committee Minutes
Location: Bethesda Main Campus
February 04, 2026
2:00 PM – 5:00 PM
Virtual via Microsoft Teams

Members present: (10)
Quorum met: Yes

Harry Malech, Chair, clinician	Stephen Denny, animal research expert	Jeanne Billioux, Clinician
Richard Baumann, BSO	Clevetta Drew, unaffiliated member	Michael Kujawa, ABSO
Emily Lee, recombinant and molecular techniques	Steve Whitehead recombinant and molecular techniques, virology	Stephanie Goff, Clinician
Robert Craigie, recombinant and molecular techniques		

- absent members: Alicia Alexion
*Provided comments *in absentia* for select reviews

Guests present (11)

Rebecca Anderson (RML)	Camila Odio (NIAID)	Mike Holbrook (NIAID)
Grace Markley (NBBTP)	Jocelyn Mendoza (NBBTP)	Althea Treacy, RSBMB Chief
Kaitlyn Connors (NBBTP)	Leah Katzelnick (NIAID)	Melissa Abel (NCI)
Rosemary Aogo (NIAID)	Krisztina Janosko (IRF)	

Announcements & Call to Order

The meeting was called to order by Dr. Malech at 2:02 PM.

Review of the Past IBC Meeting Minutes

14 January 2026 Minutes

a. Comments will be accepted for minutes, as applicable
b. The minutes were unanimously approved with minor modifications and formatting corrections by 01/21/26.

New Committee Business

I. BSO preliminary registration approvals since the previous meeting

a. Pathogen registrations (7 total): 26-BMC-027-028, -030, -032-033, -038, -043
b. rDNA and rDNA/pathogen registrations: 26-BMC-029 (Doroshow), III-E-1/ III-F-1- Characterizing the role of the NADPH oxidase (NOX) family of proteins in tumor biology by modulating their expression and/or activity using recombinant DNA (in Baculovirus); registration updates and replaces registrations: RD-12-VII-03, RD-12-VII-04, RD-12-VII-05, RD-12-VII-06, and RD-12-VII-07; 26-BMC-031 (Seder), III-D-2-a/ III-D-4-a- Vaccine and monoclonal antibody development against Plasmodium falciparum and P. vivax parasites; registration updates and replaces registrations 7109, RD-14-I-03, RD-22-V-07, and 25-BMC-029 approved by the IBC; 26-BMC-034 (Cao), III-D-3-a/III-D-4-a- The Molecular and Pathological Basis of Obesity and its Related Diseases. This registration is an administrative update and replaces the previously approved registrations 5417, 6482, 6558, RD-11-IV-04, and RD-12-II-11; 26-BMC-035 (Reich), III-E-1- Investigating multiple sclerosis in human induced pluripotent stem cell-derived models of the central nervous system; 26-BMC-036 (Schiller), III-D-3-a / III-D-4-a- Therapeutic vaccination with viral vectors; registration updates and replaces registrations 5258 and RD-10-VIII-22, This is an administrative replacement with no significant changes from previous IBC approval. No new work has been submitted, reviewed, or approved with this new registration; 26-BMC-037 (Clore), III-E-1 - Expression of Hsp104, Fyn SH3, RfaH in E.coli; NMR of barrier to auto-integration factor

(BAF), N-term dom. of HIV-1 integrase, HOX trans. factor, Hpr1/E1 interaction; 26-BMC-040 (Bax), III-E-1- PRE Ubiquitin I2 (Bacterial expression of mutant ubiquitin L50A, L50A/L73C and L50A/T66V/L67N variants using pET11a plasmid vectors); 26-BMC-041 (Bax), III-E-1- Ab40 oligomerization (Bacterial expression of a fusion protein that after cleavage yields the Ab40 peptide); 26-BMC-042 (Nath), III-D-3-a/ III-D-4-a- Identification and inhibition of persistent HIV reservoirs. This registration updates and replaces registrations RD-11-VI-15, RD-22-II-07, 5448, 8416, and 8417. This is an administrative replacement with no significant changes from previous IBC approval. No new work has been reviewed or approved with this updated registration; 26-BMC-044 (Levin), III-E-1/III-D-2-a- The role of transposable elements in neurologic and psychiatric diseases. This registration updates and replaces registration 7936, with no significant changes from prior approval.

c. Registration amendments: **Approved RD amendments ('amend 260114') for the Minutes**: RD-22-XI-14- (amend-Fox), RD-17-I-12 (amend-Le Pichon), RD-20-II-20 (amend-Wu), RD-19-XI-02 (amend-Bonnemann), RD-23-IV-03 (amend-Rosenberg), 25-BMC-024 (amend-Penzo), RD-22-IX-14 (amend-Bourne), RD-16-X-10 (amend-Yang), RD-21-II-05 (amend-Shah)

d. Committee discussion: No committee members voiced comments or concerns.

e. After providing descriptions, the BSO asked if there were any questions or concerns with the preliminary approvals. Hearing none and following the formal review and discussion at the meeting, the IBC concurs unanimously with and formally approves the registrations and registration amendments.

II. Registrations and other submissions for Committee Review

a. Clinical trial reviews

26-BMC-045, Leah Katzelnick (Presented by Camila Odio, Leah Katzelnick and others)

i. Reviewers: Goff, Billioux, All

ii. Review summary: This is a phase 1 challenge trial where healthy adults with no flavivirus antibodies (naïve), dengue virus serotype 2 (DENV2)-dominant antibodies (homotypic), or non-DENV2-dominant antibodies (heterotypic) will be infected with the live attenuated DENV2 challenge strain rDEN2Δ30-7169. Investigators will evaluate the safety and immunogenicity of the challenge strain as well as how immune history influences IP-10 signaling, bone marrow cellularity, and the development of bone marrow DENV2-specific cells. Exploratory objectives include examining the immunological and clinical impact of homotypic and heterotypic infection, how viral replication affects the bone marrow and induces protective or dysregulated immune responses, and the determinants of long-lived immunity to inform dengue vaccines and therapeutics. They hypothesize that the challenge strain will be safe. The heterotypic group is predicted to have the highest viremia as measured by RNA (viral RNAemia) and boost in neutralizing antibodies, and the homotypic challenge group will have the lowest. They also expect that the heterotypic group will have the biggest changes in IP-10 signaling between days 0 and 19. During acute infection, they expect that the heterotypic and naïve groups will have altered bone marrow cellularity such that it differs from the reference range, but the homotypic group will not have altered cellularity. At day 57, they expect that there will be DENV-specific antibody secreting cells in the bone marrow

iii. Committee discussion:

- The protocol is well described, but one reviewer wasn't sure if participants were required to stay locally. The group responded that they will be sequestered in the early period. The group requests participants not to travel to DENV endemic areas. Participants were supported to have housing for first 28 days, and if they move, they may also be supported. Most are local.
- Another reviewer asked about the naïve population and what could be done to prevent potential issues with them receiving this product, and the group will educate them regarding travel to endemic areas or areas where a vaccine is offered to advise them to be vaccinated if they travel to those areas. This was discussed a bit about how to potentially protect the naïve population.

iv. Bloodborne pathogen training (BBP) for anyone handling clinical samples, and PPE as appropriate for standard precautions and as determined by risk assessment including gloves, gown, and face protection would help mitigate risks of inadvertent exposure during preparation and administration, especially when working outside of primary containment such as a Biological Safety Cabinet (see protocol details in registration).
v. Animal studies proposed: N/A
vi. The committee discussed the dual-use and ePPP potential of these experiments and agreed that there were no dual-use or ePPP concerns with this clinical protocol.
vii. There were no additional public comments.
viii. The clinical protocol is approved with standard precautions as described in place for handling therapeutic agent including gown gloves and surgical mask.
ix. Relevant sections of the NIH Guidelines: III-C-1.
x. The committee unanimously approved as written.
xi. Dr. Steve Whitehead recuses himself from the review of this trial as he is associated with the group.

b. Special reviews

SR01: 26-BMC-046, Mike Holbrook (Coronavirus)

i. Reviewers: Lee, Whitehead
ii. Review summary: The title is Coronavirus Pathogenesis. The project is being developed to manage their existing MERS coronavirus (MERS CoV) and SARS-CoV-2 stocks as well as to evaluate potential therapeutics and cell culture assays using human or non-human primate cells. This has no recombinant work. There are no immunizations, pre- or post-exposure therapy treatments available for MERS-CoV. For SARS-CoV-2 they note that COVID-19 vaccines are widely available and recommended for both viruses.

The group says no permit is needed for work with these stocks (that may be because they already have many of them), but it is not clear if that is the case for new strains because the reviewer experience from sources for these viral strains is that a permit is needed to work with them. Dr. Holbrook confirmed this is just focused on stocks we already have, and the only two MERS isolates around are those they have. If they need to get new strains, which is not currently anticipated, they'll get whatever permits are required.

iii. Committee Discussion:

- This group is managing existing viral stocks. Viruses are MERS-CoV (2012 EMC/Jordan), many variants, no immunization or post-exposure prophylaxis available for MERS-CoV (these available for SARS-CoV-2). Centrifugation and filtration will be used; they should use a containment centrifuge. New isolates were discussed. The group agreed they did not want to take any isolates from higher containment into lower containment but did want to work with new isolates of SARS-CoV-2 at BSL-2 with additional practices. It is noted that most work will be carried out in BSL-4 settings for both MERS-CoV and SARS-CoV-2 existing isolates, which is fine since MERS-CoV is a RG-3 agent. It was also noted that any new isolates of SARS-CoV-2 are proposed to be performed at BSL-2.
- There was a question to the BSO for comment if NIH has approved BSL-2 for some SARS-CoV-2 intramural work. This was an important question, and clarification was given that all 4 IBC committees at the NIH have worked on guidance related to SARS-CoV-2 work. Also, while the NIH Office of Science Policy has recently determined that for SARs-CoV-2, Risk Group (RG) 2 could be used as a starting point for risk assessments by the IBC, it was clarified that senior NIH leadership is being approached for concurrence before any IBC registration is approved at BSL-2.
- It was further clarified that such work should comply with Executive Order 14292 that describes dangerous gain of function. Lowering containment would need to account for biosafety as well as biosecurity, if the materials were handled with other materials concurrently, and if the if the agents are recombinant in in some manner. Updated biosecurity

policy is pending, and the lab is seeking to approve work at lower containment for this agent before they begin.

- The chair clarified that their understanding of the policy discussion was that the IBC would consider, on a case-by-case basis, going to the level that's now allowed for that agent, but other criteria need to be met to demonstrate the absence of other possible contaminants before approval at lower containment. The laboratory clarified it was not their intent to take any stocks they had at BSL-3 and take them down to a BSL-2 level laboratory. Dr. Holbrook clarified that they will not be isolating any virus from serum, as one IBC reviewer was explaining that it was already approved that serum could be worked with in a BSL-2 level laboratory.
- Despite what is the case with certain samples, safety representatives stated in the interest of being conservative and knowing that the NIH has received a lot of scrutiny regarding SARS-CoV-2, they will pass this through the ICDUR / and DURC Institutional Review Entity for agreement, knowing that they will be assessed moving forward.
- For the work described here with isolates (and on rDNA work) there are no DURC related issues.

iv. Training and PPE requirements as established with BSL to be in line with a BSL-3 laboratory, or BSL-4 for laboratory as it applies and to include laboratory safety training and BBP training for individuals handling any human materials. PPE standards as established by risk assessment and laboratory.

v. Animal studies proposed: Not described here.

vi. The committee discussed the dual-use and ePPP potential of these experiments. All answers were ‘no’. The committee agreed that there were no dual-use or ePPP concerns with the proposal.

vii. There were no additional public comments.

viii. Work is approved at: Work in the laboratory is approved at BSL-3. No animal work is currently being proposed.

ix. Relevant sections of the NIH Guidelines: N/A as no rDNA work is being proposed. Work with established recombinant strains in cultured cells is approved under III-D-3-a.

x. The committee unanimously approved the registration as written, pending decision on SARS-CoV-2 biosafety guidance for intramural work.

xi. There were no conflicts of interest identified

SR02: 26-BMC-047, Mike Holbrook (MPXV)

i. Reviewers: Craigie, Goff

ii. Review summary: The purpose of the registration is to generate virus stocks of monkeypox virus (MPXV) and potentially test antiviral compounds against MPXV in cell culture. This registration updates and replaces registration 7701 and 8426. Existing MPXV stocks need to be routinely tested for loss of viability and expanded as necessary. In addition, new isolates of MPXV may be expanded and titrated. BSL-3 is appropriate and it is assumed people doing the work are vaccinated, which would be warranted.

iii. Committee Discussion:

- This group will generate virus stocks, and this registration replaces previous approvals. New isolates of MPXV may be expanded and titrated. BSL-3 is appropriate with vaccination.
- There are no DURC related issues; all questions are appropriately answered no. The secondary reviewer had no additional comments.

iv. Training and PPE requirements as established with BSL are in line with a BSL-3 laboratory, to include laboratory safety training and BBP training for individuals handling any human materials. PPE standards include protective labcoat, gloves and eyewear.

v. Animal studies proposed: Not described here.
vi. The committee discussed the dual-use and ePPP potential of these experiments. All answers were ‘no’. The committee agreed that there were no dual-use or ePPP concerns with the proposal.
vii. There were no additional public comments.
viii. Work is approved at: Eukaryotic work is approved at BSL-3, eukaryotic work and vaccination is recommended. No animal work is proposed by this investigator.
ix. Relevant sections of the NIH Guidelines: No recombinant work is currently being proposed in this registration.
x. The committee unanimously approved the registration as written.
xi. There were no conflicts of interest identified.

c. Registrations for committee review

26-BMC-048, Peter McGuire

i. Reviewers: Billioux, Craigie
ii. Review summary: To confirm the cellular mechanisms under study, the investigator will perform knockdown experiments in established human and animal cell lines. Specific targets will be reduced using shRNA constructs delivered by lentiviral vectors or other nonreplicating recombinant delivery systems. These modified cell lines will be used to assess how loss of targets affects cellular functions. All work will be conducted under Biosafety Level 2 conditions.

iii. Committee Discussion:

- The reviewer was unsure what the ”other non-recombinant delivery systems” proposed would be and wanted clarification. shRNA plasmids were added although the registration covered lentiviral vector use, so it is possible these were for the other delivery systems.

iv. Training and PPE requirements as established with BSL to be in line with a BSL-2 laboratory, to include laboratory safety training and BBP training for individuals handling any human materials. PPE standards include protective labcoat, gloves and eyewear.
v. Animal studies proposed: None
vi. The committee discussed the dual-use and ePPP potential of these experiments. All answers were ‘no’. The committee agreed that there were no dual-use or ePPP concerns with the proposal.
vii. There were no additional public comments.
viii. Work is approved at: Eukaryotic work is approved at BSL-2.
ix. Relevant sections of the NIH Guidelines: Eukaryotic work is approved under III-D-3-a.
x. The committee unanimously approved the registration after minor clarifications.
xi. There were no conflicts of interest identified.

26-BMC-049, Avindra Nath

i. Reviewers: Denny, Lee
ii. Review summary: The primary aim of these studies is to understand how reactivation of the human endogenous retrovirus K (HERV-K) causes injury to neurons. To address this aim, they will utilize a variety of in vitro, ex vivo and in vivo mouse studies to characterize the role of HERV-K in neurodegeneration.

iii. Committee Discussion:

- The primary and secondary reviewers stated that the registration was very well detailed and they had no comments.

iv. Training and PPE requirements as established with BSL to be in line with a BSL-2 laboratory, to include laboratory safety training and BBP training for individuals handling any human materials. PPE standards include protective labcoat, gloves and eyewear.
v. Animal studies proposed: Mice
vi. The committee discussed the dual-use and ePPP potential of these experiments. All answers were 'no'. The committee agreed that there were no dual-use or ePPP concerns with the proposal.
vii. There were no additional public comments.
viii. Work is approved at: Prokaryotic work is approved at BSL-2, eukaryotic work is approved at BSL-2, animal work is approved at ABSL-1/2.
ix. Relevant sections of the NIH Guidelines: Prokaryotic work is at III-D-2-a, eukaryotic work is approved under III-D-3-a. Animal work is approved at III-D-4-a
x. The committee unanimously approved the registration.
xi. There were no conflicts of interest identified.

26-BMC-050, Andrew Holmes

i. Reviewers: Whitehead, Denny
ii. Review summary: To express light sensitive viruses in mouse brain in order to allow for cellular recordings and manipulations of brain circuits. The procedure will entail intracerebral injections of non-replicative viral DNA via brain cannulation. The viral vectors will carry DNA into the brain for viral expression of light sensitive, exogenous proteins (e.g. polyphenol oxidase (PPO) into specific cell types in the brain. Light will be shone via an implanted optic fiber or miniature microscope at specific points during behavioral procedures described in the animal study proposal. The endpoint of the study will be sacrifice for verification of cannula localization and viral expression.

iii. Committee Discussion:
- The reviewer noted that the AAV vectors given were missing OPM-3 expression but had many other AAV vectors listed that seemed unrelated, although maps were provided for all of the vectors. Blending and mixing were checked, but pipetting was not which confused the reviewer. It was requested that clarification was given on this list of vectors given and what they were used for.

iv. Training and PPE requirements as established with BSL to be in line with a BSL-2 laboratory, to include laboratory safety training and BBP training for individuals handling any human materials. PPE standards include protective labcoat, gloves and eyewear.
v. Animal studies proposed: Mice
vi. The committee discussed the dual-use and ePPP potential of these experiments. All answers were 'no'. The committee agreed that there were no dual-use or ePPP concerns with the proposal.
vii. There were no additional public comments.
viii. Work is approved at: Animal work is approved at ABSL-1.
ix. Relevant sections of the NIH Guidelines: Animal work is approved at III-D-4-a
x. The committee unanimously approved the registration after minor clarifications.
xi. There were no conflicts of interest identified.

26-BMC-051, Mark Connors (First)

i. Reviewers: Lee, Craigie
ii. Review summary: To develop cell lines that express antibodies of interest on the cell surface using 4th generation lentiviral vectors and to use the cell lines to (1) measure the ability of antigens to activate B cells as a model to identify promising vaccine candidates and (2) validate

fluorescently labeled proteins that can be used in B cell isolation and monoclonal antibody discovery.

iii. Committee Discussion:
- The reviewers had no comments or concerns.

iv. Training and PPE requirements as established with BSL to be in line with a BSL-2 laboratory, to include laboratory safety training and BBP training for individuals handling any human materials. PPE standards include protective labcoat, gloves and eyewear.
v. Animal studies proposed: None
vi. The committee discussed the dual-use and ePPP potential of these experiments. All answers were 'no'. The committee agreed that there were no dual-use or ePPP concerns with the proposal.
vii. There were no additional public comments.
viii. Work is approved at: Eukaryotic work is approved at BSL-2.
ix. Relevant sections of the NIH Guidelines: Eukaryotic work is approved under III-D-3-a.
x. The committee unanimously approved the registration.
xi. There were no conflicts of interest identified.

26-BMC-052, Mark Connors (Second)

i. Reviewers: Craigie, Lee
ii. Review summary: To use cell lines transduced with 2nd generation packaged lentiviral vectors to express antibodies of interest on the cell surface to (1) measure the ability of antigens to activate B cells as a model to identify promising vaccine candidates and (2) validate fluorescently labeled proteins that can be used in B cell isolation and monoclonal antibody discovery.

iii. Committee Discussion.
- The reviewers had no comments or concerns.

iv. Training and PPE requirements as established with BSL to be in line with a BSL-2 laboratory with BSL-3 practices, to include laboratory safety training and BBP training for individuals handling any human materials. PPE standards include protective labcoat, gloves and eyewear.
v. Animal studies proposed: None
vi. The committee discussed the dual-use and ePPP potential of these experiments. All answers were 'no'. The committee agreed that there were no dual-use or ePPP concerns with the proposal.
vii. There were no additional public comments.
viii. Work is approved at: Eukaryotic work is approved at BSL-2/3.
ix. Relevant sections of the NIH Guidelines: Eukaryotic work is approved under III-D-3-a.
x. The committee unanimously approved the registration.
xi. There were no conflicts of interest identified.

26-BMC-053, Jackson

i. Reviewers: Whitehead, Denny
ii. Review summary: The investigators will use lentiviruses to transduce human glioma cells.

iii. Committee Discussion:
- It was unclear if the packaging system is second or third generation. It also was unclear as to who will be packaging the lentiviral packages; from NINDS or themselves.

iv. Training and PPE requirements as established with BSL to be in line with a BSL-2 laboratory, to include laboratory safety training and BBP training for individuals handling any human materials. PPE standards include protective labcoat, gloves and eyewear.
v. Animal studies proposed: Mice
vi. The committee discussed the dual-use and ePPP potential of these experiments. All answers were 'no'. The committee agreed that there were no dual-use or ePPP concerns with the proposal.
vii. There were no additional public comments.
viii. Work is approved at: Eukaryotic work is approved at BSL-2, animal work is approved at ABSL-1/2.
ix. Relevant sections of the NIH Guidelines: Eukaryotic work is approved under III-D-3-a. Animal work is approved at III-D-4-a
x. The committee unanimously approved the registration after minor clarifications.
xi. There were no conflicts of interest identified.

26-BMC-054, Dima Hammoud

i. Reviewers: Billioux, Goff
ii. Review summary: The investigator would like to develop an animal model that is infected with the pseudotyped (but replication-defective) virus that expresses the HIV protease. This model will be an alternative to tumor model with cell overexpressing the protease and will be used to assess 18F-darunavir binding by PET imaging before future translation studies can be conducted.

iii. Committee Discussion:
- The reviewer was unsure if the DURC question for novel pathogen should be marked 'Yes', but this isn't quite a novel pathogen. It was also discussed to make sure the collaborating registration by another investigator is up to date to support the work discussed here.

iv. Training and PPE requirements as established with BSL to be in line with a BSL-2 laboratory, to include laboratory safety training and BBP training for individuals handling any human materials. PPE standards include protective labcoat, gloves and eyewear.
v. Animal studies proposed: Mice
vi. The committee discussed the dual-use and ePPP potential of these experiments. All answers were 'no'. The committee agreed that there were no dual-use or ePPP concerns with the proposal.
vii. There were no additional public comments.
viii. Work is approved at: Animal work is approved at ABSL-2.
ix. Relevant sections of the NIH Guidelines: Animal work is approved at III-D-4-a.
x. The committee unanimously approved the registration.
xi. There were no conflicts of interest identified.

26-BMC-055, Whitehead

i. Reviewers: Craigie, Lee
ii. Review summary: This study supports dengue virus (DENV) research by characterizing a broad collection of DENV isolates. The primary focus of the laboratory's research is to create live attenuated vaccine candidates to protect against dengue. The research flow includes isolation of wt DENV, sequencing, recombinant derivation of DENV, attenuation of recombinant viruses using genetic methods, and preclinical testing of candidate vaccine strains. This registration document is a consolidation of previous PRD 8424 and RD-00-II-07.

iii. Committee Discussion:

- The reviewers had no comments or concerns.

iv. Training and PPE requirements as established with BSL to be in line with a BSL-2 laboratory, to include laboratory safety training and BBP training for individuals handling any human materials. PPE standards include protective labcoat, gloves and eyewear.
v. Animal studies proposed: Mice, NHPs, Mosquitoes
vi. The committee discussed the dual-use and ePPP potential of these experiments. All answers were 'no'. The committee agreed that there were no dual-use or ePPP concerns with the proposal.
vii. There were no additional public comments.
viii. Work is approved at: Prokaryotic work is approved at BSL-1, eukaryotic work is approved at BSL-2, animal work is approved at ABSL-2. Arthropod work is approved at ACL-2.
ix. Relevant sections of the NIH Guidelines: Prokaryotic work is at III-D-2-a, eukaryotic work is approved under III-D-3-a. Animal work is approved at III-D-4-a.
x. The committee unanimously approved the registration.
xi. There were no conflicts of interest identified.

d. Registration amendments for committee review

24-BMC-134 amend 260204, John Chiorini

i. Reviewers: Goff, Denny
ii. Review Summary: This group was previously performing experiments in mice. They are expressing a leptin protein from AAV vectors. They were approved to inject into the salivary glands via a microcapillary tube injection SOP and IM injection, and they received very encouraging results. They would now like to administer recombinant AAV in monkey muscles by IM injection.

iii. Committee Discussion.
- The reviewers had no comments or concerns.

iv. Training and PPE requirements as already established.
v. Animal studies proposed: NHP
vi. The committee discussed the dual-use and ePPP potential of these experiments. All answers were 'no'. The committee agreed that there were no dual-use or ePPP concerns with the proposal.
vii. There were no additional public comments.
viii. Work is approved at: Animal work is approved at ABSL-2.
ix. Relevant sections of the NIH Guidelines: Animal work is approved at III-D-4-a.
x. The committee unanimously approved the registration.
xi. There were no conflicts of interest identified.

RD-20-VIII-11 amend 260204, Philip Adams

i. Reviewers: Denny / Billioux
ii. Review Summary: The investigator would like to amend their animal work to include removal of infected ticks during mouse feeding. This amendment does not require significant changes to the study objectives or additional animals. This amendment complements the currently approved work and allows them to utilize mice in tick studies to collect ticks that are actively feeding. In the currently approved animal work, only ticks that are fed to repletion are collected. This amendment does not significantly change any safety risks or significantly increase the possibility

of tick escape. This amendment would greatly expand the research capabilities to study the Lyme disease pathogen at specific time-points during tick feeding.

iii. Committee Discussion.
- The reviewers had no comments or concerns.

iv. Training and PPE requirements as already established.
v. Animal studies proposed: Mice
vi. The committee discussed the dual-use and ePPP potential of these experiments. All answers were 'no'. The committee agreed that there were no dual-use or ePPP concerns with the proposal.
vii. There were no additional public comments.
viii. Work is approved at: Animal work is approved at ABSL-2.
ix. Relevant sections of the NIH Guidelines: Animal work is approved at III-D-4-a
x. The committee unanimously approved the registration.
xi. There were no conflicts of interest identified.

III. Committee Review of Inactivation Procedures

IV. Standard Operating Procedures/Plans: None

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

Reports

I. Biosafety Officer Report: In November and December 2025, there were 23 research related incidents at the Bethesda campus areas. None involved recombinant DNA. There were 8 sharps related incidents. There were also six NHP related incidents. There were 12 incidents related to other animals. There were no incidents related to human blood and body fluids, nor any incidents related to other pathogens.

The BSO reminded everyone he has reviewed the preliminarily approved registrations and registration amendments and asked again if there were any other concerns or questions about those approvals. In the absence of any further comments, these registrations and registration amendments are formally approved.

Other reports: None

Around the Room/Committee Discussion

- The March meeting will take place March 4th as scheduled
- A reminder the OSP has mandated all IBC minutes will be publicly posted in a streamlined format. Please review the minutes in our new template and it is expected that IBC members must recuse themselves from discussions where they have conflicts of interest (as they have always done).
- The BSOs are always available prior to the meeting for any questions or concerns on reviews.

Adjournment

The meeting was adjourned by Dr. Malech at 2:03 PM.

Next meeting: March 4, 2026