NIH Institutional Biosafety Committee Minutes
Location: Bethesda Main Campus
June 03, 2026
2:00 PM – 5:00 PM
Virtual via Microsoft Teams

Members present: (9)
Quorum met: Yes

Mike Kujawa, Associate BSO	Stephen Denny, animal research expert	Alicia Alexion, unaffiliated member
Richard Baumann, BSO	Clevetta Drew, unaffiliated member	Stephanie Goff, Clinician
Robert Craigie, recombinant and molecular techniques	Harry Malech, Chair, clinician	Emily Lee, recombinant and molecular techniques

- absent members: Luz Angela Rosas, Steve Whitehead, *Brigette Billioux
*Provided comments *in absentia* for select secondary reviews

Guests present (9)

Krisztina Janosko (IRF)	Suk See De Ravin	Kaitlyn Connors
Kevon Sampson	Jocelyn Mendoza	Althea Treacy (Biorisk Chief)
Kyle O'Donnell	David Hawman	Mike Holbrook

Announcements & Call to Order

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

Review of the Past IBC Meeting Minutes

06 May 2026 Minutes

a. Comments on minutes, as applicable
b. The minutes were unanimously approved with minor modifications and formatting corrections.

New Committee Business

I. BSO preliminary registration approvals since the previous meeting

a. **Pathogen registrations** (8 total): 26-BMC-145, -148-154
b. **rDNA and rDNA/pathogen registrations**: 26-BMC-146 (Ramamurthi), III-E-1/III-D-4-a- Use of human a cancer cell line that express the Luciferase (luciferase expressing cell line used is purchased); 26-BMC-147 (Wray), III-D-III-a/III-D-4-a- Development and Regulation the GnRH Neuroendocrine system in vivo models; registration updates and replaces RD-15-I-18 and 6336. This registration is an administrative replacement and update with no significant changes from previous IBC approval; 26-BMC-155 (Lee), III-E-1- Generation of mouse models with mutations in Cdh3; 26-BMC-156 (Brownell), III-E-1- Plasmids vectors to study development and metastasis of Merkel cell carcinoma as well as normal Merkel cell development; 26-BMC-157 (Tschernia), III-E-1- Discovery and Preclinical Characterization of Antibody-Based Binders Against Tumor-Associated Antigens for Future Cellular Therapy Development
c. **Registration amendments**: Approved RD amendments ('amend 250603') for the Minutes: 26-BMC-059 (amend-O'Shea), 24-BMC-044 (amend-Norberg), RD-19-IX-06 (amend-Jacobson), 26-BMC-085 (amend-Gahl), 24-BMC-028 (amend-Chudasama), RD-20-VI-20 (amend-Chudasama), RD-23-IV-08 (amend-Chudasama), RD-22-VIII-18 (amend-Tisdale), RD-22-V-09 (amend-Chudasama), RD-15-VIII-31 (amend-Ruckwardt), RD-22-II-08 (amend-Ruckwardt), RD-23-IV-02 (amend-Gerfen), RD-20-X-05 (amend-Gerfen), RD-22-IV-08 (amend-Pierson), RD-20-

XII-08 (amend-Dekker), RD-23-II-03 (amend-Plenz), RD-19-VI-01 (amend-Kanekiyo), RD-17-XI-05 (amend-Ryba)

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-130, De Ravin, Suk See (presenting slides)

i. Reviewers: Goff, Billioux, All

ii. Review summary: Dr. De Ravin presented the study "*Phase 1/2 Base-Edited Hematopoietic Stem/Progenitor Cell Gene Therapy for Treatment of CXCR4-WHIM*". The purpose of this trial is to determine whether base-edited HSPCs (BE-HSPCs) are safe, can reconstitute immunity in WHIM participants, and improve participants' clinical status. The study will determine whether BE-HSPCs engraft and whether targeted CXCR4 mutation repair at the endogenous locus restores physiologic CXCR4 expression to prove safety and efficacy of gene therapy in WHIM.

Patients with WHIM syndrome due to CXCR4 mutations experience life-long problems with warts, hypogammaglobulinemia, infections, and myelokathexis. CXCR4 is a G protein-coupled receptor for the chemokine CXCL12 that regulates positioning and trafficking of HSPCs as well as most subsets of mature leukocytes. Anti-CXCR4 small molecules rapidly improve panleukopenia but have short half-lives and are therefore given daily. Stem cell transplants can potentially cure WHIM syndrome but carry significant chemo-toxicities, graft versus host disease (GvHD) risk; and this treatment is limited by donor availability. Gene therapy using autologous HSPCs has proven beneficial for many monogenic inborn errors of immunity (IEI) and has advantages of needing less intense preparative chemotherapy and no GvHD risk. WHIM syndrome is caused by autosomal dominant gain-of-function mutations in CXCR4, so current lentivector-mediated gene therapy which adds copy(s) of transgenes to supplement function, is not applicable. Recent developments in gene correction technologies allow targeted genome editing. Clustered regularly interspaced short palindromic repeats (CRISPR)/Cas9 base editors are capable of transversion of specific single nucleotides, thereby restoring regulation by endogenous promoters and physiological expression. Base-editing has repaired multiple pathogenic variants and treated patients with IEIs including X linked severe combined immunodeficiency (X-SCID) and CD40L Deficiency.

Background information was provided in a presentation given to the committee.

iii. Committee discussion:

- From a biosafety standpoint, all concerns have been addressed. There will be 10 participants in this trial with primary goal of safety. Will look at 3-month and 12-month points following infusion.
- The first two patients will be adults before accruing younger participants.
- From an IBC perspective this is similar to an IBC-reviewed protocol proposing to correct a genetic defect with the goal of making a normal protein with proper regulation. Therefore, there are no safety issues for handling the therapeutic that is being proposed.
- The protocol, evaluating both safety and response, is well written and was elegantly described by Dr. De Ravin. Secondary reviewer raised no additional safety concerns.
- One reviewer asked about the rate of base editing, and the criteria for use of the product must be 5-10% of CD34 cells to be edited. High rates of editing, sometimes over 80%, are expected.
- There are no DURC or ePPP safety concerns related to this work.

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 agent preparation and administration, especially when working outside of primary containment such as a Biological Safety Cabinet (see other 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. Malech recuses himself from reviewing this protocol and serving as IBC chair during its review, for which Dr. Bob Craigie serves as chair for this review.

b. Special reviews

SR01 26-BMC-158, Feldmann, Heinz

i. Reviewers: Lee, Denny, All
ii. Review summary: This submission is entitled "*Filoviruses*". This registration covers work with filoviruses such as Ebola and Marburg viruses. Viruses will be propagated and titered in eukaryotic cells. These viruses will be characterized in vitro using standard virological assays including growth kinetics, assessment of genome replication and transcription by strand specific qRT-PCR, viral gene expression by Western blotting, and microscopy (immunofluorescent and electron). Some viruses will be analyzed in relevant animal models of infection.

Filoviruses, such as Ebola and Marburg viruses, cause highly lethal hemorrhagic fevers and continue to pose a significant global health threat due to recurring outbreaks and their potential for rapid spread. These viruses will be used to investigate host pathogen interactions to determine correlates of pathogenesis and evaluate countermeasures. Ebola strains include Zaire, Sudan, Tai Forest, Reston, Bundibugyo, Bombali, Mengla (rodent adapted viruses: MA-ZEBOV, GPA-ZEBOV; Marburg: Musoke, Angola, Ozolin, Ravn, Popp, Ci67, (Rodent Adapted viruses: MA-MARV, HA-MARV, GPA-MARV)

iii. Committee Discussion:

- Viruses will be propagated and titrated on various cell lines. Viral protein expression may be measured by qRT-PCR, immunofluorescence or western blot under various conditions. Viruses may be used in eukaryotic cell-based screens for small molecule antivirals and antibody-based countermeasures. Eukaryotic cells may be used as in vitro models of host responses to various pathogens. Virus present in the supernatant or cell lysates may be concentrated by ultra-centrifugation for use as antigens for assays such as ELISAs.
- Animal experiments in this project will use laboratory mice as an in vivo model to evaluate the efficacy of candidate countermeasures against filoviruses. Delivery methods were specified. All procedures will be conducted in accordance with established ethical guidelines for animal research, with protocols designed to minimize discomfort and use the smallest number of animals necessary to achieve scientifically valid results.
- Vaccine is only effective against Zaire and therefore is not effective again some strains.
- Any infectious work with filovirus is approved at BSL-4. No mention of animal work with Ebola viruses other than Marburg. Cell lines being used should be added.
- One reviewer also mentioned a need to list the human cell types they are using and the extent of work with Marburg. One reviewer mentioned the necessity to ensure permits are in place regarding different strains they will be receiving, which was clarified. In cases of work with select agents, new CDC Form 2 forms will be referenced in the registration. Current

agents were received in 2014. Approval language can indicate that subsequent permits necessary to get material can be added to the registration as an amendment.
- The DURC questions were indicated as “no”, and there are no ePPP concerns.

iv. Training in line for work in the BSL-4 environment, including laboratory safety training and BBP training for those working with human materials, and all select agent requirements as applicable. PPE requirements in-line with risk assessment and regular laboratory requirements for this level.

v. Animal studies proposed: Yes (mice and macaques) to be done at ABSL-4.

vi. 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 proposed amendment.

vii. There were no additional public comments.

viii. Work is approved at: No prokaryotic work is described. Eukaryotic work is approved at BSL-4. Animal work is approved at ABSL-4, there currently are no plans to do VLP work at ABSL-4. Approval is pending IRE review in compliance with Executive Order 14292.

ix. Relevant sections of the NIH Guidelines: n/a, no recombinant work is described in this registration.

x. The committee unanimously approved as written with minor changes as discussed.

xi. There were no conflicts of interest indicated.

SR02 24-BMC-211 amend 260603, Holbrook, Michael

i. Reviewers: Denny, Craigie, All

ii. Review summary: The group is working to understand mechanisms of Arenavirus pathogenesis and evaluation of medical countermeasures. The purpose of the amendment is to add additional animal work at ABSL-4 entitled “*Immune regulation of arenavirus infections in the placenta*”. The amended animal study proposal (ASP) describes a project that is focused on understanding the impact of Arenavirus infection on pregnancy. Abortion is a known problem with infection with these viruses. This project will evaluate infection by wild-type Lassa and Junin viruses in pregnant guinea pigs to evaluate outcome, target maternal and fetal cell populations and degree of virus movement across the placental membrane to infect fetal tissues. Once fundamental aspects of the infection are determined, additional studies may be added by amendment.

iii. Committee Discussion:
- The reviewer mentioned guinea pigs are an established model for this virus. Strains are listed appropriately and no vaccines are available.
- All waste appears to be treated appropriately and consistent with IBC standards. ASP was attached and very informative. LASV plasmids were described in detail in this and the previous Lassa RD on record, including the original process which uses 5 different plasmids.
- The committee discussed the potential for DURC or ePPP concerns. B question was “Yes” only for “synthetic biology” which is based on the mechanism to create this but does not relay any additional issues regarding DURC or ePPP.
- Secondary reviewer had no additional comments.

iv. Expected training is BBP for anyone handling human cells or materials, and appropriate training per the BSL- level for the high containment laboratories. A 1-2-3 poster must be displayed in the laboratory and all personnel on this registration must maintain annual lab safety through the Division of Safety. PPE as established for these laboratories and locations (see in registration).

v. Animal studies proposed: Yes (Guinea pigs) at ABSL-4.

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. Work is approved at: Eukaryotic work is approved at BSL-4. Animal work is approved at ABSL-4. Approval is pending IRE review in compliance with Executive Order 14292.

ix. Relevant sections of the NIH Guidelines: N/A no new recombinant work is being performed in this amendment. Previously described recombinant work in this registration was cited under III-D-3-a.

x. The committee unanimously approved as written.

xi. There were no conflicts of interest indicated.

SR03 26-BMC-159, Feldmann, Heinz

i. Reviewers: Goff, Lee, All

ii. Review summary: This registration is entitled "*Tick-borne flavivirus: In vitro and in vivo studies with TBEV, Omsk hemorrhagic fever virus, Powassan, Kyasanur Forest disease virus, and Alkhumra virus*". Viruses will be propagated and titered in eukaryotic cells. These viruses will be characterized *in vitro* using standard virological assays including growth kinetics, assessment of genome replication and transcription by strand specific qRT-PCR, viral gene expression by Western blotting, and microscopy (immune-fluorescent and electron). Some viruses will be analyzed in relevant animal models of infection.

Tick-borne flaviviruses, such as Omsk, Kyasanur Forest disease virus and tick-borne encephalitis virus (TBEV), are emerging and reemerging pathogens that can cause severe neurological disease in humans, including encephalitis and long-term complications. Their expanding geographic range, driven in part by changes in climate and vector distribution, poses an increasing public health concern. These viruses will be used to investigate host–pathogen interactions, with the goal of identifying determinants of neuroinvasion and immune evasion, as well as defining correlates of disease severity. Insights gained from these studies will support the development and evaluation of effective vaccines and antiviral countermeasures.

iii. Committee Discussion:

- No permit was attached here, and as discussed previously these issues are accounted for with Select Agent-specific transfer forms, and with QPSO and safety personnel for others.
- ASP is specific to one virus, they are opting to work with Risk Group 3 viruses (like Powassan) at BSL-4, and all work is being proposed at BSL-4.
- No prokaryotic work is proposed only work in eukaryotic cell lines.
- Secondary reviewer had no additional comments. Multiple viruses listed, but no details for cell lines being used. A description of the cell lines being proposed for both human and NHP, would be helpful.
- There are no DURC or ePPP related concerns with this amendment proposal.

iv. Expected training is BBP for anyone handling human cells or materials, and appropriate training per the BSL-4 level for the maximum containment laboratories. A 1-2-3 poster must be displayed in the laboratory and all personnel on this registration must maintain annual lab safety through the Division of Safety. PPE as established for these laboratories and locations (see in registration).

v. Animal studies proposed: YES (mice), but only Alkhumra strain is listed.

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. Work is approved at: No prokaryotic work proposed. Eukaryotic work is approved at BSL-4. Animal work is approved at ABSL-4. Approval is pending IRE review in compliance with Executive Order 14292.

ix. Relevant sections of the NIH Guidelines: N/A, no rDNA work is being proposed here.

x. The committee unanimously approved with minor details to be added as discussed.

xi. There were no conflicts of interest indicated.

SR04 26-BMC-160, Feldman, Heinz

i. Reviewers: Denny, Lee, All

ii. Review summary: The NIAID investigators have submitted the registration entitled "Influenza virus: In vitro/in vivo experiments with influenza A and B including HPAI viruses". Influenza viruses are the cause of significant morbidity in humans and animals worldwide. In vitro and in vivo work with influenza viruses will be performed to understand viral pathogenesis, host determinants of

disease and evaluate urgently needed antivirals and vaccines. Seasonal influenza A H1N1, influenza A H3N2 and influenza B are the cause of annual, seasonal epidemics throughout the world. Continual antigenic shifts and drifts require continual updating of vaccines and can occasionally result in viruses capable of causing worldwide pandemics. Highly pathogenic avian influenza (HPAI) such as H5N1 causes high mortality in avian and other wild animal species. Human infections with HPAI can also result in high mortality and there is concern of pandemics caused by H5N1 and other HPAI. A better understanding of the host and viral determinants of influenza pathogenesis and countermeasures is urgently needed. Influenza A strains include seasonal and pandemic IFV A strains, subtypes H1-H18 and N1-N11, *except* HPAI subtypes H5 & H7, LPAI H7N9. Also using B strains and animal work is proposed. No work with influenza 1918 is being proposed. The overall purpose is to generate infected material from animals that inactivation testing can be performed on among other goals.

iii. Committee Discussion:

- The registration is for working with influenza viruses A and B as well as HPAI in animals, and no rDNA work is being proposed. This work supports efforts to understand virus and antigenic drift, etc., using a deep learning model.
- For the animal work and for work with other viruses any work not described here, will be submitted with amendment. Mice may be challenged with the virus at III-D-4-b at ABSL-3. Research group states that no prokaryotic work is being performed here, and the registration should be updated to reflect this. No federal permits are attached, which may be required in some cases, but these agents have been in inventory for many years.
- Attempting to understand the pathogenicity of HPAI in ferrets. There was further discussion regarding how to approve this work with these multiple RG (risk group) agents, and all work here is being approved at ABSL-4.
- A discussion regarding what the appropriate surrogates are for various families of viruses occurred. One issue is the families have undergone taxonomic changes and what was previously considered “Bunyaviruses,” as mentioned also in this registration, is a larger class of viruses and not a family. The IBC recognized surrogates of the same family. This was brought up again in the discussion and it will be clarified with the CDC what is acceptable to use as particular surrogates for particular families this latter discussion was specifically surrounding Hazara virus and whether it was an appropriate surrogate for all ‘bunyaviruses’ (an Order now, due to their diversity), and this will be clarified. It was mentioned that CDC bases their information on the prior taxonomy that existed and this is indeed the issue the IBC is cautioning about.
- There was another question about the nature of the project-based registration and how that fits into this with some of the additional work described.
- It was also clarified again that the Select Agent Regulation Form 2 process will be used for select agent transfers, and permits may be required for non-select agents.

iv. Expected training is BBP for anyone handling human cells or materials, and appropriate training for BSL-4 and the maximum containment laboratories. A 1-2-3 poster must be displayed in the laboratory and all personnel on this registration must maintain annual lab safety through the Division of Safety. PPE as established for these laboratories and locations.

v. Animal studies proposed: Yes, proposed in mice and ferrets.

vi. 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 proposed amendment.

vii. There were no additional public comments.

viii. Work is approved at: Eukaryotic work is approved at BSL-4 for the higher RG influenza viruses, some work with RG-2 viruses may be performed in cells at BSL-2, where applicable (with the RG-2 strains included). Animal work is approved at ABSL-4. It was discussed and stated that ABSL-2 level work at the IRF is only in the discussion phases at this stage. It is possible that such work may have to be performed elsewhere. Just recently they have a particular space which is listed as a BSL-4 which they will be able to perform BSL-3 practices in, a special laboratory area.

Currently there is no ABSL-3 work possible at the IRF. Approval is pending IRE review in compliance with Executive Order 14292.

ix. Relevant sections of the NIH Guidelines: N/A no recombinant work is being proposed.

x. The committee unanimously approved as written.

xi. There were no conflicts of interest indicated.

SR05 26-BMC-163, Feldman, Heinz

i. Reviewers: Craigie, Denny, All

ii. Review summary: The NIAID investigators study Henipaviruses and will be propagating these viruses and characterizing them. This registration is entitled “Henipavirus (Hendra, Nipah, Cedar virus); in vivo and in vitro work”. Despite the severe disease burden associated with henipaviral infections, fundamental gaps remain in understanding the molecular mechanisms governing host-pathogen interactions and the determinants of pathogenesis. Current countermeasures, including vaccines and therapeutics, are limited and inadequately characterized in their protective capacity. These viruses will be used to investigate host pathogen interactions to determine correlates of pathogenesis and evaluate countermeasures.

iii. Committee Discussion:

- There is no prokaryotic work. Eukaryotic work is approved at BSL-4 for cell work. Animal work in Syrian golden hamsters.
- Henipaviruses to study host/pathogen interactions by propagating on cell lines that are listed. Viral protein expression will be done by quantitative PVC and Western blotting will be performed. Grown virus will be titered.
- No DURC or ePPP concerns are present in this project, no work with rDNA or synthetic NA is described.
- Work is approved at BSL-4 and ABSL-4 for animal work. Approval is pending IRE review in compliance with Executive Order 14292.
- Conducting inactivation testing is mentioned

iv. Expected training is BBP for anyone handling human cells or materials, and appropriate training per the BSL-3 level for the high containment laboratories. A 1-2-3 poster must be displayed in the laboratory and all personnel on this registration must maintain annual lab safety through the Division of Safety. PPE as established for these laboratories and locations (see in registration).

v. Animal studies proposed: No animal work was discussed in context of this amendment.

vi. 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 proposed amendment.

vii. There were no additional public comments.

viii. Work is approved at: No prokaryotic work is approved. Animal work is approved at ABSL-4.

ix. Relevant sections of the NIH Guidelines: N/A, as no recombinant work is proposed. Approval is pending IRE review in compliance with Executive Order 14292.

x. The committee unanimously approved as written.

xi. There were no conflicts of interest indicated.

c. Registrations for committee review

26-BMC-161, Connors, Mark

i. Reviewers: Lee, Goff (review around 1:30)

ii. Review summary: This study is entitled “Use of synthetic mRNA and self-amplifying RNA vaccine candidates for preclinical animal testing” They wish to study HIV specific immunity. They will investigate immunogenicity of viral proteins and of synthetic mRNA and self-amplifying RNA (saRNA) vaccine candidates encoding viral antigens (HIV and Influenza) in animal models.

Comparing conventional mRNA and saRNA vaccine formats in the same animal model will provide information on relative immunogenicity, reactogenicity, dose-sparing potential, durability of immune responses, and suitability for further vaccine development.

Preclinical studies have demonstrated that mRNA vaccine platforms can induce immune responses in animal models against multiple infectious disease targets. Self-amplifying RNA, or saRNA, is a related RNA vaccine platform that contains RNA replication/amplification elements in addition to the antigen-coding sequence. Unlike conventional non-replicating mRNA, saRNA is designed to amplify the RNA intracellularly, which can increase antigen expression from a lower input amount of RNA. Reviews of saRNA vaccines note that both conventional RNA and self-amplifying RNA platforms have shown protective immunization in preclinical studies against infectious disease targets, and that saRNA can provide enhanced antigen expression at lower doses compared with conventional mRNA. This study will generate preclinical data needed to determine whether the vaccine candidates produce measurable immune responses and acceptable safety profiles before advancing to larger animal studies, challenge studies, or other downstream development. The project will also help identify whether the saRNA format offers advantages over conventional mRNA for this antigen, including stronger or more durable antigen expression, improved immunogenicity, or reduced RNA dose requirements.

iii. Committee Discussion:
- Prokaryotic work will be working with cells- III-D-2 at BSL-1. They are only proposing to express the viral proteins. The attachment of the plasmid maps was incorrect, but the PDFs were available in the system. The proposal involves only expressing flu proteins HA and NA.
- Risk of integration is very low as no homology is expected.
- Eukaryotic work with expressing mRNAs etc. is proposed at BSL-2.
- Secondary reviewer- The SHIV and the MVA are under separate registration numbers. This registration is just for the siRNA. VSV and AAV boosts will be submitted by future amendment. The self-replicating mRNA technology is very interesting as described here.
- There are no DURC or ePPP related issues.

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: Yes- in Rhesus macaques expressing mRNAs HIV or flu antigens, and also in rabbits.

vi. The committee discussed the dual-use and ePPP potential of these experiments. All answers were “no” and the committee agreed that there were no dual-use or ePPP concerns with the proposal so long as no GOF experiments were being performed.

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 BSL-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 under III-D-4-a. No challenge work is being approved here.

x. The committee unanimously approved with minor modifications and clarifications as discussed.

xi. There were no conflicts of interest identified.

26-BMC-162, Mock, Beverly

i. Reviewers: Craigie, Goff

ii. Review summary: The protocol is entitled “*Labeling of Murine cell line with Luciferase*”. The investigators have cell lines generated from tumors originating on the tongue of Black/6 mice with a Cas9 transgene. They plan to label these cells lines with luciferase so that we can follow the tumor growth and possible metastasis in vivo via imaging using an IVIS system. They have generated cell lines from oral cancers induced in the black/6 Cas9 transgenic mouse and will

transduce these cell lines with a luciferase tag. They have seen metastasis in vivo and would like to be able to track the tumor development in real time.

iii. Committee Discussion:
- The group has cell lines generated, and they are going to label them with luciferase to follow tumor growth delivered with lentivirus.
- No prokaryotic work is described. Cell lines will be transduced with second generation lentiviral vectors under III-D-3-a with BSL-2 with 3 level practices. Animal work for injection of stably transduced murine cell lines into animals is approved at ABSL-1 under section III-D-4-a.
- Secondary reviewer was unclear what generation LVV system this was. Safety group will follow up to clarify.
- The DU questions are all answered no which is appropriate, and there are no DURC or ePPP issues.

iv. Training and PPE requirements as established with the ABSL-2 level, to include laboratory safety training and animal training requirements per OACU.

v. Animal studies proposed: Yes, mice. (III-D-4-a) ABSL-1.

vi. There were no dual-use and ePPP potential of these experiments. 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 at BSL-2. Animal work at ABSL-1 practices and containment

ix. Relevant sections of the NIH Guidelines: III-D-3- a for eukaryotic work. Animal work at III-D-4-a, ABSL-1, and using NIH MC 3044-2 for work with NHPs.

x. The committee unanimously approved as written.

xi. Dr. Whitehead abstained from voting as this was his registration proposal.

d. Registration amendments for committee review

RD-24-BMC-075 amend 250603, Lifson, Jeffrey

i. Reviewers: Denny, Craigie

ii. Review Summary: They study SIV and HIV and wish to add two ASPs. SIV variants are naturally occurring, and they wish to study the ”viral bottleneck” that occurs with transmission. Using bar-coded SIV will support molecular techniques to detect virus in animals and animal specimens. Semen will be collected from infected animals as part of this amendment.

iii. Committee Discussion.
- All to be done under BSL-2 for eukaryotic work (under III-D-3-a). Animal work will use various forms of SIV into Rhesus macaques via different routes and will be performed at ABSL-2, consistent with rDNA guidelines III-D-4-b.
- Secondary reviewer had no additional comments.
- All DURC questions are answered no, which is appropriate. There are no DURC issues. Question B about ‘Synthetic Biology’ referred to their mutagenesis work and was not relevant to DURC concerns.

iv. Training and PPE requirements as established including standard precautions.

v. Animal studies proposed: Yes, NHPs in referenced animal study proposal

vi. The committee discussed the dual-use and ePPP potential of these experiments. The committee agreed that they felt were no dual-use or ePPP concerns with the proposal, but to be cautious they will advance the proposal on for consideration by the NIH ICDUR for determination as to whether the DURC-IRE will need to review.

vii. No additional public comments were received.
viii. Work is approved at: Eukaryotic work is established at BSL-2.
ix. Relevant sections of the NIH Guidelines: Eukaryotic work at III-D-3-a.
x. The committee unanimously approved as written.
xi. No conflicts of interest were identified.

26-BMC-100 amend 250603, Duffy, Patrick

i. Reviewers: Lee, Denny
ii. Review Summary: LMIV is working with a collaborator that has expressed a modified PfCSP in a recombinant Herpes Simplex virus 2 (HSV-2) based vaccine vector. This vector is named HSV delta-g(GJDI)-2 because it lacks the major glycoproteins gG, gJ, gD and gI that are essential for virus entry, cell to cell spread and neuronal migration which makes this a single cycle- replication defective virus. Our collaborators have assessed its safety in both immunocompetent and immune- compromised mice. This vaccine vector specifically induces Fcy receptor activating antibodies against HSV and the cloned exogenous antigen as well, which in this case will be the CSP. Described in the amendment to LMIV-1E, LMIV would like to immunize mice intramuscularly with 5 x 10^6 PFUs of the virus (HSVdelta-g(GJDI)-2 expressing CSP) and do intra-nasal immunization (to assess which route of immunization gives better protection) as prime and boost immunizations at a 3-week interval followed by challenge with virulent P. berghei 3 weeks post the booster immunization. For this work, they have added a pathogen (HSV) and recombinant material (explaining how the mutated HSV is made and used) to the Project Information section. They have also uploaded the amended ASP LMIV-8E which is renewed and there are no significant changes to that ASP as compared to what was approved previously.

iii. Committee Discussion.
- They note they already have an ASP amendment where they will deliver IP or IM. LMIV8E also uploaded.
- Dr. Denny agreed and had no additional comments.
- All DURC related questions indicated as no which is appropriate, there are no DURC or ePPP concerns.

iv. Training and PPE requirements as established.
v. Animal studies proposed: yes
vi. 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.
vii. No public comments were given.
viii. Animal work is approved at the established level of ABSL-2 practices and containment and following the standard procedures for working with NHP as established in NIH MC 3044-2.
ix. Relevant sections of the NIH Guidelines: Animal work at III-D-4-b
x. The committee unanimously approved as written.
xi. No conflicts of interest were identified.

RD-23-XII-02 amend 250603, Wess, Jurgen

i. Reviewers: Goff, Craigie
ii. Review Summary: The original rDNA registration RD-23-XII-02 is approved to do Adeno-associated viruses. Now they want to use a knockout mouse and use an adenoviral vector construct to re-introduce Ffar1 to restore glucose stability.

iii. Committee Discussion.
- Experiments are being performed to introduce adenoviral vector by tail vein into mice to reintroduce Ffar1 expression.

- should be handled at BSL-2. Prokaryotic work is approved at BSl-1 under section III-D-2-a.
- Eukaryotic work is approved at BSL-2, under section III-D-3-a. Animal work is approved at ABSL-2→1 containment under II-D-4-a.

iv. PPE and training requirements as established and to include BBP training for individuals handling human materials.
v. Animal studies proposed: Nothing additional here.
vi. 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.
vii. No public comments were given.
viii. Work is approved at: Eukaryotic work at BSL-2, animal work is approved at BSL-2.
ix. Relevant sections of the NIH Guidelines: Eukaryotic work is established at III-D-3-a, animal work is approved under section III-D-4-a.
x. The committee unanimously approved the registration with minor corrections as mentioned.
xi. No conflicts of interest were identified.

24-BMC-065 SAE1 250603, Hassan, Raffit

i. Reviewers: Malech, Goff
ii. Review Summary: The investigators report an original concern which turned out to be falsely identified replication competent particles (RCP) of viral vector. They extended the passage of transduced cells to prove that there was no replication competent viral vector present. The IBC has reviewed and accepted the report.

iii. Committee Discussion:
- The report was originally a concern for RCP which turned out to be false.
- Dr. Goff mentioned the false positive was from the patient's blood and now the FDA has given some freedom to do follow-up testing now and it can be demonstrated that RCP was not in the product.

iv. PPE and training requirements as established.
v. Animal studies proposed: N/A – SAE report form a clinical trial.
vi. 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.
vii. No public comments were given.
viii. Prokaryotic work is approved at BSL-1. No eukaryotic work. Animal work is approved at ABSL-1 containment and practices.
ix. Relevant sections of the NIH Guidelines: prokaryotic work is approved under III-D-02-a, animal work at III-D-4-a
x. The committee unanimously approved with minor modifications.
xi. No conflicts of interest were identified.

III. Committee Review of Inactivation Procedures: None other than as reviewed in the #6718 amendment.

IV. Standard Operating Procedures/Plans: None

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

Reports

I. Biosafety Officer Report will be electronically sent for committee review. In April 2026, there were 25 research related incidents, none involved rDNA, there were 7 sharps- related incidents, 8 involving

non-human primates (NHP -3 Old World/ 5 with New World animals), 11 involving incidents working with “Other animals”, 1 potential exposure to HBBF material, and 1 involving a potential exposure to a human pathogen.

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 July meeting will be scheduled to avoid potential conflicts around July 4th.
- As of June 2025, the OSP has mandated all IBC minutes will be publicly posted in a streamlined format. The four NIH IBCs have agreed on and are using a 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. Craigie at 4:09 PM.

Next meeting: The BSO will communicate and determine what works best, tentatively scheduling for July 22, 2026 (and one reviewer already knew this was a conflict)