NIH Institutional Biosafety Committee Minutes
Location: Bethesda Main Campus
April 1, 2026
2:00 PM – 5:00 PM
Virtual via Microsoft Teams

Members present: (10)
Quorum of 5 met: Yes

Harry Malech, Chair, clinician	Stephen Denny, animal research expert	Alicia Alexion, unaffiliated member
Jeanne Billioux, Clinician	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: Richard Baumann,
*Provided comments *in absentia* for select reviews

Guests present (5)

Grace Markley (NBBTP)	Jocelyn Mendoza (NBBTP)	Kaitlyn Connors (NBBTP)
Raluca Semeniuc (DS)	Luz Angela Rosas (NIAID)	

Announcements & Call to Order

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

Review of the Past IBC Meeting Minutes

11 March 2026 Minutes

a. Comments on minutes, as applicable
b. The minutes were unanimously approved with minor modifications and formatting corrections by 04/15/26.

New Committee Business

I. BSO preliminary registration approvals since the previous meeting

a. **Pathogen registrations** (10 total): 26-BMC-087, -088, -090, -092, -094-097, -099, -102
b. **rDNA and rDNA/pathogen registrations**: 26-BMC-085 (Gahl) III-D-3-a/III-D-4-a- Preclinical Gene and Supportive Therapies in Murine Models of Lysosome-Related Organelle Disorders; registration updates and replaces registrations: RD-14-V-06, 7027, RD-17-IV-11, 7103 and 6048. This registration is an administrative replacement and consolidation with no significant changes from previous IBC approvals; 26-BMC-086 (Vishwasrao) III-E-1- General biological imaging experiments with human/animal cell line and tissues at the Advanced Imaging and Microscopy Resource; registration updates and replaces registrations: 8723, 8724, 8429 and RD-22-IV-01. This registration is an administrative replacement and consolidation with no significant changes from previous IBC approvals; 26-BMC-089 (Wingfield) III-E-1- Ongoing Projects in the Protein Expression Laboratory; 26-BMC-091 (Buchholz) III-D-3-a- Vesicular Stomatitis Virus (VSV) registration updates and replaces registrations: RD-11-VI-20 and 5468. This registration is an administrative replacement with no significant changes from previous IBC approvals; 26-BMC-093 (Robey) III-E-1/III-E-3- Generation of a Smad3-S264Y mutant mouse model; 26-BMC-098 (Buchholz) III-D-3-a / III-D-4-a - Assessing avian paramyxovirus (APMV) types 2 - 9 as potential vaccine vectors; registration updates and replaces registrations RD-10-X-05 and 5291. This registration is an administrative replacement and consolidation with no significant changes from

previous IBC approvals; 26-BMC-100 (Duffy) III-D-2-a/III-D-3-a/III-D-4-a- Infectious Diseases Vaccine Development and Antimicrobial Resistance; registration updates and replaces registrations: 5137, 5199, RD-10-III-15, RD-10-IV-10, RD-10-V-06. This registration is an administrative replacement and consolidation with no significant changes from previous IBC approvals. 26-BMC-101 (Hinshaw) III-E-1- E. coli containing expression plasmids for recombinant protein production

c. **Registration amendments**: **Approved RD amendments ('amend 260401') for the Minutes:** 25-BMC-191 (amend-Gonzalez), 25-BMC-068 (amend-Goldman), 24-BMC-028 (amend-Chudasama), RD-14-VIII-15 (amend-Cai), RD-17-I-13 (amend-Cai), 26-BMC-031 (amend-Seder), RD-17-X-20 (amend-Buchholz), RD-14-X-25 (amend-Buchholz), RD-20-IV-18 (amend-Buchholz), RD-20-IV-04 (amend-Buchholz), RD-20-IV-02 (amend-Buchholz), RD-16-III-04 (amend-Buchholz), RD-15-V-10- (amend-Buchholz), RD-19-VI-01 (amend-Kanekiyo), RD-20-II-22 (amend-Murgai), RD-20-II-23 (amend-Murgai), RD-13-VI-22 (amend-Su), RD-21-XII-10 (amend-Tan), 24-BMC-230 (amend-Su), RD-20-III-06 (amend-Gu), RD-16-IV-14 (amend-Germino), RD-17-X-04 (amend-Pierson), RD-18-IX-14 (amend-Reilly), RD-23-XII-02 (amend-Wess), RD-22-III-02 (amend-Ferre), 24-BMC-237 (amend-Wu), RD-15-X-08 (ConRev-Yang), RD-22-VIII-06 (amend-Cameron), RD-21-X-07 (amend-Ruckwardt)

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. Registrations for committee review

26-BMC-104, Brandon Harvey

i. Reviewers: Lee, Denny

ii. Review summary: Title: Delivery of engineered virus-like particles (eVLPs) into the rat brain
In this study, investigators will use eVLPs to deliver a protein called Cre-recombinase (iCre) into normal rats and genetically modified rats (DIOmCherry rat) that can produce a red fluorescent signal. The iCre protein turns on this red signal in the modified rats. This will help them to improve eVLPs so they can be designed to target specific types of brain cells. Engineered virus-like particles (eVLPs) are a relatively new way to carry proteins into cells, including the tools used for gene editing. Many new treatments need safe and reliable ways to deliver these materials into the right cells, both in the lab and in the body.

iii. Committee Discussion:

- A reviewer noted prokaryotic work was only for propagation of the plasmids since it was created by a Core. They were also unsure what section of the guideline sit should go under since they are VLPs and III-D feels like playing it too safe. Other committee members stated that VLPs are becoming increasingly common and may even be exempt since they aren't delivering mRNA and it's just a protein.

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: Rats

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 due to use of human cells, but work in animal cells may be performed at ABSL-1. Rats at ABSL-1.
ix. Relevant sections of the NIH Guidelines: Prokaryotic work is approved under III-E-1, eukaryotic work is approved under III-E-1, animal work is approved under III-D-4-a.
x. The committee unanimously approved the registration as written.
xi. There were no conflicts of interest identified.

26-BMC-105, John Schiller

i. Reviewers: Billioux, Whitehead
ii. Review summary: Title: Yeast, bacterial and baculovirus produced non-infectious polyomavirus VLPs

The investigators have designed a polyomavirus vaccine based on VLPs expressed in the baculovirus expression system (insect cells). However, large scale production is challenging. Production of VLPs in yeast or bacterial cells is theoretically cheaper, faster and potentially more efficient. The team would like to explore production of VLPs in yeast and bacteria and perform pilot experiments to see if the VLPs are immunogenic in mice. Several human polyomavirus VLPs have been successfully expressed in yeast. An expansion of this work would be to express the VLPs in a yeast strain that is commonly used in the lab and another strain sold as a probiotic (S. cerevisiae and S. c. var. boulardii). This would allow for testing and developing an oral vaccine for polyomaviruses.

They also wish to express non-infectious VLPs in non-pathogenic E. coli strain K-12 and in probiotic strain Lactobacillus sakei. In addition, they would like to apply this same VLP production method in yeast to the related Human Papillomaviruses.

iii. Committee Discussion:
- The reviewers stated that there was no real ASP attached, but the PI stated that it is currently being re-written. They wished to know who exactly is making the pFastBac plasmid as it is not clear. Also wanted to know why mutation by truncating one of their capsid genes is occurring, since they want VLPs to be created and this would likely prevent it.

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 with yeast is approved at BSL-1. Prokaryotic work with bacteria is approved at BSL-1. Eukaryotic work in human cell lines is approved at BSL-2. Baculovirus eukaryotic work is approved at BSL-2. Mouse work can be approved at ABSL-1 upon receipt of a full ASP.
ix. Relevant sections of the NIH Guidelines: Yeast eukaryotic work is approved under III-D-2-a, bacteria work is approved under III-D-2-a, baculovirus is approved under III-D-1-a. Mouse work can be approved under III-D-4-a upon receipt of a full ASP.
x. The committee unanimously approved the registration with minor clarifications.
xi. There were no conflicts of interest identified.

26-BMC-106, Todd Macfarlen

i. Reviewers: Whitehead, Goff

ii. Review summary: Title: Lipid Nanoparticle–Based mRNA Delivery.

Lipid Nanoparticle (LNP)-mediated RNA delivery provides a safer and more flexible alternative to viral vectors for transient gene expression. This approach is particularly well-suited for studies of germ cell and testis biology relevant to NICHD mission priorities promoting healthy pregnancies and fertility, enabling efficient evaluation of multiple constructs while maintaining animal welfare and minimizing biosafety risk. This study employs lipid nanoparticle-mediated delivery of RNA as a non-viral, non-integrating strategy to enable transient modulation of gene expression in the testis, allowing temporally controlled interrogation of epigenetic mechanisms without permanent genetic modification. The RNA payload is non-replicating and degrades naturally, and the lipid-based delivery system is non-infectious and incapable of propagation, substantially reducing biosafety risks relative to viral vectors. This approach provides a flexible, low-risk platform to investigate epigenetic reprogramming during mouse spermatogenesis.

iii. Committee Discussion:

- PI accidentally marked 'yes' to toxin question and that needs to be changed. In the animal section there is mention of a virus being injected but these are actually VLPs. BSOs will ask the PI to clarify that there is no viral work planned.

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-1. Eukaryotic work is approved at BSL-2. Mouse work is approved at ABSL-1.

ix. Relevant sections of the NIH Guidelines: Prokaryotic work is approved under III-E-1, eukaryotic work is approved under III-E-1, animal work is approved under III-D-4.

x. The committee unanimously approved the registration with minor clarifications.

xi. There were no conflicts of interest identified.

26-BMC-107, Rafael De Cabo

i. Reviewers: Denny, Lee

ii. Review summary: Title: Role of SIRT6 in delaying or reverting age-related phenotypes: for recombinant work in adeno-associated virus. The purpose of the study is to evaluate the role of liver SIRT6 in delaying or reverting age-related phenotypes. Constructs expressing the marker eGFP (VB2008), or mouse SIRT6 (AAV-279532) under a hepatocyte specific promoter (hcrApoE/hAAT1) will be introduced by tail vein injection. The impact of expression of SIRT6 on a number of age-related phenotypes and pathologies will be evaluated. Following the completion of the experiment mice will be euthanized for tissue collection and molecular characterization. The main objective of this protocol is to assess novel genetic, pharmacological, nutritional, and environmental interventions that may improve health span and lifespan of animal models of human aging. Specifically, we would like to add a new experiment that will be conducted following the paradigm described under longevity studies and the Mid-Late life intervention studies sections of the main ASP. This experiment will test how liver specific overexpression of SIRT6 in 12-22-month-old mice impact lifespan and the development of age-related phenotypes.

iii. Committee Discussion:

- A reviewer asked about the vector file name, but otherwise stated the review was straight forward.

iv. Training and PPE requirements as established with BSL to be in line with a BSL-1 laboratory, to include laboratory safety training. PPE standards include protective labcoat and gloves.
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: Mouse work is approved under III-D-4-a.
x. The committee unanimously approved the registration as written.
xi. There were no conflicts of interest identified.

26-BMC-108, Ellen Sidransky

i. Reviewers: Denny, Craigie
ii. Review summary: Title: Development of systemic AAV gene therapies for neuronopathic Gaucher disease and GBA1-associated Parkinson disease. The goal of this study is to develop viral-based gene therapies and to evaluate their efficacy in murine models of neuronopathic Gaucher diseases (GD) as well as a human cellular model of GBA1-Parkinson disease. Adeno-associated viral vectors (AAVs) expressing engineered the human GBA1 gene will be used as gene therapy constructs.
We will also generate a new mouse model of neuronopathic GD by injecting AAVs expressing Cre recombinase in a transgenic mouse expressing floxed Gba1. Current enzyme replacement and substrate reduction therapies do not address neuronopathic manifestations of GD types 2 and 3 (GD2 and GD3), nor GBA1-associated Parkinson disease (GBA1-PD) because they fail to cross the blood–brain
barrier. Previous postnatal studies of GBA1 gene therapy in murine models of nGD failed to show durable correction, prompting this group to develop improved vectors to treat nGD and GBA1-related disorders.

iii. Committee Discussion.
- A reviewer noted that the uploaded vector map was not of the AAV backbones that were listed but, instead, contains a codon optimized coding sequence. The registration was otherwise clear and straightforward.

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.
ix. Relevant sections of the NIH Guidelines: Eukaryotic work is approved under III-D-3-a, animal work is approved under III-D-4-a.
x. The committee unanimously approved the registration with minor updates of plasmid maps.
xi. There were no conflicts of interest identified.

26-BMC-109, John Schiller (second)

i. Reviewers: Whitehead, Craigie

ii. Review summary: Title: Serology of Adintoviruses. A novel class of viruses (adintoviruses) were found by querying sequence databases (in silico). Those sequences were sometimes found in human samples. The purpose of the proposal is to try to identify whether those viruses commonly infect humans or are just a contaminant found during sequencing. For this project we will produce the non-infectious capsids (outer protein) of these adintoviruses in vitro, and test if normal human sera

(purchased commercially) have antibodies that react against these proteins.

iii. Committee Discussion:

- It was noted that the researchers are only creating proteins from the virus, but the BSOs sent it forward for committee awareness due to the novelty of the virus used.

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 as written.

xi. There were no conflicts of interest identified.

26-BMC-110, Jizhong Zou

i. Reviewers: Goff, Lee

ii. Review summary: Title: Transduction of human cells using lentivirus

As the iPSC Core at NHLBI, this group uses human cell lines, especially iPSC lines, as models to study human development and disease. Genetic modification using lentivirus-delivered transgene is a robust and efficient method. They plan to use commercially available lentivirus to transduce human cells in order to establish genetically modified human cell models. Significant improvement on lentivirus production and safety has been made in the lab, and currently the custom-made commercially available lentiviruses we use are third-generation and replication-defective. Compared to other integrated viruses, lentivirus is the most efficient in transducing human iPSCs therefore this is the preferred virus for genetic modification for human iPSCs. This registration updates and replaces registrations RD-11-VI-10 and 5588.

iii. Committee Discussion:

- A reviewer asked about why the investigator selected BSL-2/3, the BSO clarified that the original approval was for BSL-2/3 back in 2011 but this resubmission was to request BSL-2. There was a discussion that due to the oncogenic potential when using the Yamaka factors specifically in lentiviral vectors, the work needs to be at BSL-2/3 even though it is a third-generation system. A reviewer noted that the product insert from Sigma Aldrich said BSL-2 was appropriate. The final decision by the committee was work to be performed at BSL-2. The committee voted 6-1 (chair abstained) to apply this BSL-2 designation to all future reviews using this system combination.

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: Prokaryotic work is approved at BSL-1. Eukaryotic work is approved at BSL-2.
ix. Relevant sections of the NIH Guidelines: Prokaryotic work is approved under III-D-2-a, eukaryotic work is approved under III-D-3-a.
x. The committee unanimously approved the registration as written.
xi. There were no conflicts of interest identified.

26-BMC-111, Daniel Douek

i. Reviewers: Lee, Craigie
ii. Review summary: Title: Use of parainfluenza viruses for characterization of immune responses
The intent of this study is to use live virus isolates of PIV 1, 2, 3, 4a, and 5 to characterize serological responses across human populations in neutralization assays. As needed, recombinant viral protein products may also be expressed in HEK293 cells to characterize the epitopes of antibodies identified through the course of this study. VRC will assess human serum and/or plasma samples for reactivity to PIVs using a Meso Scale Discovery binding assay or similar platform. Understanding the immune response to, as well as antigenic characterization of these viruses is essential to design and develop technologically advanced medical countermeasures with a reasonable expectation of high efficacy in the field. The VRC has expertise in human immunology and vaccinology and this work will help to developed high-throughput serological and cellular assays which can identify antigen-specific responses to known and previously unknown pathogens.

iii. Committee Discussion:
- A reviewer asked whether animal work was occurring or not due to a mention of animal work without an animal section, but they are getting NHP samples. There is no mention of where the samples come from. The reviewer asked for clarification on this, and if the prokaryotic work mentioned was meant to be eukaryotic since there was no actual prokaryotic work proposed.

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 with minor clarifications.
xi. There were no conflicts of interest identified.

26-BMC-112, Hong Xu

i. Reviewers: Billioux, Lee
ii. Review summary: Title: Development of Stable Mammalian Cell Lines for Elucidating Mitochondrial Metabolic Pathways.

This proposal aims to establish stable mammalian cell lines for investigating mitochondrial physiology and gene function. We will use human-derived cell lines, specifically HEK-293T and HeLa, as primary model systems. The project involves the production and transduction of Lentiviral vectors to achieve stable integration and constitutive/inducible expression of various genetic components, including Tet-3G (inducible systems), iCre (recombinase), and CRISPR/Cas9 (genome editing), alongside specific genes-of-interest
related to mitochondrial metabolism. The lab's preliminary data has identified several candidate genes and reporter constructs potentially involved in mitochondrial regulation. To validate these functions, they want to generate robust cell line models that provide consistent expression levels. They plan to use lentivirus-mediated gene delivery because it is the gold-standard for creating stable cell lines, with high transduction efficiency and long-term genomic stability of the transgene compared to transient transfection method

iii. Committee Discussion:
- The reviewer said the registration was straightforward and they had nothing to add.

iv. Training and PPE requirements as established with BSL to be in line with a BSL-2/3 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: 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: Prokaryotic work is approved at BSL-1. Eukaryotic work is approved at BSL-2/3.

ix. Relevant sections of the NIH Guidelines: Prokaryotic work is approved under III-D-3-a, eukaryotic work is approved under III-D-3-a

x. The committee unanimously approved the registration as written.

xi. There were no conflicts of interest identified.

26-BMC-113, Ellen Sidransky (Second)

i. Reviewers: Craigie, Denny

ii. Review summary: Title: Study Gaucher disease and Parkinson disease using human blood and body fluids and cell lines. The researchers' working goals require the use of collecting patient blood, blood products, and tissue samples in the clinic. Additionally, they process these blood and body fluid products in their research laboratory. This work includes DNA/RNA/Protein extraction from patient blood, plasma, and serum; genotyping from DNA extracted from blood, and cell-culture expansion and work from patient skin samples. They also work with iPSC lines reprogrammed from patient skin fibroblasts. PiggyBac and lentivirus plasmids will be used to express genes of interest in cell lines including Lysosomal proteins such as GBA1, LAMP1, Cathespin F, and GPNMB.

iii. Committee Discussion:
- A reviewer said they are likely doing prokaryotic work but there was no prokaryotic section.

iv. Training and PPE requirements as established with BSL to be in line with a BSL-2/3 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: 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: Prokaryotic work is approved at BSL-1. Eukaryotic work is approved at BSL-2/3.
ix. Relevant sections of the NIH Guidelines: Prokaryotic work is approved under III-D-2-a, eukaryotic work is approved under III-D-3-a
x. The committee unanimously approved the registration with minor clarifications.
xi. There were no conflicts of interest identified.

26-BMC-114, Avi Nath

i. Reviewers: Whitehead, Craigie
ii. Review summary: Title: Neuropathogenesis of Human Endogenous Retrovirus K. The purpose of this research is to increase our understanding of the role of Human Endogenous Retrovirus-K (HERV-K) in the etiology of neurodegenerative diseases such as Amyotrophic Lateral Sclerosis (ALS). We will introduce pseudotyped HERV-K virions into the brain of rhesus macaques and assess subsequent neurotoxicity. The mechanisms involved in HERV-K-mediated illness are not fully understood. The purpose of this research is to establish an animal model to investigate the role of HERV-K in ALS and motor neuron disease. The species used in this work are rhesus macaques due to the tropism of HERV-K; only Old-World Monkeys have HERV-K (HML-2) insertions indicating that they were infected by this retrovirus in the past. This study utilizes a HERV-K consensus sequence to generate an intact virion that is pseudotyped with vesicular stomatitis virus glycoprotein (VSVG) to aid in entry into the cell. The lab’s preliminary data using a macaque fibroblast cell line shows feasibility of infection and the transgenic mouse model that uses only the envelope protein of the virus demonstrates some ALS symptoms but is limited in their ability to study the entire virus. Given the preliminary findings, they expect that HERV-K will establish an infection within the macaque particularly in neuronal cells and recapitulate ALS pathology.

iii. Committee Discussion:
- The reviewer noted that the truncated terminal repeat renders the retrovirus incapable of integrating into the host genome. HERV-K needs to be updated in Section K of the ASP.

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: NHP
vi. The committee discussed the dual-use and ePPP potential of these experiments. All answers were “no” except A5. The addition of VSV-G expression can cause a broader tropism, but only on initial entry. However, all copies of HERV-K after have the regular envelope of HERV-K. The committee agreed that there were no dual-use or ePPP concerns with the proposal and this was a case of the investigator checking ‘Yes’ in order to give an explanation..
vii. There were no additional public comments.
viii. Work is approved at: Eukaryotic work is approved at BSL-2. NHP work is approved at ABSL-2.
ix. Relevant sections of the NIH Guidelines: Eukaryotic work is approved under III-D-3-a, animal work is approved under III-D-4-a.
x. The committee unanimously approved the registration as written.
xi. There were no conflicts of interest identified.

b. Registration amendments for committee review

(AM01) 24-BMC-104 amend 260401, Tifft

i. Reviewers: Goff, Whitehead

ii. Review Summary: Amendment Reason: The lab was previously approved for use of AAV9, and they are now adding AAV8 and lipid nanoparticle encapsulated mRNA for treatment of GM2 gangliosidosis mouse models to generate pre-clinical data for possible clinical trials. This amendment is also for the G-11-4 resubmission triennially for the use of these agents.

iii. Committee Discussion.

- A reviewer stated that it was not clear how the human transferrin knockins will be created, but it was not a concern for this amendment as it may be covered by another registration. They also asked to confirm how the mRNA is being created and if it is all performed by Genescript, or if they are doing anything themselves. An updated ASP will be needed.

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: Mouse work is approved at ABSL-1.

ix. Relevant sections of the NIH Guidelines: Animal work is approved under III-D-4-a.

x. The committee unanimously approved the registration with minor clarifications.

xi. There were no conflicts of interest identified.

(AM02) RD-18-XI-02 amend 260401, Nilubol

i. Reviewers: Billioux, Goff

ii. Review Summary: Amendment reason: The laboratory requests the addition of a second-generation lentiviral system to generate a KPNA2 stable knockdown in human adrenocortical cancer cell lines.

iii. Committee Discussion.

- The reviewer stated that the registration was clear but needed to update the registration from stating III-E to III-D-3-a.

iv. Training and PPE requirements as already established.

v. Animal studies proposed: Mice, but no new animal work

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 with minor fixes noted above.

xi. There were no conflicts of interest identified.

(AM03) RD-17-V-17 amend 260401, Buchholz

i. Reviewers: Denny. Billioux

ii. Review Summary: Amendment reason: The investigators are consolidating pathogen registration 7341 into RD and update of legacy registration to ERS format. They also request to add swine orthopneumovirus (SOV). SOV is closely related to MPV, and they will determine if MPV and SOV are to be considered strains of a single species (very likely) or two distinct virus species

(unlikely). They are planning to clone the SOV sequence in a conventional commercial plasmid (pBluescript) as well, similar to work performed previously for MPV under this registration. This will generate the SOV full-length cDNA plasmid by cloning synthetic DNA fragments (virus isolate and sequence analysis described by Park et al., Viruses 2023)

iii. Committee Discussion.
- A reviewer noted that future animal work may come, but the PI stated that it would come in an amendment.

iv. Training and PPE requirements as already established.
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: Prokaryotic work is approved at BSL-1. Eukaryotic work is approved at BSL-2.
ix. Relevant sections of the NIH Guidelines: Prokaryotic work is approved under III-D-2-a, eukaryotic work is approved under III-D-3-a.
x. The committee unanimously approved the registration as written.
xi. There were no conflicts of interest identified.

(AM04) RD-18-IX-04 amend 260401, Franchini

i. Reviewers: Whitehead, Denny
ii. Review Summary: Amendment reason: With this amendment, the laboratory is including the VB045 Renewal ASP in the present registration. VB045 will study the immunogenicity and efficacy of a prime-boost anti-HTLV vaccine protocol. Non-human primates will receive 4 doses of nucleic acid immunogens based on messenger RNAs expressing HTLV-1 subtype A and C envelope proteins and HIV p55 gag protein. The final immunization will be administered concomitantly with a boost of HTLV-1 subtype A envelope protein. At the completion of the vaccine regimen, the non-human primates will be exposed either to HTLV-1A-infected cells via intravenous inoculation or to chimeric HTLV-1 A/C-infected cells via intravaginal inoculation. The virus and the route of administration for viral

exposure will be determined based on preliminary studies currently ongoing in other ASPs conducted by Dr. Franchini lab.

iii. Committee Discussion.
- A reviewer noted that all of the integrative machinery of HTLV is missing from the newly proposed work, making the pathogenic potential near zero. They asked for an example of what cells will be used in the eukaryotic work, and that BSL-2 would be appropriate for the work despite BSL-2/3 marked by the investigator.

iv. Training and PPE requirements as already established.
v. Animal studies proposed: NHPs, but no changes in this amendment.
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 with minor clarifications.
xi. There were no conflicts of interest identified.

(AM05) RD-17-X-04 amend 260401, Pierson

i. Reviewers: Goff, Craigie
ii. Review Summary: Amendment Reason: The investigators request that the ABSL level for the Guinea Pig study be reduced from level 2 to level 1. The risk assessment warrants an ABSL-1 classification because infectious agents are not being administered in these studies, the original approval for mice was at ABSL-1, and there is no significant risk increase when using guinea pigs. The group claims to only immunize animals with recombinant proteins and mRNAs encoding glycoproteins.

iii. Committee Discussion.
- The reviewers noted that they could not find any reason why this was put at ABSL-2 back in 2017 and fully agreed that ABSL-1 was appropriate.

iv. Training and PPE requirements as already established.
v. Animal studies proposed: Guinea pigs
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: Guinea pig work is approved at ABSL-1.
ix. Relevant sections of the NIH Guidelines: Animal work is approved under III-D-4-a.
x. The committee unanimously approved the registration as written.
xi. There were no conflicts of interest identified.

III. Committee Review of Inactivation Procedures: None

IV. Standard Operating Procedures/Plans: None

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

Reports

I. Biosafety Officer Report: In February 2026, there were 19 research-related incidents. none apparently involved work with rDNA, 8 sharps, 7 NHP related incidents- of these 5 were from direct work with old-world NHP and 2 involved either indirect work or work with new world NHPs, 6 incidents from ‘other animals’ (4 of those mouse bites), 0 apparent HBBF exposures.

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: Glas-Col Incident
- On 3/4/2026 a person was using a Glas-col nebulization apparatus to expose mice with recombinant M. tuberculosis in an ABSL-3 space. After they performed the run, they noticed the tube going to the incinerator on the outside of the machine had become disconnected during the

aerosolization run, with the tube sitting just beneath the incinerator connector as shown in the picture below. It was not clear when this occurred. This was the only person in the laboratory during the run, and they were in full PPE including a PAPR the entire time. While the risk of personnel exposure was zero, and even though most of the air released may have passed through the incinerator toward which it was directed, there was the possibility of laboratory exposure with the nebulized agent. Mitigation strategies have now included clamping the tube and pre-run checks on the tubing. Reporting to OSP was completed in accordance with the NIH Guidelines.

Around the Room/Committee Discussion

- The May meeting will take place May 6th as typically scheduled. The Chair will not be able to attend the next meeting due to a conference. The BSOs will ask for an Acting Chair before the meeting is set.
- A reminder the OSP has mandated that all IBC minutes will be publicly posted in a streamlined format. As always, each new registration should be reviewed for potential DURC, 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 3:39 PM.

Next meeting: May 6, 2026