Institutional Biosafety Committee

Date | time 3/19/2026 10:00 AM / Meeting called to order by:

Dr. Andrew Hayhurst

Meeting adjourned at 10:40 AM

In Attendance by ZOOM

Member	Expertise	Present
Andrew Hayhurst, Ph.D.	Protein engineering, display systems, BoNT, BSL-2, 4 (chair)	Y
Tim Anderson, Ph.D.	Pathogen evolution, malaria & schistosome drug resistances	Y
Hsiang Ming (Anthony) Wang, Ph.D.	Director EHS, RO, alternate BSO, BSL-2, 3, 4	Y
Marie-Claire Gauduin, Ph.D.	Recombinant virus vectors, NHP, HIV vaccines, retroviruses, BSL-2, 3	N
Trent Peacock, Ph.D.	BSO, ARO, molecular diagnostics, BSL-2, 3, 4 (vice-chair)	N
Yan Xiang, Ph.D.	Mechanisms of poxvirus pathogenesis, (community member)	N
Felicia Ponce	IACUC Manager	N
Olena Shtanko, Ph.D.	Molecular virology, viral entry, pathogenesis, BSL-2, 3, 4	Y
Davida Smyth, Ph.D.	Microbial epidemiology & genomics, (community member)	N
Diako Ebrahimi, Ph.D.	Viral evolution, HIV, statistical biology	Y
Olga Gonzalez, D.V.M.	Veterinary pathology at ABSL-2, 3, 4, infectious/natural diseases and aging of NHP	Y
Jack Dutton, D.V.M.	Veterinarian, ABSL-2, 3, 4, animal models of infectious disease, countermeasure assessment	Y
Kathy Brasky, V.M.D.	Primary veterinarian, ABSL-2, 3, 4, animal models of infectious disease, countermeasure assessment, diverse NHP biology	N
Jason Bowling, M.D.	Human infectious disease medicine, epidemiology, infection prevention	Y
John Choe, M.D.	Occupational health	Y
Greg Ippolito, Ph.D.	Immunology, antibody repertoires, B-cell biology, vaccines and infectious diseases	Y
Viraj Kulkarni, Ph.D.	Virology, microbiology, vaccine immunology and NHP research	Y

Quorum: 11/17 voting members present (65 %) – Quorum present.

Other Individuals in Attendance: Winka Le Clec'h, Ph.D. – recording the Institutional minutes.

Call to order: The IBC Chair called the meeting to order at 10:00 AM.

Conflicts of Interest: Request was made to members to self-identify if conflicts of interest arise and recuse as necessary.

Approval of Minutes: Notes and Minutes from IBC February 2026 meeting were reviewed and approved. The committee welcomed Dr. Viraj Kulkarni, Assistant Professor. Dr. Kulkarni joins with specialized expertise in virology, vaccine design, and immune responses.

Update on previous business: Revisions Received: The committee received updated applications for protocols IBC26-001, BSC>IBC24-015.1, and IBC26-002. **NIH OSP Update:** Official approval was received from the NIH OSP on 03/04/2026 regarding the biologically contained Ebola viral VP30del system (PI: Kulkarni, Smita). Authorized work may now proceed.

New IBC Applications & Amendments for Review

Note: All IBC members were provided with all applications and amendments at least seven days prior to the meeting for comprehensive review and comment.

PI Name: Frederick Heath Damron / Smriti Mehra

IBC26-005– Development of mRNA vaccine platforms for *Bordetella pertussis* (5-year renewal).

Lay description provided by PI: Evaluation of mRNA-pertussis toxin vaccine efficacy in baboons. The study involves mRNA vaccination followed by a pertussis toxin challenge. Outcomes will be assessed via hematology (leukocytosis), continuous telemetry monitoring, and serological analysis (ELISA).

Agent characteristics: Pertussis Toxin (PT) is a non-transmissible, multi-subunit protein derived from *Bordetella pertussis*. It poses a biosafety risk via inhalation, ingestion, and parenteral routes. The protocol used a 10µg/kg dose in baboons, consistent with previously established work. Risk is mitigated by purchasing the toxin in 50µg lyophilized aliquots and performing all reconstitution via rubber septum to avoid the handling or aerosolization of dry powders.

Types of manipulations planned: Baboons will be immunized with an mRNA-LNP vaccine encoding a catalytically inactive S1 subunit of PT. This construct lacks B subunits to prevent cellular entry of the expressed protein. The study includes standard vaccine and mRNA controls, with immune responses monitored via cytokine and antibody analysis.

Sources of nucleic acids: Collaborating laboratory for the synthetic mRNA within LNP (Lipid Nanoparticles).

Nature of sequences: Construct utilizes mRNA encoding a catalytically inactive S1 subunit of PT, with an ovalbumin gene serving as the control.

Foreign gene(s) expressed: mRNA encoding a catalytically inactive S1 subunit of PT.

Host to be used: Baboon.

Biosafety Level and containment: ABSL-2 for animal work, BSL-2 for toxin preparation, sample storage, analysis.

PI and lab staff trained: This application is a five-year renewal. Laboratory and veterinary staff have successfully conducted similar studies under the previous protocol with no reported safety or compliance incidents.

Occupational Health Representative Review (if applicable): The medical surveillance, response, and treatment protocols are adequately addressed in the application.

Risk Assessment and Discussion: PT and mRNA constructs are handled within a Biosafety Cabinet (BSC) in BSL-2 spaces. Hardened secondary containers are used for transport to and from animal containment. Decontamination involves a 10% bleach treatment followed by a 70% ethanol rinse. PPE is appropriately defined and sufficient for all laboratory and animal-handling personnel.

Applicable section(s) of NIH guidelines: Synthetic nucleic acids *in vivo*, III-D-4-a.

The following will require clarification: Prior to final review, the protocol underwent three revision cycles to ensure consistency and compliance. Key clarifications included reconciling BSL-2 versus BSL-1 designations, standardizing "PT" nomenclature, and confirming the mRNA-LNP formulation. The risk assessment was expanded to include the recombinant mRNA vaccines under NIH Guideline III-D-4-a. Administrative updates identified specialized research units for NHP handling and clarified that toxin reconstitution occurs via septum in a BSC to mitigate aerosolization. Finally, the project narrative was refined for public transparency, and institutional leadership roles were updated to reflect current oversight.

Motion: **Approved** | **11 Approve, 0 Against, 0 Abstain.**

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PI Name: Victoria Baxter

IBC26-004– Effect of prior infection exposure on tumor development in mice.

Lay description provided by PI: The study aims to determine how prior infection exposure (PIE) influences immune responses to tumor development. Utilizing the PIE mouse model—which more closely mimics the adult human immune system than standard specific pathogen-free (SPF) models—the project will compare breast tumor growth, metastasis, and the immune cell composition of the tumor microenvironment between these two models.

Agent characteristics: The PIE model utilizes four BSL-2 murine pathogens—MHV68, MCMV, Sendai virus, and the nematode *H. polygyrus*—to simulate a natural immune history. While these agents are classified as BSL-2 for laboratory handling, they are not known to cause disease in humans.

Types of manipulations planned: Mice will be sequentially infected with four pathogens at two-week intervals, alongside mock-infected controls. Six weeks post-infection, primary mammary tumors (E0771 cells) will be implanted into the mammary fat pad. Tumor progression will be monitored until sacrifice, at which point samples will undergo immunological, omics, and histological analysis.

Sources of nucleic acids: None. The project involves exclusively non-recombinant work.

Nature of sequences and vectors to be used: NA.

Foreign gene(s) expressed: NA.

Host to be used: Mouse.

Biosafety Level and containment: Work with pathogens will be conducted at BSL-2, with animal procedures at ABSL-2. While E0771 cells are classified as BSL-1, they will be handled under BSL-2 precautions. All procedures involving open containers will be performed within a biosafety cabinet to ensure containment.

PI and lab staff trained: The PI is a DVM and Vivarium Assistant Director with extensive BSL-2 and BSL-3 experience. Her team is proficient in managing diverse murine models, including a proven five-year track record of maintaining SPF and PIE cohorts on the same rack without cross-contamination.

Occupational Health Representative Review (if applicable): NA.

Risk Assessment and Discussion: To mitigate pathogen transmission risks to existing rodent colonies, the committee required clarifications on experimental workflows, specialized housing, and validated disinfection protocols to ensure continued biosecurity in the vivarium.

Applicable section of guidelines: NA (no recombinant work).

The following will require clarification: The committee requested details on risk mitigation strategies to protect existing rodent colonies. Key clarifications included the use of filtered caging, mandatory biosafety cabinet protocols, and the efficacy of disinfectants against the parasitic nematode, supported by peer-reviewed literature. A BSO-annotated version was provided to assist the PI in addressing these granular biosecurity concerns.

Motion: **Approved** | **11 Approve, 0 Against, 0 Abstain.**

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Meeting adjourned at 10:40 AM

Next meeting is:

4/16/2026 10:00 AM, Zoom