Institutional Biosafety Committee

Date | time 12/18/2025 10:00 AM / Meeting called to order by:

Dr. Andrew Hayhurst

Meeting adjourned at 10:47 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	N
Marie-Claire Gauduin, Ph.D.	Recombinant virus vectors, NHP, HIV vaccines, retroviruses, BSL-2, 3	Y
Trent Peacock, Ph.D.	BSO, ARO, molecular diagnostics, BSL-2, 3, 4 (vice-chair)	Y
Yan Xiang, Ph.D.	Mechanisms of poxvirus pathogenesis, (community member)	N
Felicia Ponce	IACUC Manager	Y
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	N
Olga Gonzalez, D.V.M.	Veterinary pathology at ABSL-2, 3, 4, infectious/natural diseases and aging of NHP	N
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	Y
Jason Bowling, M.D.	Human infectious disease medicine, epidemiology, infection prevention	Y
John Choe, M.D.	Occupational health	N
Greg Ippolito, Ph.D.	Immunology, antibody Repertoires, B-cell biology, vaccines and infectious diseases	Y

Quorum: 10/16 voting members present (62.5 %)

Other Individuals in Attendance: Erica Arreola and Winka Le Clec'h – recording the Institutional minutes.

Approval of Minutes: Notes from IBC Nov 2025 approved.

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 Previous Minutes: Minutes from IBC November 2025 meeting reviewed and approved.

Update on previous business: Revisions requested at the last meeting were made to the tabled applications, and votes were subsequently solicited by email, as detailed below.

Protocols Reviewed:

BSC24-010.5 - *Addition of LASV mRNA candidate* **(PI: Victoria Baxter)**

Types of manipulations planned: Sponsor-provided mRNA vaccine will be used to vaccinate mice and guinea pigs; some animals will be euthanized for tissue collection, and others will proceed to ABSL-4 for challenge.

Sources of nucleic acids: Sponsor-provided synthetic mRNA, enveloped in a lipid nanoparticle and encoding a LASV immunogen.

Nature of sequences and vectors to be used: No vector; mRNA only encoding a LASV glycoprotein–derived immunogen.

Expression of a foreign gene: LASV GPC.

PI and lab staff trained: An ASI collective of PIs was formed due to the relatively rapid departure of the previous PI. The staff performing the in vivo and in vitro procedures remain unchanged. A flowchart outlining the reporting hierarchy was provided to explain the ASI structure. Clarification was also provided that this study will be conducted as a Co-PI effort with GI. It was advised that any questions or concerns regarding

procedures involving DSAT should be directed to ARO/RO/4-Director well in advance, particularly with respect to sample inactivation.

Occupational Health Representative Review (if applicable):

Risk Assessment and Discussion:

Biosafety Level and containment: Vaccinations: ABSL-2. Challenge phase: ABSL-4.

Applicable section of NIH guidelines: III-D-4-A

Motion: **Approved** | **14 Approve** (10 present at the meeting + 4 votes by email following recirculation)**, 0 Against, 1 Abstain as COI.**

IBC25-019 - *Studies with VEEV and EEEV* **(PI: Luis Martinez-Sobrido)**

Revised materials and a response-to-comments document were distributed. Regulatory categories had been addressed in the prior meeting. Discussion confirmed that access to plasmids used to generate RNA is limited to protocol-approved personnel and that all work will occur in registered BSL-3 space. Although the viruses are not transmitted person to person, they are recognized agricultural threats and are highly infectious via the aerosol route, with documented laboratory-acquired infections.

Motion: **Approved** | **10 Approve, 0 Against, 0 Abstain.**

New IBC Registrations & Amendments for Review

PI Name: Luis Martinez-Sobrido

BSCRDC21-018.1– Identifying dominant negative domains in NiV and Hev, amendment to Studies with Nipah (NiV) and Hendra virus (HeV).

Lay description provided by PI: This amendment to protocols BSC21-018 and RDC21-018 proposes additional studies on Nipah virus (NiV) and Hendra virus (HeV). In collaboration with Dr. Carolina Lopez (WashU), a dominant-negative region in a viral structural protein that inhibits NiV and HeV infection has been identified. The amendment aims to validate these findings using minigenome assays in BSL-4. These studies are

consistent with the original protocol's objectives to identify potential prophylactics and therapeutics against NiV and HeV.

Agent characteristics: Recombinant Sendai virus, a risk-group 2 mouse pathogen.

Types of manipulations planned: Approved NiV and HeV minigenomes will be used to assess replication inhibition in cell culture using Sendai virus expressing the dominant-negative domain. If successful, studies will progress to BSL-4 to evaluate effects on authentic NiV and HeV replication using fluorescent reporter recombinants. No animal work is proposed.

Sources of nucleic acids: The Sendai virus genome encodes the dominant-negative (DN) region and a 670 nm fluorescent reporter, allowing monitoring independent of the green minigenomes or virus.

Nature of sequences: DN region represents a portion of the structural proteins of NiV and HeV.

Foreign gene(s) expressed: Fluorescent reporter proteins and DN regions.

Host to be used: Sendai virus, *E. coli, in vitro* cultured cells.

Biosafety Level and containment: BSL-2 and BSL-4.

PI and lab staff trained: The PI and staff conducting this work are trained in the appropriate BSL-2 and BSL-4 procedures.

Occupational Health Representative Review (if applicable):

Risk Assessment and Discussion:

Applicable section of NIH guidelines: III-D-1a (Sendai as host vector); III-D-1c (NiV and HeV reporter viruses); III-D-2-a (cloning and manipulations of the DN in *E. coli*); III-D-3-a (risk group 2 Sendai recombinant virus in cell culture); III-D-3-c (Risk group 4 NiV and HeV in cell culture).

Discussion: A committee member raised concern about the undefined dominant-negative (DN) region "X," noting potential for uncontrolled experiments. The amendment cited a confidentiality agreement limiting sequence disclosure. The DN is part of existing NiV and HeV structural proteins and is unlikely to increase risk. Recombination between Sendai virus and henipaviruses is considered unlikely due to limited homology and differing genera. No viruses will be collected from infected cells in BSL-4. Overall, the proposed work does not add risk beyond the approved parent protocol.

Motion: **Approved** | **9 Approve, 1 Against, 0 Abstain.**

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PI Name: Viraj Kulkarni

IBC24-017.1&2 – Amendment to add personnel and NHP to "Evaluate pathogenicity of Dengue viruses and development on interventions"

Lay description provided by PI: Amendment to add ASI personnel and non-human primates (NHP) as hosts to the existing IBC protocol.

Agent characteristics: mRNA vaccine against dengue, consisting of synthetic mRNA encapsulated in a lipid nanoparticle.

Types of manipulations planned: The sponsor will provide the vaccine for an immunogenicity study in Cynomolgus macaques, followed by challenge with Dengue virus.

Sources of nucleic acids: Sponsor-provided synthetic mRNA vaccine encoding Dengue virus structural proteins.

Nature of sequences: mRNA encoding the structural proteins of Dengue virus.

Foreign gene(s) expressed: Dengue viral structural proteins.

Hosts to be used: Cynomolgus macaques.

Biosafety Level and containment: ABSL-2.

PI and lab staff trained: The PI has experience working with Dengue virus in vitro and in small animal models for the past year. The additional staff bring expertise in non-human primate (NHP) studies and provide additional support for in vitro sample processing.

Occupational Health Representative Review (if applicable):

Risk Assessment and Discussion:

Applicable section of NIH guidelines: III-D-4-a (rsNA <2/3 eukaryotic viral genome in any non-human vertebrate).

The following will require clarification: Questions were raised regarding the number of ASI staff added, which was noted as typical for staffing flexibility. Clarification was requested on NHP specimen sampling during the vaccination phase and the analyses planned to assess immune responses prior to challenge, as well as the Dengue serotype to be used and whether the vaccine targets all four serotypes. Sections describing animal precautions should be replicated in the amendment for NHP details. The modified hut previously used for Zika virus work was discussed, including insect misters, netting, and air curtains; the space will require inspection and possibly new SOPs for entry, exit, and waste management. Additional questions include necropsy location, hut modifications for arbovirus work, availability of a Dengue vaccine for staff, Dengue endemicity in Texas, and citation of a B virus response plan for macaques.

Motion: **Revisions required, recirculation requested** | **10 Approve, 0 Against, 0 Abstain.**

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PI Name: Victoria Baxter

IBC25-001.1 – Addition of *Helicobacter pylori* as a candidate PIE pathogen, amendment to "Establishing the effect of prior infection exposure on the immune system in a "dirty" guinea pig model"

- **No recombinant or synthetic DNA involved**

Lay description provided by PI: Amendment to the existing IBC protocol, *"Establishing the Effect of Prior Infection Exposure on the Immune System in a 'Dirty' Guinea Pig Model,"* to add *Helicobacter pylori* as a candidate PIE pathogen.

Agent characteristics: *Helicobacter pylori.*

Types of manipulations planned: *H. pylori* will be cultured in vitro, and guinea pigs will be inoculated via gavage.

Sources of nucleic acids: N/A

Nature of sequences: N/A

Foreign gene(s) expressed: N/A

Hosts to be used: Guinea pigs.

Biosafety Level and Containment: BSL-2 (*H. pylori in vitro* amplification), ABSL-2 *in vivo* infections.

PI and lab staff trained: PI and Lab staff are trained and experienced in handling these procedures.

Occupational Health Representative Review (if applicable): No additional occupational health requirements were recommended at this time.

Risk Assessment and Discussion: Risk assessment was thoroughly conducted, evaluating the pathogen, procedures, personnel, and location.

Applicable section of guidelines: N/A

The following will require clarification: The proposed work, including in vivo stages, may have begun prior to IBC approval. TP and AH will meet with the PI to provide remedial training and clarify the timeline of events. The IACUC is also reviewing the in vivo aspects.

Motion: **Revisions required, recirculation requested** | **10 Approve, 0 Against, 0 Abstain.**

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Meeting adjourned at 10:47 AM

Next meeting is:

1/15/2026 10:00 AM, Zoom