Institutional Biosafety Committee

Date | time 5/21/2026 10:00 AM / Meeting called to order by:

Dr. Andrew Hayhurst

Meeting adjourned at 10.50 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)	Y
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	Y
Jack Dutton, D.V.M.	Veterinarian, ABSL-2, 3, 4, animal models of infectious disease, countermeasure assessment	N
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: was present 12/17 = 71 %.

Other Individuals in Attendance: Winka Le Clec'h recording minutes. Elena Ganusova attending (in training).

Call to order: The IBC Chair called the meeting to order at 10:05 AM.

Approval of Minutes: Notes from IBC April 2026 approved.

Requests were made to members to self-identify if conflicts arise and recuse as necessary.

Update on previous business: Revisions received for previous applications **22-007.1&2**, study of Mpox recombinant virus and mouse work. We are awaiting response on both applications. Revisions received for previous applications **21017.3**, single-cycle H5 IAV reduction from BSL3 to BSL-2+ revised and submitted to OSP for their review; **26-007**, Dx recirculated revised version and secured quorum to approve.

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: Luis Martinez-Sobrido

BSCRDC21-022.1 - Engineering recombinant VSV vaccines, mouse vaccine safety, and mAb/drug evaluation using rVSV (parent application expires 07/11/2026)

Lay explanation provided by PI: Comprehensive evaluation of the safety, immunogenicity, and protection efficacy of recombinant vesicular stomatitis virus (rVSV)-based vaccine candidates expressing arenavirus glycoproteins (GPC) and influenza A HA and/or NA antigens in murine models.

Agent characteristics: Vesicular Stomatitis Virus (VSV), zoonotic virus that causes contagious disease of livestock, can be transmitted to human. VSV causative agent has an established track record as a platform to display heterologous coat proteins for studies of viral entry, neutralizing antibodies, and for use as vaccines (Ebola) and several vaccines in development (Lassa, Machupo, Nipah etc).

Types of manipulations planned: VSV G protein will be replaced with various envelope proteins from arenavirus (glycoproteins or GPC) and influenza A HA and/or NA antigens in murine models. No further genetic engineering.

Sources of nucleic acids: Synthetic.

Nature of sequences: Glycoproteins (GPC) for viral entry from; various lineages of Lassa virus, Lujo, Junin, Machupo, Sabia, Guanarito, Chapare; Lassa NP (nucleoprotein for RNA encapsidation) with Lassa GPC; hemagglutinin (HA) for entry, and neuraminidases (NA) for virus shedding from cell from either H9N2 or H5N1, or H7H9 as individual pseudotypes or combination pseudotypes specific to each IAV; a wild-type recombinant VSV not expressing heterologous proteins.

Foreign gene(s) expressed: Yes.

Host(s)/vector(s) to be used: should be clarified.

Biosafety Level and containment: BSL-3/ABSL-3.

PI and lab staff are trained: Yes.

Applicable section(s) of NIH guidelines: No changes in III-D-1-a, III-D-2-a, III-D-3-a, III-D-7. III-D-IV-b – needs to be added.

Occupational Health Representative Review (if applicable): needs to be clarified.

Risk Assessment and Discussion: Aberrant tropism may be a concern though this platform but appears to be safe in an NHP model when a neurotropic Nipah coat protein was inserted in similar study into the Ebo GP VSV vaccine. Previous data using similar techniques exists for Lassa candidates and others. VSV G from clinical and non-clinical studies appears to be the principal but not the only virulence factor (Clarke et al., 2016).

The following will require clarification: biosafety levels and medical surveillance of personnel; viruses backbone nature, virus purification and dosing.III-D-IV-b needs to be added to section 6 for the *in vivo* work.

Parent application expires 07/11/2026, needs to be renewed if this amendment is to stay active beyond that date especially as it involves infectious agents and animal work.

Motion: Approved pending clarifications | 12 Approve, 0 Against, 0 Abstain.

PI Name: Luis Martinez-Sobrido

BSCRDC21-017.8 – Inclusion of protection efficacy testing of rVSV-based candidate vaccines against influenza viruses in murine models

Lay summary provided by applicant: Comprehensive evaluation of the protection efficacy of recombinant vesicular stomatitis virus (rVSV)-based vaccine candidates expressing influenza A HA and/or NA antigens in murine models.

Parent application expires 06/21/2026, this amendment can't be approved. IBC suggested bundling this amendment into the renewal application.

The following would require clarification: if viral strains are suitable for BSL-2, if select agent proposed, nature of the virus shedding.

Motion: to put amendment on hold due to clarification issues and renewal of parent application

PI Name: Luis Martinez-Sobrido

BSCRDC21-013.3 – Protection efficacy using rVSV-based candidate vaccine against Lassa virus in mice

Lay summary provided by applicant: Comprehensive evaluation of the safety, immunogenicity, and protection efficacy of recombinant vesicular stomatitis virus (rVSV)-based vaccine candidates expressing arenavirus glycoproteins (GPC) in murine models.

Parent application expires 05/26/2026 this amendment can't be approved. IBC suggested bundling this amendment into the renewal application.

The following would require clarification: if viruses used in this study are shedding, if research intends to make more variants than the original recombinant LASV ; specify if samples will be analyzed at lower containment (BSL-2).

Motion: to put amendment on hold, awaiting clarifications

PI Name: Luis Martinez-Sobrido

BSCRDC23-007.1 – Protection efficacy using rVSV-based candidate vaccine against Machupo virus in mice.

Lay summary provided by applicant: Comprehensive evaluation of the safety, immunogenicity, and protection efficacy of recombinant vesicular stomatitis virus (rVSV)-based vaccine candidates expressing arenavirus glycoproteins (GPC) in murine models.

Agent characteristics: Machupo virus used in this study for challenge (Carvallo strain), an arenavirus, risk group 4, BSL-4 virus and causative agent of Bolivian hemorrhagic fever (25-35% fatality rate). The application above 21-022.1 describes the recombinant VSV vaccine virus displaying the Machupo virus glycoprotein GPC, a BSL-2 construct. Both agents are susceptible to the disinfectants employed and sterilization cycles approved.

Types of manipulations planned: Mice will be vaccinated at BSL-2, transferred to BSL-4 and challenge, Observations will be made.

Sources of nucleic acids: Synthetic.

Nature of sequences: Machupo GPC within recombinant Indiana based VSV vaccine virus, and a recombinant Machupo Carvallo challenge virus.

Vectors to be used: **VSV**.

Expression of a foreign gene: GPC for the VSV.

PI and lab staff trained: Yes, in the in vitro aspects, training on going for in vivo aspects of the LMS members, though the BSL-4 in vivo team have requisite expertise to step in.

Facilities and containment: Vaccination ABSL-2, challenge ABSL-4, all appropriate.

Applicable section of guidelines: III-D-4-a & III-D-4-b.

Occupational Health Representative Review (if applicable): Response measures in place described in Machupo parent protocol.

Risk Assessment and Discussion: Mice vaccinated with BSL-2 vaccine brought into BSL-4 space would appear to pose no more risk than standard workflow of in vivo studies.

The following will require clarification: what biocontainment level will be used for sample preparation, how study/at EOP for virus titrations will be done, what analyses will be performed aside from animal observations.

Motion: amendment approved, awaiting clarifications | 12 Approve, 0 Against, 0 Abstain.

PI Name: Luis Martinez-Sobrido

BSCRDC23-006.1 – Protection efficacy using rVSV-based candidate vaccine against Junin virus in mice.

Lay summary provided by applicant: Comprehensive evaluation of the safety, immunogenicity, and protection efficacy of recombinant vesicular stomatitis virus (rVSV)-based vaccine candidates expressing arenavirus glycoproteins (GPC) in murine models.

Agent characteristics: Recombinant Junin virus used in this study for challenge (Romero strain), an arenavirus, risk group 4, BSL-4 virus and causative agent of Argentine hemorrhagic fever (15-30 % fatality rate). The application above **21022.1** describes the recombinant VSV vaccine virus displaying the Junin virus glycoprotein GPC (BSL-2). Both agents are susceptible to the disinfectants and approved sterilization cycles.

Types of manipulations planned: Mice will be vaccinated at BSL-2, will be transferred to BSL-4 and challenged; observations will be made.

Sources of nucleic acids: Synthetic.

Nature of sequences: Junin GPC within recombinant Indiana based VSV vaccine virus, and a recombinant Junin Romero challenge virus.

Vectors to be used: VSV.

Expression of a foreign gene: GPC for the VSV.

PI and lab staff trained: Yes, in the in vitro aspects, training is ongoing for in vivo aspects of the LMS members, though the BSL-4 in vivo team have requisite expertise to step in.

Facilities and containment: Vaccination ABSL-2, challenge ABSL-4, all appropriate.

Applicable section of guidelines: **III-D-4-a & III-D-4-b.**

Occupational Health Representative Review (if applicable): Response measures in place described in Junin parent protocol.

Risk Assessment and Discussion: Mice will be vaccinated with BSL-2 vaccine and will be transferred into BSL-4 space, this setup would pose no greater risk than the standard workflow.

The following will require clarification: what samples will be collected during and at the end of the study, what biocontainment level will be used for sample preparation, how study/at EOP for virus titrations will be done, what analyses will be performed aside from animal observations.

Motion: amendment approved, awaiting clarifications | 12 Approve, 0 Against, 0 Abstain.

PI Name: Greg Ippolito

BSC24-010.6 – Addition of Nipah virus VLP candidate vaccine

Lay summary provided by the applicant: not provided, needs to be added.

Agent characteristics: **NON recombinant vaccine:** a bacteriophage capsid assembly produced in *E. coli* that has been conjugated by tag/catcher chemistry with Nipah virus G protein (produced in insect cells).
This polyvalent VLP display platform is provided by the sponsor.

Types of manipulations planned: The VLP will be used to immunize mice at ABSL-2 with a variety of individual adjuvants. Sera will be collected and analyzed for neutralization potential in BSL-4 using the Nipah-GFP for convenient readout.

Sources of nucleic acids: Synthetic.

Nature of sequences: Recombinant Nipah Malaysia expressing GFP.

Vectors to be used: Nipah virus.

Expression of a foreign gene: Yes, GFP.

PI and lab staff trained: Yes, PI, Co-PI and staff will cover BSL-2 and BSL-4 aspects.

Facilities and containment: ABSL-2, BSL-4.

Applicable section of guidelines: **III-D-3-c**.

Occupational Health Representative Review (if applicable): Biohazardous procedures fall within the scope of the parental Nipa application.

Risk Assessment and Discussion: Mouse serum from BSL-2 will be transferred into BSL-4 for assays of viral inhibition, this action falls within many of the studies currently performed in testing neutralizing antibodies to this virus. Early trainees in phase 2 will be involved in this work based on approved IBC protocols and will be accompanied by the certified trainers.

The following will require clarification: N/A.

Motion: amendment approved | 11 Approve, 0 Against, 0 Abstain (due to CoI).

Meeting adjourned: 10:50.

Next meeting is: 6/18/2026 10:00 AM, Zoom