Institutional Biosafety Committee

Date | time 2/19/2026 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	N
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	Y
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)	Y
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	Y
Jason Bowling, M.D.	Human infectious disease medicine, epidemiology, infection prevention	Y
John Choe, M.D.	Occupational health	Y (joined at 10:24AM)
Greg Ippolito, Ph.D.	Immunology, antibody Repertoires, B-cell biology, vaccines and infectious diseases	Y

Quorum: 12/16 voting members present (75 %) – 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 December 2025 meeting were reviewed and approved (no meeting was held in January).

Update on previous business: Application 24-017.1&2: Received revised application materials and a modified SOP regarding previous work in the designated space. The updates include process and safety precaution modifications implemented during the December recess in preparation for the January 5 move-in.

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

IBC26-001 – Studies with Dengue virus (DENV)

Lay description provided by PI: To utilize all four Dengue virus serotypes (DENV 1–4) in the screening and identification of effective prophylactics and therapeutics for infection management. The work includes an assessment of host-virus interactions necessary for viral propagation.

Agent characteristics: Non-recombinant Dengue virus strains (two per serotype) from BEI Resources were reviewed. These mosquito-transmitted BSL-2 flaviviruses can cause febrile illness and occasionally severe dengue. As enveloped RNA viruses, they are susceptible to Microchem disinfectants, and laboratory-acquired infections are rare.

Types of manipulations planned: Viruses will be amplified separately in tissue culture, titrated, and used in inhibition assays to evaluate antiviral antibodies or small molecules. The work does not aim to select resistant mutants. Additional studies will assess how host cell gene expression affects viral replication using siRNA or knockout approaches.

Source of nucleic acids: Information is not described in Section 6 and will need to be completed.

Nature of sequences: Information is not described in Section 6 and will need to be completed.

Foreign gene(s) expressed: NA – Non-recombinant Dengue viruses.

Vectors to be used: Information is not described in Section 6 and will need to be completed.

Biosafety Level and containment: BSL-2 - all open-container manipulations performed in a biosafety cabinet.

PI and lab staff trained: A comprehensive description of the staff's relevant experience is provided.

Occupational Health Representative Review (if applicable): A vaccine is not readily available.

Risk Assessment and Discussion: No animal work is planned at this time. Containment and PPE are appropriate for the pathogen and procedures; however, clarification is needed regarding the use of goggles, the specific disinfectant, and the autoclave system used.

Applicable section(s) of NIH guidelines: Not yet defined; Section 6 needs to be completed.

The following will require clarification: Revisions are needed: one strain appears to mismatch the BEI Resources database, and a table requires correction. The medical surveillance plan needs updates. Clarification is required on ethanol concentration, disinfectant used, and waste autoclaving. For PPE, confirm whether goggles will be worn and why. It should also be specified if BSL-2 waste is autoclaved on-site or off-site. The plan for siRNA and knockout experiments must be described, with an overview of vectors and target genes, and reference to relevant guidelines.

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

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PI Name: Luis Martinez-Sobrido

BSC>IBC24-015.1 – Addition of OROV 24003 and recombinant OROV Zs-Green (rOROV Zs-Green)

Note: Amendment proposed to add a new non-recombinant strain from BEI Resources and a recombinant reporter strain from a collaborator.

Lay description provided by PI (for parent application – unchanged for this amendment): Due to a recent surge of OROV cases in South America (>8,000 cases, 2 deaths) and no approved treatments, there is an urgent need to identify effective antivirals and neutralizing antibodies. Planned work includes testing compounds for anti-OROV activity and evaluating antibodies for neutralization, using plaque reduction, immunofocus microneutralization, viral growth kinetics, or standard plaque/fluorescent-based assays.

Agent characteristics: Oropouche virus is transmitted by biting midges and mosquitoes and causes "sloth fever," a dengue-like illness with sudden fever, headache, and muscle pain. Laboratory-acquired infections have been reported, likely via aerosols. As an enveloped bunyavirus, it is susceptible to standard disinfectants.

Types of manipulations planned: Planned work includes virus amplification in tissue culture and evaluation of neutralizing antibodies and antiviral compounds using plaque assays and fluorescent cell-based assays.

Source of nucleic acids: Table B is currently incomplete and needs to be filled in.

Nature of sequences: Fluorescent reporter protein.

Foreign gene(s) expressed: Zs Green.

Vectors to be used: Oropouche TRVL 9760.

Biosafety Level and containment: BSL-2 - all open-container manipulations performed in a biosafety cabinet.

PI and lab staff trained: All staff are trained, listed in the parent protocol, and have the required experience.

Occupational Health Representative Review (if applicable): Unchanged - As for parent application

Risk Assessment and Discussion: Risk level remains the same as in the parent application.

Applicable section(s) of NIH guidelines: Table A is currently incomplete and needs to be filled in (III-D-1-b; II-D-2-a; III-D-3-b).

The following will require clarification: Section 6 is incomplete and should include the ZsGreen source and relevant NIH guidelines. Clarify whether waste will be autoclaved on-site or via standard BSL-2 off-site service. Confirm disinfectant type and concentration (10% bleach vs. 5% Microchem) and exposure time; if bleach is used, specify active ingredient and prepare fresh daily. Verify the correct risk group (2 or 3). Check BEI catalog numbers, as the intended Oropouche virus may be NR-59930 (240023) rather than 24003/599390.

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

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PI Name: Larry Schlesinger

BSCRDC22-014.9&23-009.8 – Addition of M. tuberculosis CDC1551 mutant strain

Agent characteristics: The *Mycobacterium tuberculosis* CDC1551 reconstituted in mannoside caps (*M.tb* ΔcapA::capA) strain from a collaborator shows no significant genomic rearrangements and replicates similarly to the wild-type in THP-1 human macrophages, suggesting no difference in virulence between the mutant and parent strain.

Types of manipulations planned: Planned work includes in vitro infection of immune cells to compare immune responses, signaling pathways, cytokine production, and cell killing.

Source of nucleic acids: *Mtb*

Nature of sequences: capA gene responsible for phospho-inositol capping.

Foreign gene(s) expressed: Mutant Mycobacterium tuberculosis strains were constructed using kanamycin and hygromycin resistance markers, while capA is normally an endogenous gene.

Vectors to be used: *Mtb* CDC1551ΔcapA.

Biosafety Level and containment: BSL-3.

PI and lab staff trained: As in the parent application, staff are trained and current personnel updates have been addressed.

Occupational Health Representative Review (if applicable): As for parent application.

Risk Assessment and Discussion: No increase in risk is anticipated. Biohazard disposal and disinfection procedures are thoroughly described.

Applicable section(s) of NIH guidelines: rDNA into RG3 agents: III-D-1-b, use of recombinant RG3 in cell culture systems, III-D-3-b.

The following will require clarification: NA

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

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PI Name: Smita Kulkarni

IBC25-005.1&2 – Addition of personnel and using CRISPR/Cas13d.

Agent characteristics: Use of Lenti-X VSV-G pseudotyped lentiviral particles for cell transduction; no infectious biological agent involved.

Types of manipulations planned: CRISPR/Cas13d-mediated knockdown of host genes in VP30 helper cell lines using a multi-part Lenti-X lentiviral packaging system for delivery of Cas13d or guide RNA plasmids. Selection via blasticidin, puromycin, and RFP flow cytometry, with validation by qPCR and immunoblotting. Knockdown cells will be transduced with VP30-deleted EBOV to assess replication relative to wild-type cells. No viral genes targeted; four-part lentiviral system reduces the risk of replication-competent lentivirus formation.

Sources of nucleic acids: Plasmid constructs were sourced from Addgene.

Nature of sequences and vectors to be used: Lenti-X cells, VSV-G plasmid, gRNA vector with RFP, LentiRNACRISPR vector.

Foreign gene(s) expressed: VSV glycoprotein, red fluorescent protein, CRISPR, cas13d.

Biosafety Level and containment: BSL-2+ (including the VP30-deleted EBOV system).

PI and lab staff trained: Yes.

Occupational Health Representative Review (if applicable): NA

Risk Assessment and Discussion: All work performed at BSL-2+, with open manipulations conducted in biosafety cabinets. The lab has significant experience with lentiviral vectors and guide RNA systems. Biohazard disposal and disinfection procedures are adequately described.

Applicable section(s) of NIH guidelines: II-D-2-a; III-D-3a

The following will require clarification: The risk group designation in the application appears inconsistent and should be clarified. The applicable section of the NIH Guidelines for the Lenti-X system amendment should also be specified. In addition, the statement that the deficient construct may cause transient flu-like symptoms requires further explanation. A simple schematic illustrating the overall Lenti-X rescue process would also help clarify the work.

Motion: **Approved pending clarifications** (Parent application remains on hold with OSP; project currently on hold) | **12 Approve, 0 Against, 0 Abstain.**

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PI Name: Viraj Kulkarni

IBC26-002 – Assessment of the impact of protein-coding and non-coding human genes on influenza virus replication and immune response in cell lines.

Lay description provided by PI: The study aims to assess the impact of non-coding RNAs and related protein-coding genes on influenza A virus replication in cell lines.

Agent characteristics: Non-recombinant influenza A viruses and Lenti-X VSV-G pseudotyped particles to transduce cells.

Types of manipulations planned: A multi-component Lenti-X system will deliver CRISPR/Cas13d and guide RNAs to degrade target transcripts, followed by influenza A virus infection and titration on recombinant versus wild-type cells.

Sources of nucleic acids: Plasmid constructs were sourced from Addgene. Addgene and designed guideRNAs encoding sequences.

Nature of sequences: VSV-G protein gene, CRISPR/Cas13d, Lenti-X system.

Foreign gene(s) expressed: Sequence of the genes not provided.

Vectors and hosts to be used: pLentiRNACRISPR_007 and pLentiRNAGuide_001 vectors, E. coli host (Plasmid cloning), Human cell lines.

Biosafety Level and containment: BSL-2, all work with open containers will occur in biosafety cabinet. The project is split between two labs, one will focus on Lenti-X work and the other on influenza amplification, titration and infection of the modified cell lines.

PI and lab staff trained: Collaboration between CRISPR/Cas13d Lenti-X experts, lncRNA researchers, and an ASI laboratory working on influenza viruses. All staff are trained, and have the required experience.

Occupational Health Representative Review (if applicable): The PI should add language regarding available vaccines and therapeutics in the treatments section.

Risk assessment and discussion: None

Applicable section(s) of NIH guidelines: Need to be provided by PI.

The following will require clarification: BSO has provided a version with embedded comments. Revisions are needed for pathogenicity and toxicity, medical surveillance language, and consultation with EHS/Occupational Health to define the strains being handled. Clarification is needed regarding disinfectant use, applicable NIH Guidelines, staff flu vaccination requirements, monitoring for symptoms, and any quarantine measures. The likelihood of any cell line becoming a super-producer of influenza viruses should be assessed, along with contingency plans if observed. HPAIV is not used in this work.

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

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PI Name: Timothy Anderson

IBC26-003 - Culture and CRISPR/Cas9 gene editing of malaria parasites

Lay description provided by PI: In vitro culture of *Plasmodium falciparum* in human red blood cells is routinely performed to generate parasite DNA/RNA, assess drug resistance, perform CRISPR/Cas9 genetic manipulation, and conduct experimental studies on malaria biology.

Agent characteristics: Non-recombinant *Plasmodium falciparum* and *P. vivax*, as well as recombinant *P. falciparum* engineered via CRISPR/Cas9 to knockout genes or edit single-nucleotide polymorphisms for studies on drug resistance, host cell tropism, and growth rates. These parasites cause malaria and are transmitted by mosquitoes.

Types of manipulations planned: Work includes parasite amplification in human red blood cells, drug resistance screening, gene editing, and nucleic acid extraction.

Sources of nucleic acids: pFCL3 BSD_2A_yFCU plasmid for the CRISPR/Cas9 editing work.

Nature of sequences: Targeted genes and corresponding guide RNA sequences not provided.

Foreign gene(s) expressed: Transiently blasticidin S deaminase and yeast fusion cytosine deaminase-uracil phosphoribosyltransferase.

Vectors and hosts to be used: Plasmids encoding positive and negative selection markers along with guide RNAs.

Biosafety Level and containment: BSL-2.

PI and lab staff trained: The PI and laboratory staff are trained and have many years of experience working in this Malaria parasitology field.

Occupational Health Representative Review (if applicable): Treatment options for accidental infection are provided (risk is low due to BSC use and no sharps), and SOP1508 for bloodborne pathogen exposure is cited.

Risk Assessment and Discussion: This is a five-year renewal of ongoing parasite culture and recombinant work. No procedural changes or increased risk are noted. Biohazard disposal and disinfection procedures are thoroughly described.

Applicable section(s) of NIH guidelines: III-D-1-a, rsNA into RG-2 vector; III-D-2, RG2 rsNA cloned into *E. coli.*

The following will require clarification: The application would benefit from brief descriptions of each person's relevant experience. Clarification is requested on what "molecular work" entails for extracted parasite DNA and RNA, as well as the sources of pathogens used. Details should be provided for Cas9, guide RNAs, mutant target sequences, and examples of genes and SNPs previously targeted. The application should also explain how host cell tropism and growth rate are monitored, and describe contingency plans if modifications widen tropism or enhance growth. Correct nomenclature (e.g., Escherichia coli) should be used.

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

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Meeting adjourned at 10:50 AM

Next meeting is:

3/19/2026 10:00 AM, Zoom