Institutional Biosafety Committee

Date | time 10/16/2025 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	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)	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
Luis Martinez Sobdrido, Ph.D.	Viral reverse genetics, attenuated vaccines, antivirals, BSL-2, 3, 4	Y
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
Greg Ippolito, Ph.D.	Immunology, antibody Repertoires, B-cell biology, vaccines and infectious diseases	Y

Quorum: 15/17 voting members present = 88 %.

Other Individuals in Attendance: Winka Le Clec'h – 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 Previous Minutes: Minutes from IBC September 2025 meeting approved.

Update on Previous Business: All revisions required from last meeting were made and approved.

Discussion: none.

New IBC Registrations & Amendments for Review:

PI Name: Binhua (Julie) Ling

IBC25-014 - Targeted CRISPR/Cas editing to eliminate SIV reservoir in methamphetamine-exposed rhesus macaques on ART

Lay description, provided by PI: The project will use CRISPR/Cas gene-editing in a nonhuman primate model of HIV/SIV and methamphetamine use to study how meth worsens HIV persistence in the brain and to test strategies to reduce brain inflammation and target hidden HIV reservoirs, aiming to advance therapies beyond current treatments.

Agent characteristics: Adeno-associated virus (AAV) is a BSL-1 non-replicating gene therapy delivery system and not associated with human disease. SIVmac239M is a barcoded molecular clone of SIV and SHIV AD8EOM is a similarly barcoded chimeric clone.

Types of manipulations planned: AAV encoding guide RNAs and Cas proteins will be used in the NHP/SIV model, with stocks provided by an external collaborator. SIV (or SHIV) will be used to infect rhesus macaques.

Sources of nucleic acids: Cas proteins, guide RNAs, and barcodes are commercially available.

Nature of sequences: Editing proteins and guide RNAs excise HIV/SIV genomes; barcodes enable clonal tracking of viruses by NGS.

Foreign gene(s) expressed: Cas, guide RNAs, barcodes.

Hosts and vectors to be used: AAV: Cas/gRNA vector; SIV/SHIV: barcode host; rhesus macaque: host for both.

Biosafety Level and containment: BSL-2.

PI and lab staff trained: The Ling lab has safely conducted similar studies for years, and the animal team and veterinarians are highly experienced. However, the complete list of experienced personnel conducting the experiment is missing.

Occupational Health Representative Review (if applicable): NA

Risk Assessment and Discussion:

Applicable section of guidelines: III-D-4a and III-D-4b

The following will require clarification: The application lacks sufficient detail and will require revision and recirculation before voting. Several key sections are incomplete or unclear, including missing information on personnel experience, virus selection and handling, and methamphetamine storage, usage, and safety procedures. Updated SOPs, PPE specifications, and source details are also needed. A clear one-page diagram outlining the 28-animal study design should be added, and clarification is required regarding which challenge virus (SIV, SHIV, or both) will be used and why. The submission must include the methamphetamine SDS, specify infectious agents being shipped, and update details regarding AAV serotype, Cas versions, and relevant regulatory sections.

Motion: **Requires revision and recirculation prior to voting.**

****

PI Name: Deepak Kaushal

IBC25-015 -Immune Correlates of Protection from TB

Lay description, provided by PI: *Mycobacterium tuberculosis* (*Mtb*) causes tuberculosis (TB), the leading cause of death from a single infectious agent. The current vaccine, BCG, provides limited protection, highlighting the

need for new interventions. Deletion of sigH (ΔsigH) in *Mtb* reduces bacterial replication and disease in Indian rhesus macaques, and aerosol vaccination with ΔsigH *Mtb* induces strong lung immunity, protecting against lethal TB. Additional genetic modifications have now been introduced to ensure safety and meet Geneva consensus safety standards. The lab goal is to test and validate this new TB vaccine.

Agent characteristics: *Mycobacterium tuberculosis* CDC1551 is the parent strain for knockouts based on the initial ΔsigH deletion.

Types of manipulations planned: The lab cultivates *Mtb* CDC1551, and deletion mutants including ΔsigH. Knockouts are tested for attenuation and immunostimulatory capacity in SCID mice and rhesus macaques. Protective efficacy is evaluated using both a standard challenge model and a challenge plus SIV reactivation model to identify the best vaccine candidate.

Sources of nucleic acids: *Mtb* knockouts are generated via mycophage-mediated gene replacement. sigH is replaced with an antibiotic resistance marker (not used in TB frontline therapy) and later excised using flanking resolvase sites. Some deletions were made under the previous protocol, while others are still pending.

Nature of sequences: Deletions of the sigH gene in *Mtb*.

Foreign gene(s) expressed: NA

Hosts and Vectors to be used: *Mtb* CDC1551 is parent strain of the sigH mutant. Hosts: SCID mice and rhesus macaques.

Biosafety Level and Containment: BSL-3 (in vitro) and ABSL-3 (in vivo study).

PI and lab staff trained: The PI and lab staff have conducted these studies for the past five years without incident, and all laboratory and vivarium personnel are highly experienced with the experimental challenges of the animal models.

Occupational Health Representative Review (if applicable)

Risk Assessment and Discussion:

Applicable section of guidelines: III-D-1-b, III-D-4. The PI should clarify whether the sections III-D-1-a and III-D-2 are applicable.

The following will require clarification: The application title could be clarified to better reflect scope of the study. Clarify which work falls under sections III-D-1-a and III-D-2, as current descriptions align with III-D-1-b and III-D-4-b. Confirm whether all DKO and TKO strains have been made, and include SIVmac239 in Table A (III-D-4-b). Remove the "reclassification to BSL-2 pending" note until the supporting data package is submitted to NIH OSP. Provide details on quantities, preparation, administration, and waste disposal for BrdU experiment. Clarify discrepancies in TB testing frequency and the paraformaldehyde fixation percentage. Normalize gene names and correct typos in the mutant inventory. Include an explicit statement that all personnel have agent-specific and BBP training. Additional revision guidance will be provided via BSO comments.

Motion: **Approval pending clarifications/revision**| **15 Approve, 0 Against, 0 Abstain**

****

PI Name: Larry Schlesinger

BSCRDC22-014.8 Addition of nontuberculous mycobacteria (NTM) species and bacteriophage

Lay description, provided by PI: The project aims to obtain *Mycobacterium abscessus*, *M. chelonae*, and *M. fortuitum* strains. Phages will be sourced from a UT San Antonio collaborator or isolated from soil, then tested to identify those that infect and kill these Mycobacteria and limit their growth in eukaryotic cells. The parent application involves BSL-3 work with *Mycobacterium tuberculosis*.

Agent characteristics: *Mycobacterium abcessus*, *M. chelonae* and *M. fortuitum.* Bacteriophages.

Types of manipulations planned: Isolation of phages from soil samples, followed by testing their ability to kill different *Mycobacterium spp.* strains.

Sources of nucleic acids: No recombinant or synthetic nucleic acids are generated or used in this project

Nature of sequences: NA

Hosts to be used: Phage hosts: *Mycobacterium spp*. *Mycobacterium spp.* host: eukaryotic cells.

Foreign gene(s) expressed: NA

PI and lab staff trained: Lab staff are experienced and trained to handle these procedures and pathogens.

Biosafety Level and containment: BSL-2

Applicable section of guidelines: NA

Occupational Health Representative Review (if applicable):

Risk Assessment and Discussion:

The following will require clarification: None.

Motion: **Approved** | **15 Approve, 0 Against, 0 Abstain**

****

PI Name: Larry Schlesinger

IBC25-016– Safe biohazard practice for working with Bacillus species and bacteriophage

Lay description, provided by PI: Bacteriophages, viruses that kill bacteria, are a promising alternative to antibiotics for treating bacterial infections. This project aims to isolate phages from soil that target *Bacillus* strains and assess their ability to inhibit bacterial growth, including plaque formation. We will also evaluate phage efficacy in limiting *Bacillus* growth within eukaryotic cells (macrophages) and investigate immune cell signaling pathways that influence bacterial proliferation in vitro.

Agent characteristics: *Bacillus* strains including *Bacillus cereus.* Bacteriophages.

Types of manipulations planned: Isolation of phages from soil samples, followed by testing their ability to kill different *Bacillus spp.* strains.

Sources of nucleic acids: No recombinant/synthetic nucleic acids involved

Nature of sequences: NA

Hosts to be used: Phage hosts: *Bacillus spp*. *Bacillus spp.* host: human macrophages.

Foreign gene(s) expressed: NA

PI and lab staff trained: Lab staff are experienced and trained to handle these procedures and pathogens.

Biosafety Level and containment: BSL-2

Applicable section of guidelines: NA

Occupational Health Representative Review (if applicable):

Risk Assessment and Discussion:

The following will require clarification: None.

Motion: **Approved** | **15 Approve, 0 Against, 0 Abstain**

****

Meeting adjourned at 10:50AM

Next meeting is:

11/20/2025 10:00 AM, Zoom