Institutional Biosafety Committee

Date | time 4/16/2026 10:00 AM / Meeting called to order by:

Dr. Andrew Hayhurst

Meeting adjourned at 10:45 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 arrived for last application
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	N
Viraj Kulkarni, Ph.D.	Virology, microbiology, vaccine immunology and NHP research	N

Quorum: Not present for the first three applications (8/17 = 47% attendance). Quorum was achieved for the fourth application with the inclusion of MCG (9/17 = 53%), despite a COI noted for GI. Post-meeting electronic voting by absent members brought the final participation rate to 65% (n=3 extra votes - (8+3)/17 = 65%).

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 March 2026 meeting were reviewed and approved.

Update on previous business: NIH OSP denied the request to reduce the biosafety level from BSL-3 to BSL-2+ for Dr. Luis Martinez-Sobrido's study of the NS1 deleted monobasic HA H5 Texas influenza A (**BSCRDC21-017.4 > IBC25-007 "Request reduction in biosafety level from 3 to 2 to streamline studies with a recombinant low pathogenic influenza A/Texas/37/2024 H5N1 lacking NS1 protein (LPhTX_dNS1)**). The research must continue to be conducted under BSL-3 containment.

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: Larry Schlesinger

BSCRDC22-014.10 & 23-009.9 – Addition of *M. tuberculosis* reporter strain

Agent characteristics: *Mycobacterium tuberculosis* (Erdman strain), a highly virulent TB pathogen, is engineered as a reporter to visualize live (metabolically active) and dead bacteria via flow cytometry or fluorescence microscopy; appropriate decontamination measures, including Wexcide disinfectant and autoclaving, are in place.

Types of manipulations planned: *In vitro* infection of human or murine primary cells, clones or cell lines. *In vivo* infection of mice. No further genetic engineering planned.

Sources of nucleic acids: Reporter constructs include mCherry (from *Discosoma* spp. coral) and Kusabira Orange (from the stony coral *Fungia concinna*), along with streptomycin and kanamycin resistance genes; neither antibiotic is used in frontline TB treatments.

Nature of sequences: Chromosomally integrated fluorescent reporter proteins and antibiotic resistance genes.

Foreign gene(s) expressed: mCherry and Kusabira Orange reporter protein genes, streptomycin and kanamycin resistance genes.

Host(s)/vector(s) to be used: Human or murine primary cells (*in vitro* experiments). Mice (*in vivo* experiments).

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

PI and lab staff trained: PI and laboratory staff are trained; similar work with *M. tuberculosis* has been conducted under the parent application.

Applicable section(s) of NIH guidelines: No changes from the parent application: III-D-1-b, III-D-4-b.

Occupational Health Representative Review (if applicable): The antibiotic resistance markers used would not compromise standard *M. tuberculosis* treatment in the event of potential exposure.

Risk Assessment and Discussion: The strain and associated manipulations do not pose additional risk and remain within the scope of the parent applications.

The following will require clarification: N/A.

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

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PI Name: Luis Martinez-Sobrido

BSCRDC22-007.1&2 – 1, Animal work with monkeypox virus and 2, generate recombinant reporter Monkeypoxvirus.

Lay description provided by PI: Development of a mouse model of Mpox virus (MPXV) disease to evaluate morbidity, mortality, and viral replication of recombinant MPXV expressing ZsGreen/NanoLuc, as well as assessment of antiviral compound efficacy against MPXV.

Agent characteristics: Mpox virus (MPXV) is a double-stranded, enveloped Orthopoxvirus with Clade I (Congo Basin) being highly virulent (case-fatality rates up to ~10%) and Clade II (West Africa) being less severe (<1% mortality), with Clade IIb responsible for the 2022 global outbreak; the parent application specifies Clade I only, but this will be restated in the amendment as Clade II is a select agent. MPXV poses infection risk via inhalation, mucous membrane exposure, and accidental needlestick and is moderately stable on surfaces.

Types of manipulations planned: Recombinant MPXV expressing ZsGreen/nLuc will be generated by homologous recombination and compared to wild-type virus in vitro and in mice via intranasal infection to assess growth, pathogenicity, and tissue viral loads. Reporter virus enables imaging and improved readout for antiviral compound testing *in vitro* and *in vivo*.

Sources of nucleic acids: ZsGreen is derived from *Zoanthus* spp. reef coral, and nLuc (NanoLuc) is derived from the deep-sea shrimp *Oplophorus gracilirostris*.

Nature of sequences: Fluorescent and bioluminescent reporter genes.

Foreign gene(s) expressed: ZsGreen and NanoLuc.

Host(s)/vector(s) to be used: Homologous recombination plasmid.

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

PI and lab staff trained: PI and lab staff are trained and experienced in reverse genetics and related work with vaccinia virus, another Orthopoxvirus.

Applicable section(s) of NIH guidelines: III-D-1-b, III-D-2-a, III-D-3-b, III-D-4-b**.**

Occupational Health Representative Review (if applicable): Staff vaccination is encouraged. Risks are considered within the scope of the original application for in vitro work; animal studies will use micro-isolator cages with all manipulations performed in a biosafety cabinet, and PPE includes Tyvek suits and PAPRs. Additional staff have been added since the parent application.

The following will require clarification: Clarifications are required regarding facility location details, vivarium staff involvement, and missing material quantities. New staff should be encouraged to receive vaccination. Biosafety language must be updated to reflect BSL-3 practices. Virus strains must be specified and confirmed as non-select agent clades, and disinfectant use (PREempt vs. Wexcide) needs to be clarified and justified.

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

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PI Name: Luis Martinez-Sobrido

BSCRDC21-017.7 – Request reduction from BSL-3 to BSL-2+ to work with single-cycle infectious influenza A virus (sciIAV) based on A/Texas/37/2024 H5N1 |Moved to a separate track for OSP submission.

Lay description provided by PI: Single-cycle influenza A virus (sciIAV) H5N1 is a replication-defective system that completes only one round of infection in complementing cell lines, producing no infectious progeny in standard cells. It enables safe study of H5N1 biology, antivirals, vaccines, and resistance mechanisms under BSL2+ conditions. Preliminary data show in vitro replication dependence on complementing cells and attenuation in mice, supporting reduced biosafety level requirements.

Agent characteristics: This influenza A virus is an enveloped, segmented, negative-sense RNA Orthomyxovirus that has spilled over from dairy cattle to humans, generally causing mild illness in healthy individuals (conjunctivitis, mild upper respiratory symptoms, fatigue, and chills), typically in dairy workers with animal exposure. The virus is susceptible to inactivation by standard disinfectants.

Types of manipulations planned: The influenza A virus has been engineered by replacing the H5 HA segment with mCherry–nLuc reporter sequences, rendering it non-infectious without HA. Infectivity is restored only in HA-expressing MDCK helper cells, enabling single-cycle replication. The system supports BSL-2+ studies of replication, immunity, antivirals, and escape mutants pending OSP approval review.

Sources of nucleic acids: mCherry is derived from a sea anemone (*Discosoma* spp), and nLuc (NanoLuc) is derived from the deep-sea shrimp *Oplophorus gracilirostris*.

Nature of sequences: Fluorescent and bioluminescent reporter genes.

Foreign gene(s) expressed: mCherry and NanoLuc.

Host(s)/vector(s) to be used: The helper cell line uses a pCAGS vector to express monobasic H5 HA and a hygromycin resistance gene in MDCK cells. The binary reporter segment is based on A/Texas/37/2024 N1, with the H5 HA gene absent from produced virus particles.

Biosafety Level and containment: Viral rescue and progeny studies are currently conducted at BSL-3; following OSP review and approval, a request is made to perform this work at BSL-2+.

PI and lab staff trained: The laboratory has extensive experience working with influenza systems for several years under BSL-2 and BSL-3 conditions, with a strong focus on reverse genetics, without safety issues.

Applicable section(s) of NIH guidelines: III-D-1-d, III-D-2-a, III-D-3-b, III-D-4-b, III-D-7-b, IV-C-1-b-(2)-(a).

Occupational Health Representative Review (if applicable): Staff participate in seasonal influenza vaccination programs, antivirals are available for treatment, and personnel sign agreements restricting contact with avian species outside of work.

Risk Assessment and Discussion: A biologically contained system appears to have been established, with data indicating attenuation in a mouse model. Remaining concerns include the potential for reassortment if co-infection with other influenza viruses occurs, which could restore multi-cycle infectivity. The rationale for the proposed BSL-2+ work was questioned; cost considerations are not a factor in IBC safety review.

The following will require clarification: Clarification is needed on disinfectant use and facility practices, construct design (fusion vs bicistronic reporter), and the rationale for the rescue strategy. Key safety concerns include potential recombination restoring functional HA, reassortment with other influenza strains in the lab, and measures to prevent accidental HA complementation. Additional information is requested on validation of strict HA dependence and segregation of experimental workflows to prevent cross-contamination.

Motion: **Revisions required before the package finalization and submission to OSP for review** | **11 Approve, 0 Against, 0 Abstain.**

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PI Name: Gregory Ippolito

IBC26-007– Symphony Dx diagnostic platform integrity checkpoint and verification

Lay description provided by PI: This study between Symphony Dx and Texas Biomed will evaluate a diagnostic platform through a checkpoint and verification workflow using molecular detection only. RG2 bacterial reference materials are used solely as non-propagative controls, with no culture, growth, or expansion performed. All pre-lysis handling occurs under BSL-2 conditions in a Class II biosafety cabinet, and downstream work uses only purified nucleic acids. Synthetic PCR fragments may be used as surrogates. No recombinant agents are involved, and the work is considered exempt under NIH guidelines (III-F).

Agent characteristics: Non-recombinant work involving a panel of BSL-2 pathogens, primarily bacterial, for molecular diagnostic evaluation under controlled BSL-2 conditions.

Types of manipulations planned: Lyophilized bacterial preparations will be resuspended, and nucleic acids will be extracted for use in nucleic acid testing (NAT).

Sources of nucleic acids: Commercially sourced ATCC reference strains or equivalent materials may be used, along with synthetic nucleic acid sequences from commercial vendors, representing diagnostic target genes.

Foreign gene(s) expressed: N/A.

Nature of sequences: Synthetic, non-replicative assay controls encoding diagnostic targets will be used for PCR and sequencing validation.

Host(s)/vector(s) to be used: None.

Biosafety Level and containment: BSL-2–facilities, with all open handling of pathogen-containing materials and matrices performed within a biosafety cabinet.

PI and lab staff trained: PI and lab staff are trained, with requisite experience for the proposed work.

Applicable section(s) of NIH guidelines: III-F (EXEMPT).

Occupational Health Representative Review (if applicable): Clarification is needed to distinguish between viable lyophilized agents used for nucleic acid extraction and synthetic nucleic acid controls, as well as to reconcile inconsistencies in the listed organism scope.

Risk Assessment and Discussion: Clarification is needed on the scope and handling of bacterial pathogens to ensure appropriate biosafety controls. Non-live work should be separated from live-agent work, and all live-agent studies should include organism-specific risk assessments covering exposure, transmission, pathogenicity, and treatment options.

The following will require clarification: Clarification is required on which pathogens will be obtained as viable material versus those used only as synthetic nucleic acid controls, with clear separation between these groups. All live agents, including resuspended lyophilized preparations, must be explicitly listed and accompanied by brief risk assessments covering exposure, transmission, pathogenicity, and treatment. The scope of work must be reconciled with references to RG2 organisms and inconsistencies regarding nucleic acid-only handling. The types of sample matrices (including whether any are human-derived) should be specified, and biosafety and training requirements confirmed where applicable. Liquid volumes and use of synthetic controls should also be clearly stated.

Motion: **Needs revision and recirculation** | **10 Approve, 0 Against, 1 Abstain (COI).**

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Meeting adjourned at 10:45 AM

Next meeting is:

5/21/2026 10:00 AM, Zoom