Institutional Biosafety Committee

Date|Time: 7/16/2026 10:05 AM CT
Location: via Zoom
Meeting adjourned: 7/16/2026 11:32 AM CT

Minutes

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	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	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	N
Viraj Kulkarni, Ph.D.	Virology, microbiology, vaccine immunology and NHP research	Y

Jack Dutton, D.V.M.	Veterinarian, ABSL-2, 3, 4, animal models of infectious disease, countermeasure assessment	N#

*Member joined the Meeting at 10:12 AM (was missing for the approval of the Agenda and the IBC Meeting Minutes).

**Member was absent from 10:07 – 10:12 (for the approval of the IBC Meeting Minutes).

#Member is on medical leave from July-August 2026.

I. Call to order	a. Meeting called to order at 10:05 AM. b. Quorum i. Quorum was met; 11 voting members and 1 community member were present. c. Other individuals in attendance: Elena Ganusova, Institutional Biosafety Committee (IBC) Administrator. d. Conflicts of interest are to be declared by members as each application is discussed.
II. Agenda approval	The Meeting agenda was reviewed. All members of the IBC were furnished with all applications/amendments at least 7 days prior to the meeting for review and comments.
Vote count	**11 Approve, 0 Against, 0 Abstain (see p.1 for the explanatory notes).**
III. Review Minutes from Previous Meeting	1. Minutes approval from 06-18-26.
Vote count	**11 Approve, 0 Against, 0 Abstain (see p.1 for the explanatory notes).**
	2. Minutes approval from 06-25-26.
Vote count	**10 Approve, 0 Against, 1 Abstain (see p.1 for the explanatory notes, 1 abstain due to a conflict of interest).**
IV. Update on previous business	**1.** Approved applications pending clarifications (IBC mee□ng 06-18-26): **IBC26-010**. **2.** Approved applications with all clarifications resolved (IBC mee□ng 06-18-26): **BSC24-001.4** (final approval: 06-27-26), **IBC26-009** (final approval: 06-27-26), **IBC26-008** (final approval: 07-08-26).

	3. Applications approved after administrative error on 06-18-26: **BSCRDC21-017.5, BSCRDC22-014.10 & BSCRDC23-009.9, BSCRDC22-016.2, BSCRDC22-007.1&2, BSC21-012.2, IBC24-021.3, IBC24-017.3, IBC24-017.1&2**. 4. Tabled: **BSCRDC24-008.1**. 5. Applications approved after administrative error on 06-25-26: **IBC24-021.1**.
V. New application/ amendment review and renewal	**1. New amendment(s) review** **i. BSC21-018.2/RDC21-018.2 – PI Name: Luis Martinez-Sobrido, Studies with Nipah virus (NiV) and Hendra virus (HeV). Amendment 2, selection of NiV and HeV drug resistant mutants and characterization of their molecular mechanism of antiviral activity.**
Vote count	**Not discussed due to the expiration of the parental protocol**
	BSC24-003R.1 – PI Name: Riti Sharan, Humanized mouse model to study *Mtb*/HIV co-infection. Amendment 1, personnel changes, addition of BSL-3, addition of NHPs and ABSL3-NHP cage holding room.
Lay explanation provided by PI	*Our research seeks to understand why people living with HIV are at much greater risk of developing active tuberculosis (TB), even while receiving treatment for HIV. We study how HIV changes the immune system and disrupts the body's ability to keep latent TB under control. Using advanced technologies and clinically relevant animal models, we identify immune pathways that could be targeted to prevent TB reactivation. Ultimately, our goal is to develop new immune-based therapies that improve outcomes for people affected by both HIV and TB.*
Research summary	The Sharan Laboratory investigates the immunological mechanisms underlying HIV-mediated reactivation of latent tuberculosis infection (LTBI) and the chronic immune activation that drives disease progression in TB/HIV co-infection. Our research integrates nonhuman primate models of SIV/Mtb co-infection with cutting-edge immunological approaches, including single-cell and spatial transcriptomics, high-parameter flow cytometry, and systems-level immune profiling, to define the cellular and molecular pathways that fail during co-infection. We examine how antiretroviral therapy influences immune restoration and identify persistent immune defects that contribute to TB reactivation despite treatment. A major focus of our program is discovering biomarkers and immune correlates that predict disease progression and therapeutic response. These mechanistic insights provide the foundation for developing host-directed immunotherapies that complement antimicrobial treatment and improve long-term control of TB/HIV co-infection. Our long-term goal is to translate these discoveries into interventions that reduce morbidity and mortality associated with the dual epidemics of HIV and tuberculosis.

<table>
<tr><td>Risk Assessment</td><td></td></tr>
<tr><td>Agent characteristics</td><td>Mycobacterium tuberculosis is a species of pathogenic bacteria and the causative agent of tuberculosis. It is primarily a respiratory pathogen and infects the lungs. Humans are the only known reservoirs of Mtb. The major route of transmission is through air droplets originating from a person who has the disease either coughing or sneezing.

Simian immunodeficiency virus (SIV) belongs to the family Retroviridae (subfamily Lentivirinae) and is closely related to human immunodeficiency virus types 1 and 2 (HIV-1 and HIV-2), the etiologic agents of acquired immunodeficiency syndrome (AIDS).</td></tr>
<tr><td>Types of manipulations planned</td><td>We will infect NCG mice CD34+ Humanized with a low dose of Mtb CDC1551 to establish Mtb infection via aerosol route using Glas-col located in BSL3 facility in building 12. Mice will be euthanized at up to 3 time points post Mtb infection. Blood, Liver, Spleen, Lung and BAL will be collected for downstream analysis.

The study will be conducted within the BSL-3 and ABSL-3 suites. Nonhuman primates will be experimentally infected with Mycobacterium tuberculosis (Mtb) strain CDC1551 and simian immunodeficiency virus (SIVmac239). Study animals may receive combination antiretroviral therapy (cART), anti-tuberculosis therapy consisting of isoniazid and rifapentine, and/or IL-21-IgFc fusion protein as part of the experimental protocol. For samples obtained from Mtb- and SIV-infected macaques, procedures conducted within the BSL-3 laboratory will include PBMC isolation, BAL cell isolation, lung tissue digestion, processing of spleen, liver, and bronchial lymph node tissues, flow cytometry staining, colony-forming unit (CFU) plating. These activities will be performed in BSL-3 laboratory in accordance with approved biosafety procedures and containment practices.</td></tr>
<tr><td>Sources of nucleic acids</td><td>N/A.</td></tr>
<tr><td>Nature of sequences</td><td>N/A.</td></tr>
<tr><td>Vectors to be used</td><td>N/A.</td></tr>
<tr><td>Expression of a foreign gene</td><td>N/A.</td></tr>
<tr><td>PI and lab staff trained</td><td>Yes.</td></tr>
<tr><td>Facilities and containment</td><td>BSL-2, BSL-3.</td></tr>
<tr><td>Applicable section of guidelines</td><td>III-D-1, III-D-2, III-D-4.</td></tr>
<tr><td>Initial risk determination</td><td>
<table>
<tr><th>Assessed initial risk</th><th>Potential consequences</th><th>Actions</th></tr>
<tr><td>☒ Medium</td><td>If an incident occurred, harm would result that would require basic</td><td>Additional risk control measures are advisable.</td></tr>
</table>
</td></tr>
</table>

		medical treatment and/or simple environmental measures.	

Occupational Health Representative Review (if applicable)	N/A.
Discussion	It was discussed that the way the amendment is written would benefit from the re-writing protocol in a standard language. Protocol would also benefit from listing the staff or NHP groups that's involved in working with these critters, that is standard. IBC members pointed out that the amendment was missing "Animal use" section. Committee also mentioned that protocol is missing and an experimental design, for example how many animals are going to be used. It was also pointed out that the parental protocol has mice work, in this amendment NHPs were proposed. IBC's concern was about parental protocol including use of mice and no NHPs. IBC Chair proposed that if PI has a protocol with NHP use, then PI has to link this amendment to the NHP-related protocol. Assistant Director of IACUC mentioned that PI has an IACUC protocol for working with mice only.
The following will require clarification	There are a substantial number of changes from the parent application that should be addressed in this amendment: - animal use (sections 4 and 5) needs additional information; - recombinant nucleic acid (section 6) need addition for SIVmac239; - B-virus response SOP should be included, since macaques were added to the study; - Staff experience relevant to the current work should be clarified and/or some indication of any training should be provided; - HIV and SIVmac239 agent characteristic should be added (section 2); - provide the relevant support groups (e.g. macaque group) pathologists and veterinarians for any of the NHP work planned in the study; - provide information about histo/path facilities that are going to be used on campus; - provide a schematic figure of the timeline of an example of challenge/reactivation/treatment etc. (section 1); - technical language correction and review should be performed.

Overall risk determination	Select the overall residual risk	☐ Very low	☐ Low	☒ Medium	☐ High	☐ Very high
	Will work require additional risk control measure?	Yes ☐ No ☒				

	Reference: Risk Assessment. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). p.47. License: CC BY-NC-SA 3.0 IGO.
Vote count	**12 Approve with conditions, 0 Against, 0 Abstain (see p.1 for the explanatory notes).**
	2. Annual application renewal. **i. BSC24-003R – PI Name: Riti Sharan, Humanized mouse model to study *Mtb*/HIV co-infection.** **ii. IBC25-009 – PI: Corinna Ross, Establishing hepatitis B virus infection in marmosets through targeted viral adaptation.** **iii. IBC24-021 – PI: Olena Shtanko, Pathogenesis and drug efficiency studies of high-containment viruses**
	3. New application review **i. IBC26-011 – PI Name: Tori Baxter, Working with *Mycobacteria* spp. in rodent models**
Lay explanation provided by PI	*The purpose of this study is to define how prior infection exposure (PIE) influences immune responses to M.tb exposure. The PIE mouse model has been used to compare the immune response to various drugs and vaccines against specific pathogen free (SPF) mice, as their immune system is more comparable to an adult human immune system. The Baxter lab has similarly developed a guinea pig model of PIE and aims to determine the effect of PIE on immune responses and clinical disease following experimental M.tb. infection and BCG vaccination.*
Research summary	The purpose of this study is to evaluate the effects of prior infection exposure (PIE) on the rodent immune system's response to *M.tb*. Mice will be sequentially infected with four natural mouse pathogens as described in IBC protocol 26-004. Guinea pigs will be sequentially infected with four pathogens as described in IBC protocol 25-001.Up to 24 weeks following infection with the last of four PIE pathogens, animals will be exposed to *M.tb*. by an accepted route of infection (e.g., intranasal inoculation, aerosol infection). A subset of animals may be vaccinated or infected with Bacillus Calmette-Guerin (BCG) by an accepted route of infection (e.g., subcutaneous, intraperitoneal, intradermal injection) up to 16 weeks prior to or in place of infection with *M.tb*. Following infection, animals will be monitored for signs of clinical TB disease, and *M.tb* dissemination will be measured by IVIS (mice only) in the BSL3 facility. Experimental protocols include necropsy of mice and guinea pigs with *M.tb*, homogenization and plating of organs for CFU determination, digestion of tissues for isolation and manipulation of RNA (e.g., qPCR, RNA-Sequencing) and immune cells (e.g., culture, flow cytometry), and isolation and fixation of tissues for histopathology.

<table>
<tr><td>Risk Assessment</td><td></td></tr>
<tr><td>Agent characteristics</td><td>Mycobacterium tuberculosis (strain H37Rv). M. tuberculosis is the causative agent of tuberculosis (TB) and is considered a RG3 (Risk Group 3) pathogen. M. tuberculosis BCG (bacille Calmette–Guérin), considered RG2 (Risk Group 2) and has been extensively employed as a vaccine against disseminated TB in children.</td></tr>
<tr><td>Types of manipulations planned</td><td>Stock preparations of BCG and M.tb. will be obtained from the Schlesinger lab or purchased from ATCC, and working dilutions used for animal infection will be made directly from these stocks. Percutaneous risks include using needles to inject BCG via intraperitoneal, subcutaneous, or intradermal routes, during survival blood collection in guinea pigs, and during necropsies. Potential aerosol risks include intranasal inoculation and aerosol infection of M.tb., tissue collection, centrifuging samples, and homogenizing samples.</td></tr>
<tr><td>Sources of nucleic acids</td><td>Synthetic</td></tr>
<tr><td>Nature of sequences</td><td>Fluorescent protein mCherry from marine animal (sea anemone), luciferase from Photinus pyralis, Aph-A2 aminoglycoside phosphotransferase from Escherichia coli (E. coli).</td></tr>
<tr><td>Vectors to be used</td><td>Plasmid-base vectors with mCherry or luciferase with kanamycin resistance (KanR), (kanamycin not used in TB treatment).</td></tr>
<tr><td>Expression of a foreign gene</td><td>Yes, mCherry, luciferase, Aph-A2 aminoglycoside phosphotransferase from</td></tr>
<tr><td>PI and lab staff trained</td><td>Yes.</td></tr>
<tr><td>Facilities and containment</td><td>BSL-2, ABSL-3</td></tr>
<tr><td>Applicable section of NIH guidelines</td><td>III-D-4</td></tr>
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</td></tr>
<tr><td>Occupational Health Representative Review (if applicable)</td><td>N/A</td></tr>
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<tr><td>Discussion</td><td>This is an extension of the previous work. PI wants to apply it to mice and guinea pigs and is going to work with Mycobacterium tuberculosis and BCG. PI brought some team members from other labs who have experience to do TB aerosol infection. No further discussion.</td></tr>
<tr><td>The following will require clarification</td><td>II-A-3, II-D-1, III-D-2.</td></tr>
<tr><td>Overall risk determination</td><td>
<table>
<tr><td>Select the overall residual risk</td><td>☐ Very low</td><td>☐ Low</td><td>☒ Medium</td><td>☐ High</td><td>☐ Very high</td></tr>
<tr><td>Will work require additional risk control measure?</td><td colspan="5">Yes ☐ No ☒</td></tr>
</table>
Reference: Risk Assessment. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). p.47 License: CC BY-NC-SA 3.0 IGO.
</td></tr>
<tr><td>Discussion</td><td>No discussion.</td></tr>
<tr><td>The following will require clarification</td><td>Recombinant nucleic acid section 6 has section III-D-4 only.</td></tr>
<tr><td>Vote count</td><td>12 Approve, 0 Against, 0 Abstain (see p.1 for the explanatory notes).</td></tr>
<tr><td>VI. Other business</td><td>
1. New IBC Policy
BSO gave an update on the sections of the IBC Policy. In general, the following updates have been made in compliance with NIH/OSP guidelines for IBC Policy:
I. Section 1, Purpose and Section 2, Scope of the Policy were defined and added.
II. Section 3, Definitions, was added, explaining various abbreviations mentioned in the Policy. Section was introduced to ensure clarity, consistency, and a common understanding of the terms used throughout the document.
III. Section 4, Roles and Responsibilities of the institution (Texas Biomed), IBC members, Biosafety officer (BSO) and Principal Investigators (PIs) were clarified.
IV. Section 5, General Policy, was added, to clarify the role of the Institutional Biosafety Committee (IBC), including the requirement under the NIH Guidelines to establish an IBC that provides oversight of all Texas Biomed–sponsored research involving recombinant and synthetic nucleic acid molecules, while recognizing that the IBC's responsibilities extend beyond oversight of only recombinant and synthetic nucleic acid molecule research.
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	V. Section 6, Procedures, including IBC membership, selection and service in the IBC, and Procedures of the IBC meetings, protocol reviews and discussions, IBC meetings must be conducted in a manner that demonstrates proof of life, permits recording of IBC Meeting Minutes, and permits public attendance. VI. IBC Meeting Minutes Policy will be separate from the IBC Policy. VII. Voting at the IBC meetings was also clarified and defined emphasizing four different outcomes: full approval, approval with conditions, disapproval and tabling.
Discussion	The committee reviewed IBC Policy and discussed several sections. Major points of discussion are summarized below. • **Incident Reporting:** Members agreed that the current definition and reporting language are confusing. It was noted that no additional report should be required when a report has already been submitted by either the PI or the IBC, and the language should be revised for clarity. • **BSO Requirement:** A question was raised regarding whether a Biological Safety Officer (BSO) is required for research conducted at BSL-2. It was noted that, under the IBC Policy, appointment of a BSO is not required solely because research is conducted at the BSL-2 level. • **PI Response Timelines:** A comparison was made to IUACUC's 90-day response period. The committee discussed how quickly investigators typically respond to IBC requests, and it was noted that PIs generally respond promptly, allowing many protocols to be approved well before the 90-day deadline. • **IBC Responsibilities and Protocol Review:** The committee discussed the IBC's role in ensuring compliance with NIH Guidelines, recombinant and synthetic nucleic acid molecule research requirements, biological safety standards, and physical containment measures. Members emphasized the importance of evaluating containment levels, facilities, personnel, and research practices. A recent significant protocol amendment was cited as an example of why thorough review is necessary. • **NIH Guideline Classifications:** IBC members discussed the definition of a research projects that can be conducted according to Section III-E – Experiments that Require IBC Notice Simultaneous with Initiation. It was acknowledged that, in practice, protocols on campus often contain a combination of III-E activities and other NIH Guideline categories. • **Documentation of Risk Assessments:** The committee discussed NIH expectations for documenting risk assessment discussions. NIH requires evidence of these discussions in the IBC Meeting Minutes, rather than through email exchanges. BSO noted that the **IBC Meeting Minutes Policy** has been prepared and will be submitted to the Texas Biomed Policy Committee for review. This Policy will be maintained as a separate document from the **IBC Policy**. • **Conflict of Interest:** A question was raised regarding whether PIs should recuse themselves from voting when conflicts of interest exist. It was

	confirmed that this requirement is addressed and will be formally incorporated into the IBC Policy. **Alternate Members:** Members discussed the role of alternate IBC members. Alternate members will be appointed by the Executive Vice President for Research and will retain full IBC membership and voting rights. An example was provided in which two appointed alternates serve the same role, but only one attends a meeting and is counted toward quorum. Members noted that this process is new and is not currently reflected in the policy.
Vote count	**11 Approve, 0 Against, 1 Abstain (see p.1 for the explanatory notes, BSO wrote the IBC Policy).**
	2. NIH communication BSO gave a brief update on the email communication with NIH regarding internal processes and policies that ensure staff comply with quorum voting requirements.
	3. Reportable incidents. No accidents have been reported.
VII. General discussion	One IBC member/PI asked about the timeline for review of recently submitted protocols and whether there is a defined submission deadline before an IBC meeting. IBC Chair indicated that one of the protocols of interest is expected to be discussed at the next IBC meeting, while BSO clarified that another protocol had already been reviewed and was conditionally approved pending investigator revisions. BSO also explained that protocols should ideally be submitted 90 days before the anticipated project start date, allowing at least 30 days for IBC review, although exceptions can be considered when justified by project timelines or contractual obligations. It was also noted that the IBC Policy allows flexibility for protocols submitted shortly before a meeting when circumstances warrant expedited consideration. The discussion also addressed upcoming IBC member training, annual renewal requirements, and protocol renewals, with BSO explaining that annual renewals help track active protocols and that only one renewal is needed when related protocols are linked together.
VIII. Adjourn	Meeting adjourned at 11:32 AM.
Next meeting	**8/20/2026 10:00 AM, Zoom.**