TEXAS BIOMEDICAL RESEARCH INSTITUTE
Biohazard committee

Biohazard and Safety Committee and Recombinant DNA Committee co-meeting

Date | time 6/18/2025 10:00 AM | *Meeting called to order by:*

Dr. Andrew Hayhurst

Meeting adjourned at 10:55 AM

In Attendance by ZOOM

BSC: Jason Bowling, Olena Shtanko, Tim Anderson, Anthony Wang, Andrew Hayhurst, John Dutton, Diako Ebrahimi, Felicia Ponce, Olga Gonzalez, Luis Martinez-Sobrido (Erica Arreola and Winka Le Clec'h – recording minutes)

Absent: Yan Xiang, Davida Smyth, Trent Peacock, Kathy Brasky, John Choe, Marie-Claire Gauduin

RDC: Olena Shtanko, Tim Anderson, Andrew Hayhurst, Anthony Wang, Diako Ebrahimi, Felicia Ponce, Luis Martinez-Sobrido, (Erica Arreola and Winka Le Clec'h – recording minutes)

Absent: Yan Xiang, Davida Smyth, Trent Peacock, Marie-Claire Gauduin

Quorums were present for BSC and RDC

Request was made to self-identify if conflicts arise and recuse as necessary

Approval of Minutes

Minutes from RDC/BSC May 2025 approved.

Discussion

Update on previous business – all revisions required from last meeting made and approved.

Discussion – Restructuring the Institutional Biosafety Committee (IBC) and Recombinant DNA Committee (RDC). A proposal was discussed to merge the BSC into the RDC, creating a single, integrated IBC structure similar to models used at other high-containment research institutes (e.g., NEIDL and GNL). This rounded RDC would include all necessary expertise on one voting panel. The current RDC member list is available on the OBA

website, though only the Chair, BSO, and institutional contact (currently AH, TP, and AH respectively) are publicly listed with contact details. JC, JB, OG, KB, JD would need to submit a biosketch or CV to be added to the roster and reported to the OBA. This consolidation is expected to enhance efficiency, particularly because recombinant DNA applications are often submitted alongside biohazard protocols, which benefit from input from experts in animal research, pathology, and infectious diseases.

Starting in June, IBC meeting minutes will be publicly posted on the Texas Biomed website upon approval at the subsequent IBC meeting.

Motion for IBC restructuring: N/A

New Applications

IBC25-009 Alexander Ploss – Establishing hepatitis virus infection in marmosets through targeted viral adaptation

Lay description provided by PI: An estimated 2 billion people have been exposed to hepatitis B virus (HBV) causing chronic infection in an estimated 290-400 people. Chronic carriers are as risk of developing severe liver disease including liver cancer. In fact, an estimated 900,000 people die every year of the consequences of chronic hepatitis B. HBV infection can be readily prevented with a safe and highly effective vaccine. While established infection can be suppressed with antiviral drugs this treatment rarely results in a cure. Development of more effective therapies has been hampered by the lack of animal models for the disease. To address this critical need we propose to test the susceptibility of marmosets, a small monkey species that is commonly used in biomedical research, to HBV, a closely related HBV variant from wooly monkeys (WMHBV) and a chimeric genome of HBV and WMHBV which is built to establish more readily infections in marmosets.

Agent characteristics: Hepatitis B virus (HBV), woolly monkey hepatitis B virus (WMHBV), and a chimera of the two will be used in this study. These are blood-borne pathogens. HBV is a human pathogen, and personnel at Texas Biomed are generally vaccinated against it. An AAV construct will be used to deliver the receptor for HBV in one cohort.

Types of manipulations planned: Viruses will be supplied by the Ploss Lab and administered by Texas Biomed staff.

Sources of nucleic acids: Hepatitis B Virus (HBV), Woolly Monkey Hepatitis B Virus (WMHBV), chimeric genome of HBV and WMHBV and AAV vector.

Nature of sequences: Wild-type viral sequences, chimeric constructs, and an AAV vector expressing the human taurocholate co-transporting polypeptide (NTCP) [foreign gene] will be used. All materials will be sent as viral particles ready for administration. No viral propagation in tissue culture will occur at Texas Biomed.

Hosts: Marmosets

Expression of foreign gene: Yes. Human taurocholate co-transporting polypeptide (NTCP) expressed in AAV vector.

PI and lab staff trained: All personnel involved at Texas Biomed are experts in marmoset handling and infectious disease research, including HBV and WMHBV research and development of the HBV vaccine.

Facilities: BSL-2 and ABSL-2 required.

Applicable section of guidelines: III-D-1-a, III-D-4-a, III-D-4-b

The following will require clarification: Details on the types of samples collected, sampling frequency/duration, and the specific analyses to be performed must be clearly described. Clarification is needed regarding the location, containment level, and handling logistics for the planned analytical work. Metrics of success for the study should also be defined. BMBL Version 6 should be followed and the applicable EHS SOP must be included to outline exposure response controls.

Motion: **Approval with clarifications** | 7 Approve, 0 Against, 0 Abstain

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IBC25-010rev1 Viraj Kulkarni – To study measles virus pathogenicity and evaluate interventions against MeV.

Lay description provided by PI: The goal of the project is to study pathogenicity of MeV and test antivirals and vaccines against MeV.

No recombinant DNA involved. The initial application proposed work at BSL-2. However, concerns were raised regarding the risk posed to the Texas Biomed NHP colonies, due to the transmissibility and potential severity of MeV. As a result, a revised application was submitted, with all proposed studies—both in vitro and in vivo—to be conducted at BSL-3/ABSL-3.

Agent characteristics: MeV (Measles virus).

Types of manipulations planned: Tissue culture will be used to amplify an early-passage isolate for stock preparation and characterization. Plaque reduction and neutralization assays will be performed to evaluate antiviral drugs and therapeutic antibodies. Rhesus macaques will be used to develop the animal model, which will then be applied to mAb efficacy testing.

Sources of nucleic acids: NA

Nature of sequences: NA

Hosts: Rhesus macaques.

Expression of foreign gene: NA

PI and lab staff trained: Not provided

Facilities and containment: BSL-3 and ABSL-3 required.

Applicable section of guidelines: NA

The following will require clarification: Personnel from the macaque and pathology teams should be identified. PI should clarify use of BSL-2 and clarification on the need for BSL-3 containment when working with Risk Group 2 agents. Staff need up-to-date antibody titer testing (vaccinate individuals with low titers). Include institutional SOPs for Herpes B virus PEP due to handling of rhesus macaque samples. Clarify whether shower-out is required for MeV work to minimize fomite transmission risk to NHP colonies. Containment level designations and viral titer information estimates should be reviewed and updated to reflect the appropriate ABSL designation.

Motion: **Approval with clarifications** | 10 Approve, 0 Against, 0 Abstain

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BSCRDC21-027.2 Luis Martinez-Sobrido – Efficacy study of mRNA vaccine against SARS-CoV-2 in baboons

Lay summary provided by PI: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was responsible for the coronavirus disease 2019 (COVID-19) pandemic. We have previously tested the efficacy of a proprietary subunit vaccine in a baboon SARS-CoV-2 infection model. This study's aim is to evaluate the protective effect of a proprietary mRNA vaccine towards SARS-CoV-2.

Agent characteristics: Natural isolates of SARS-CoV-2 obtained from BEI. Externally supplied proprietary synthetic mRNA vaccine

Manipulations planned: Immunization of Baboons, challenge with SARS-CoV-2, tissue sampling, assays, monitoring of immunized and challenged animals, pathology.

Sources of nucleic acids: Proprietary Synthetic mRNA.

Hosts: Baboons.

Expression of foreign gene: SARS-CoV-2 immunogen.

PI and lab staff trained: All study personnel are trained and experienced in conducting both animal and non-animal research involving SARS-Cov-2.

Facilities and containment: Animal studies will be conducted at ABSL-2+. Non-animal studies will be conducted at BSL-2+. All work will be conducted in accordance with CDC/NIH guidelines. Study will be conducted at ABSL-3/BSL-3 if ABSL-2+/BSL-2+ space is unavailable.

Applicable section of guidelines: III-D-4-A

The following will require clarification: Confirm whether baboon BSL-2 housing will be used during the pre-challenge vaccination period, if so, this location should be added to the Project Location section. Specify whether BSL-2+ or BSL-3 will apply for viral work location currently listed as TBD. Pathology staff should be listed if involved. Remove References to Rift Valley Fever. Clarify PPE distinctions between BSL-2+ and BSL-3 in vitro work and reference institutional BSL-2+ memo. Update aerosol generation response to "YES" and note dry husbandry practices. Indicate PAPR use under both ABSL-2+ and ABSL-3 conditions. Confirm that no special health surveillance is required, select "NO" and remove PPE list. Include relevant NIH Guidelines in the appropriate section.

Motion: **Approval with clarifications** | 7 Approve, 0 Against, 0 Abstain

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IBC25-011 Smriti Mehra – Discrete multiwalled carbon nanotube HIV therapy

Lay summary provided by PI: The project aims to load plasmid DNA encoding a broadly neutralizing anti-HIV antibody onto the company's proprietary nanotubes and use these assemblies to genetically immunize rhesus macaques, with subsequent monitoring of antibody levels in plasma.

Agent characteristics: Plasmid DNA.

Manipulations planned: Nanotube-DNA assemblies will be provided in solution by the company and delivered to rhesus macaques via IM route.

Sources of nucleic acids: The plasmid backbone is a commercial vector designed to express the constant domains of the Ig heavy and light chains. Variable domains of interest, along with signal sequences, are inserted to enable secretion of a complete IgG following delivery into mammalian cells.

Nature of sequences: Plasmid encoded IgG with variable domains from a broadly neutralizing anti-HIV mAb.

Hosts: Rhesus macaques from Indian origin.

Expression of foreign gene: Human IgG within an NHP.

PI and lab staff trained: The PI, staff, macaque group, and core personnel are all experts in conducting complex NHP studies and analyses.

Facilities and Containment: ABSL-2 facilities are suitable for work with rhesus macaques, and BSL-2 with a biosafety cabinet are suitable for processing blood to plasma.

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

The following will require clarification: Include a brief lay summary of the project and its potential public health benefits. Clarify the need for BSL-3 and ABSL-3 containment, given that the project involves genetic immunization with plasmid DNA encoding an antibody, and explain how this aligns with plans to return animals to the colony. Specify the storage method for plasma samples. Clarify the role of Integrated Research Core personnel, since only plasma samples are being collected and shipped to the sponsor. Include institutional SOPs for Herpes B virus post-exposure prophylaxis (PEP), due to the handling of rhesus macaque samples, and confirm that the external facility processing these samples will follow similar guidelines. Select ABSL-2 instead of ABSL-1. Clarify the biocompatibility and persistence of nanotubes, including any potential long-term health impacts

and proposed monitoring plans. Explain the rationale for citing Sections III-F-1 and III-F-8, in addition to III-D-4-a. Clarify the host ID in Table B. Define the success metrics for the study.

Motion: **Requires clarification and recirculation** | 7 Approve, 0 Against, 0 Abstain

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***Non-affiliated community members were unable to attend and were solicited by email for input on findings and votes – 1 in agreement, 1 no response**

Meeting adjourned at 10:55 AM

Next IBC meeting:

7/17/2025 10:00 AM, Zoom