# Institutional Biosafety Committee

**Date|Time: 6/18/2026 10:00 AM CT**
**Location: via Zoom**
**Meeting adjourned: 6/18/2026 11:15 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) | 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 |
| 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 | N |
| Viraj Kulkarni, Ph.D. | Virology, microbiology, vaccine immunology and NHP research | Y ** |

*Member joined Meeting at 10:27 AM (between votes)

**Member joined Meeting at 11:15 AM (between votes)

#Member left Meeting at 10:58 AM (between votes)

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|---|---|
| **I. Call to order** | a. Meeting called to order at 10:03 AM.<br>b. Quorum<br>i. Quorum was met; 10 voting members and 1 community member was present.<br>c. Other individuals in attendance: Elena Ganusova, Institutional Biosafety Committee (IBC) Administrator.<br>d. Conflicts of interest are to be declared by members as each application is discussed. |
| **II. Agenda approval** | The Meeting agenda was reviewed.<br>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** | **12 Approve, 0 Against, 0 Abstain (see p.1 for the explanatory notes).** |
| **III. Review Minutes from Previous Meeting** | Minutes from 05-21-26 meeting reviewed. |
| **Vote count** | **12 Approve, 0 Against, 0 Abstain (see p.1 for the explanatory notes).** |
| **IV. Update on previous business** | Approved applications: protocol application **BSC24-010.6** was approved (final approval 05-21-26);<br>Approved applications pending clarifications: **BSCRDC21-022.1**, **BSCRDC23-007.1**, **BSCRDC23-006.1**. |
| **V. New application review** | **IBC26-008 – PI Name: Luis Martinez-Sobrido, Studies with Cedar virus (CedV).** |
| ***Lay explanation provided by PI*** | *Cedar virus (CedV) is a bat-derived henipavirus related to Nipah (NiV) and Hendra (HeV), but evidence indicates that CedV itself is non-pathogenic in animal models and, to date, CedV has not been associated with human disease. Because of these reasons, CedV can be safely handled at BSL-2 since it lacks key virulence characteristics associated with other henipaviruses (e.g., NiV and HeV). In this protocol we will generate recombinant (r)CedV wild-type (WT) or expressing reporter fluorescent and luciferase proteins to identify compounds and neutralizing antibodies able to inhibit and neutralize, respectively, viral infection of henipaviruses.* |
| ***Research summary*** | Cedar virus (CedV) is a bat-derived henipavirus related to Nipah (NiV) and Hendra (HeV), but evidence indicates that CedV itself is non-pathogenic in animal models and, to date, CedV has not been associated with human disease. Because of these reasons, CedV can be safely handled at BSL-2 since it lacks key virulence characteristics associated with other henipaviruses (e.g., NiV and HeV). In this protocol we will generate recombinant (r)CedV wild-type (WT) or expressing reporter fluorescent and luciferase proteins to identify compounds and neutralizing antibodies able to inhibit and neutralize, respectively, viral infection. We will also generate rCedV expressing the F and G proteins of NiV and/or HeV to identify antivirals and neutralizing antibodies against NiV and/or HeV F and G proteins at |

<table>
<tr><td></td><td>BSL-2. Finally, we will explore the feasibility of using the rCedV expressing NiV and/or HeV F and G proteins as potential vaccines against NiV and/or HeV infections.</td></tr>
<tr><td>Risk Assessment</td><td></td></tr>
<tr><td>Agent characteristics</td><td>Cedar virus (CedV) is a bat-derived henipavirus related to Nipah and Hendra viruses, belonging to the Paramyxoviridae family. Unlike its relatives, CedV is non-pathogenic and has not been linked to disease in humans or animals. It is an enveloped, single-stranded RNA virus that uses similar entry proteins but lacks key virulence factors. Because of its low risk, CedV can be safely studied in BSL-2 laboratories and is useful for research on antivirals and vaccines.</td></tr>
<tr><td>Types of manipulations planned</td><td>The protocol involves generating recombinant Cedar virus (rCedV), including wild-type and versions engineered to express fluorescent or luciferase reporter proteins for studying viral infection and inhibition. It also includes creating rCedV variants that express Nipah and Hendra virus surface proteins (F and G) to evaluate antiviral compounds, neutralizing antibodies, and potential vaccine candidates.</td></tr>
<tr><td>Sources of nucleic acids</td><td>Synthetic.</td></tr>
<tr><td>Nature of sequences</td><td>Cedar virus (CedV) wild type (WT), sequences encoding F and G proteins of NiV and/or HeV.</td></tr>
<tr><td>Vectors to be used</td><td>Wild-type (WT) Cedar virus (CedV).</td></tr>
<tr><td>Expression of a foreign gene</td><td>Yes, ZsGreen, Nanoluciferase (Nluc).</td></tr>
<tr><td>PI and lab staff trained</td><td>Yes, experts at reverses genetics and virology, BSL-2 aspects satisfactorily, a chart of staff members explaining the division of work is present.</td></tr>
<tr><td>Facilities and containment</td><td>BSL-2.</td></tr>
<tr><td>Applicable section of guidelines</td><td>II-A-3, III-D-1, III-D-2, III-D-3.</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>☒ High</td><td>If an incident occurred, harm would result that would require medical treatment and/or substantial environmental measures.</td><td>Additional risk control measures need to be implemented before the laboratory activity is undertaken.</td></tr>
</table>
</td></tr>
<tr><td>Occupational Health Representative Review (if applicable)</td><td>N/A.</td></tr>
<tr><td>Discussion</td><td>The committee discussed the growing research interest in Cedar virus (CedV), noting its genetic relationship to highly pathogenic Nipah (NiV) and Hendra (HeV) viruses. Concerns were raised following NIH Office of Science Policy (OSP) feedback indicating that current safeguards to prevent environmental release of recombinant viruses may be insufficient. Members emphasized the need to strengthen risk</td></tr>
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<tr><td></td><td>assessment in the Meeting Minutes, particularly regarding how recombinant CedV could potentially gain pathogenic traits. A key concern involved the possibility of CedV acquiring the W protein from NiV, which plays an important role in immune evasion and pathogenicity. While CedV is normally cleared by the human immune system, the addition of such factors could significantly increase its pathogenic potential. The roles of viral surface proteins (F and G) were also discussed, highlighting their importance in host cell entry and viral assembly, though these alone would not confer pathogenicity without additional factors like the W protein. Questions were raised about whether non-pathogenic viruses can become infectious to humans and whether modifications proposed in the protocol (e.g., removal of F and G proteins) are being implemented; according to the application, such modifications are not planned. The project was described as vaccine-related research, and some participants expressed cautious confidence given similar prior work. Additional protocol concerns included the need to update the medical surveillance section with standard language, resolve conflicting responses in the animal use section, and incorporate appropriate references.</td></tr>
<tr><td>The following will require clarification</td><td>The application lacks details on the final repertoire of recombinant Cedar virus constructs and provides more information about F and G proteins from Nipah and Hendra viruses. A clear diagram outlining generation of the constructs should be added. Several sections are unclear, including information about animal use, risks for CedV acquiring the human pathogenicity traits of Nipah/Hendra by the engineering you plan. Clearly articulate what the pathogenicity factors are that separate Nipah/Hendra from CedV and whether there is any overlap with what your plans are. The medical surveillance section must be rewritten in the standard language.</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>Vote count</td><td>13 Approve, 0 Against, 0 Abstain (see p.1 for the explanatory notes).</td></tr>
<tr><td>New application</td><td>IBC26-010 - PI Name: Viraj Kulkarni, Counter Measures for Hantaviruses in rodents and nonhuman primates.</td></tr>
<tr><td>Lay explanation provided by PI</td><td>The main purpose of this IBC application is to develop countermeasures against Hantaviruses.</td></tr>
<tr><td>Research summary</td><td>The main purpose of this IBC application is to develop countermeasures against Hantaviruses. This will involve developing small and large animal models for Hantaviruses. We will also use well established animal models to determine the efficacy of novel vaccines and therapeutics.</td></tr>
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<tr><td>Risk Assessment</td><td></td></tr>
<tr><td>Agent characteristics</td><td>Hantaviruses, including the Andes virus (ANDV) and Sin Nombre virus, pose a high-fatality risk (up to 40-60% in severe cases) primarily through inhalation of aerosolized virus from rodent excreta. While most cases occur sporadically in rural, rodent-prone areas, certain strains, like ANDV, can transmit from person to person. The overall risk to the general public is low, with highest exposure risks linked to cleaning infested areas. Less pathogenic hantavirus strains generally cause milder forms of illness, such as nephropathia epidemica (NE) in Europe, or result in asymptomatic infections.</td></tr>
<tr><td>Types of manipulations planned</td><td>Hantaviruses will be propagated in established cells lines (Vero and BHK). Titration of viral stocks will be performed using conventional plaque assay or focus forming unit plaque assay. Animals will be infected in the ABSL-4 lab. Tissue from infected animals will be homogenized using aerosol resistant homogenizers. For nucleic acid extraction, the box containing the tubes will be decontaminated prior to removal from the BSL-3 for subsequent purification and analysis within the BSL-2.</td></tr>
<tr><td>Sources of nucleic acids</td><td>No recombinant nucleic acid involved.</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. Listed personnel are BSL-3, ABSL-4 and BSL-4 trained.</td></tr>
<tr><td>Facilities and containment</td><td>BSL-3/ABSL-3 and ABSL-4.</td></tr>
<tr><td>Applicable section of guidelines</td><td>N/A.</td></tr>
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<tr><td>Occupational Health Representative Review (if applicable)</td><td>N/A.</td></tr>
<tr><td>Discussion</td><td>Committee members pointed out that clarification is needed regarding the process and requirements for bringing tissues out of the ABSL-4 facility. There was also a discrepancy between sections concerning the list of animals, which should be reviewed and reconciled.</td></tr>
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<tr><td>The following will require clarification</td><td>The application lacks details on inactivation procedures while removing samples from BSL-3 and ABSL-4, lab protocols validating the procedure must be in place. Specify the list of personnel in terms of species planned to be employed.</td></tr>
<tr><td>Vote count</td><td>12 Approve, 0 Against, 1 Abstain (Conflict of Interest) (see p.1 for the explanatory notes).</td></tr>
<tr><td>Overall risk determination</td><td>
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</td></tr>
<tr><td>New Amendment review</td><td>BSCRDC24-008.1 - PI Name: Shouxiong Huang, Amendment, Addition of mice to Antigen presentation and T cell responses in M. tuberculosis.</td></tr>
<tr><td>Lay explanation provided by PI</td><td>This protocol will permit the study of the effects of small molecules on mucosal-associated invariant T (MAIT) cell activation to inhibit Mycobacterium tuberculosis (M.tb) infection in mice. MAIT cells are unconventional T cells capable of rapid activation and response in bacterial infection. Knowing small molecules that activate MAIT cells will provide strategies to activate MAIT cells and protect against Mycobacterium tuberculosis infection in broad human populations. This animal BSL3 protocol will allow us to test the anti-mycobacterial effect of MAIT-stimulatory small molecules and small molecule-activated MAIT cells in mouse models of Mycobacterium tuberculosis infection.</td></tr>
<tr><td>Research summary</td><td>T cells are essential in immune defenses and immune surveillance in microbial infections, inflammations, and cancers. Conventional CD4+ and CD8+ T cells respond to the peptide antigens presented by major histocompatibility complex (MHC) proteins (or human leukocyte antigens, HLA). Unlike conventional T cells, innate-like T cells generally respond to non-peptidic metabolite antigens presented by nonclassical MHC-like molecules, such as MHC class I-related protein 1 (MR1) and cluster of differentiation 1 proteins (CD1a, CD1b, CD1c, and CD1d). Although conventional T cells are fundamental to defend or surveil infections, inflammations, and cancers, innate-like T cells play novel and poorly characterized roles, likely providing new targets to fight diseases. My lab is interested in defining the activation and response of innate-like T cells, functioning with conventional T cells, in Mycobacterium tuberculosis (M. tuberculosis or M.tb) infection. Specifically, we aim to define the mycobacterial and host antigens or stimulants that activate metabolite-reactive mucosal-associated invariant T (MAIT) and lipid-reactive T cells in tuberculosis. Results will provide candidate compounds to stimulate innate-like T cell responses, in parallel with conventional T cells, to fight infections.</td></tr>
<tr><td>Risk Assessment</td><td></td></tr>
<tr><td>Agent characteristics</td><td>Mycobacterium tuberculosis (M.tb) H37Rv, Erdman, CDC1551 (and fluorescent reporter derivatives).</td></tr>
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<tr><td>Types of manipulations planned</td><td>This research involves infecting mice with virulent strains of Mycobacterium tuberculosis through aerosol exposure to model lung infection. Multiple established clinical and laboratory strains, including fluorescently labeled versions (GFP or mCherry), will be used to track infection in mice. Tissues from infected mice will be collected to study bacterial growth and immune responses.</td></tr>
<tr><td>Sources of nucleic acids</td><td>Synthetic</td></tr>
<tr><td>Nature of sequences</td><td>mCherry is DsRed fluorescent protein derivative from Discosoma sp. coral.<br>Green Fluorescent Protein (GFP) is from the bioluminescent jellyfish Aequorea victoria.</td></tr>
<tr><td>Vectors to be used</td><td>Plasmid-base vectors with mCherry or GFP, mycobacteriophage carrying a recombinant cosmid with homologous recombination fragments targeting the lprG gene.</td></tr>
<tr><td>Expression of a foreign gene</td><td>Yes, GFP, mCherry.</td></tr>
<tr><td>PI and lab staff trained</td><td>No experiences provided for any personnel for the in vitro Mtb BSL3 portion, and for the in vivo ABSL-3 work and Glas-Col aerosol chamber. Protocol requires that personnel have relevant experiences, the documentation of training on this device, and the SOP for the Glas-Col.</td></tr>
<tr><td>Facilities and containment</td><td>BSL-3 and ABSL-3.</td></tr>
<tr><td>Applicable section of guidelines</td><td>II-A-3, Appendix C-1, II-A-3, III-D-1, 2.</td></tr>
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</td></tr>
<tr><td>Occupational Health Representative Review (if applicable)</td><td>Facility has been performing these types of experiments for several years and much experience exists, though the applicant PI will need to lean on this expertise for training in relevant approaches.</td></tr>
<tr><td>Discussion</td><td>The committee raised multiple concerns regarding biosafety, procedures, and personnel training. Questions were asked about who is qualified to work at the BSL-3 level, including responsibilities for necropsy and related tasks. Significant gaps were identified in the experimental procedures, such as insufficient detail on mouse challenge protocols, dosing schedules, monitoring duration, and administration methods. Additional issues included the absence of information on mouse husbandry and lack of documentation confirming appropriate training for necropsy, tissue collection, and processing. Members emphasized the need for greater procedural detail and verified training records for personnel and discussed whether to approve the protocol with revisions or reject it. The consensus was to</td></tr>
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<tr><td></td><td>table the protocol pending substantial clarification, with a preference not to approve until concerns are adequately addressed. It was suggested that the Principal Investigator (PI) attend an IBC meeting to provide clarification. Concerns were also raised about potential timing issues related to grant submission deadlines. Further points included uncertainty about whether the protocol falls under rDNA guidelines, the need to avoid approving protocols via email in unclear cases, and the importance of completing personnel training and maintaining accessible training logs before protocol submission.</td></tr>
<tr><td>The following will require clarification</td><td>The application lacks sufficient detail and will require revision. Several key sections are incomplete or unclear, including insufficient personnel experience for BSL-3 and ABSL-3 work including usage of Glas-Col aerosol chamber, necropsy and tissue handling. Detailed standard operating procedures (SOPs) and documentation of training must be provided. Risk assessment needs to be revised, along with clarification of applicable biosafety guidelines and appropriate protective equipment. The experimental design needs to be revised, including mouse husbandry practices, infection monitoring timelines, dosing regimens, and administration routes, as well as procedural steps for tissue processing.</td></tr>
<tr><td>Overall risk determination</td><td>
<table>
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<tr><td>Will work require additional risk control measure?</td><td colspan="5">Yes ☐ No ☒</td></tr>
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</td></tr>
<tr><td>Vote count</td><td>13 Approve, 0 Against, 0 Abstain (see p.1 for the explanatory notes).</td></tr>
<tr><td>New Amendment review</td><td>BSC24-001.4 - PI Name: Shouxiong Huang, Amendment, Addition of more BSL-2 pathogens to Antigen presentation and T cell responses in microbial infections, inflammations, and cancers.</td></tr>
<tr><td>Lay explanation provided by PI</td><td>This protocol will permit the study of the effects of bacteria-stimulated glial cells on the activation of mucosal-associated invariant T (MAIT) cells to protect against glioma, a central nervous system tumor. We added multiple bacterial strains of risk group two, such as Streptococcus agalactiae, Klebsiella pneumoniae, Borrelia burgdorferi, together with previously approved mycobacterial species, to treat glial cells for MAIT cell activation. The activated MAIT cells will be further tested for their effects on glioma cell killing in vitro and tumor growth inhibition in mice.</td></tr>
<tr><td>Research summary</td><td>The selected bacterial species, including Acinetobacter baumannii, Borrelia burgdorferi, Borrelia spps. Enterococcus faecalis, Klebsiella pneumoniae, and Streptococcus agalactiae, generally infect macrophages, epithelial cells, glial cells, as facultative intracellular bacteria that can survive extracellularly as well. As either opportunistic or regular pathogens, these bacteria can cause lung and brain infections. However, it is a critical unknown whether bacterial invasiveness to infect lung cancer or glioma cells, and their ability to activate MAIT cells, can induce cancer cell killing. To address this critical unknown, we will test the</td></tr>
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<tr><td></td><td>hypothesis that mucosal-associated invariant T (MAIT) cells enhance cytotoxicity against lung cancer and glioma cells upon bacterial infection or stimulation. We will infect or treat lung cancer and glioma cells with the listed bacteria and bacterial metabolites to observe MAIT cell activation and cancer cell killing. In these assays, Enterococcus faecalis and Listeria monocytogenes will be negative controls, while Mycobacterium bovis and E.coli will be positive comparisons for MAIT cell activation.</td></tr>
<tr><td>Risk Assessment</td><td></td></tr>
<tr><td>Agent characteristics</td><td>Acinetobacter baumannii, Borrelia burgdorferi, Enterococcus faecalis, Klebsiella pneumoniae, Streptococcus agalactiae, all BSL-2 bacterial pathogens.</td></tr>
<tr><td>Types of manipulations planned</td><td>Bacterial strains will be used to infect antigen-presenting cells at specified multiplicities of infection to induce antigen presentation and enable downstream recombinant protein expression and purification. Co-culture systems with human immune cells will be employed to characterize antigen-specific activation and functional responses. Subsequent assays will quantify immune activation, microbial growth inhibition, and cytotoxic effects under tightly regulated experimental conditions.</td></tr>
<tr><td>Sources of nucleic acids</td><td>No recombinant nucleic acid involved.</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. Listed personnel have been performing similar methods with a variety of BSL-2 bacteria and viruses for 2 years at this site and many years elsewhere.</td></tr>
<tr><td>Facilities and containment</td><td>BSL-2.</td></tr>
<tr><td>Applicable section of guidelines</td><td>N/A.</td></tr>
<tr><td>Overall risk determination</td><td>
<table>
<tr><th>Assessed initial risk</th><th>Potential consequences</th><th>Actions</th></tr>
<tr><td>☒ Low</td><td>If an incident occurred, there would be a small likelihood of harm.</td><td>Use risk control measures if needed.</td></tr>
</table>
</td></tr>
<tr><td>Occupational Health Representative Review (if applicable)</td><td>N/A.</td></tr>
<tr><td>Discussion</td><td>IBC members raised questions regarding the Occupational Health section. During the discussion, it was determined that no additional review was required. The committee also discussed the incomplete fields in the protocol. The Chair clarified that, because this submission is an amendment to an existing protocol, completion of those fields is not necessary.</td></tr>
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| ***The following will require clarification*** | None. |
| ***Overall risk determination*** | <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. |
| **Vote count** | **13 Approve, 0 Against, 0 Abstain (see p.1 for the explanatory notes).** |
| **Five years renewal application** | **IBC26-009 - PI Name: Luis Martinez-Sobrido, Studies with SARS-CoV (5yr Renewal of BSC21-021).** |
| ***Lay explanation provided by PI*** | *Severe acute respiratory syndrome (SARS) is a viral respiratory disease caused by SARS-CoV. In this protocol, we will generate stocks of SARS-CoV and recombinant (r)SARS-CoV, mouse adapted or reporter-expressing rSARS-CoV. These viruses will be used to help identify compounds and neutralizing antibodies able to inhibit and neutralize, respectively, viral infection.* |
| ***Research summary*** | *Severe acute respiratory syndrome (SARS) is a viral respiratory disease caused by SARS-CoV. In this protocol, we will generate, propagate, and characterize stocks of SARS-CoV and recombinant (r)SARS-CoV, mouse adapted or reporter-expressing rSARS-CoV. Virus stocks will be quantified by plaque assays, and plaque reduction neutralization tests will be used to evaluate the antiviral activity of therapeutic compounds and the neutralizing capacity of antibodies. Reporter-expressing recombinant SARS-CoV will also be developed to facilitate antiviral screening and neutralization studies using sensitive reporter-based assays.* |
| ***Risk Assessment*** | |
| ***Agent characteristics*** | SARS-CoV Urbani strain, icSARS-CoV, SARS-CoV Urbani v2163 coronavirus capable of causing respiratory disease in humans and is transmissible. Enveloped positive stranded RNA virus. Select agent. Mouse adapted viruses are also present. Human pathogens from BEI Resources. |
| ***Types of manipulations planned*** | SARS-CoV virus stocks will be generated by infecting Vero E6 cells and collecting culture supernatants after cytopathic effects are observed, followed by clarification, storage, and titration using plaque assays. Viral infectivity will be quantified through plaque assays involving serial dilutions, agar overlay, and staining or immunostaining of infected cell monolayers. Plaque reduction neutralization tests (PRNT) will be used to evaluate the effectiveness of antibodies and antiviral compounds in inhibiting viral infection under controlled conditions. Viral inactivation methods (e.g., formalin or Trizol) will be applied for downstream analyses, including RNA extraction, sequencing, and qRT-PCR assay optimization. These approaches will also be used to identify antiviral compounds and assess neutralizing antibody activity against SARS-CoV. |

<table>
<tr><td>Sources of nucleic acids</td><td>Synthetic and mouse adapted SARS-CoV.</td></tr>
<tr><td>Nature of sequences</td><td>Recombinant mouse adapted rSARS-CoV, mCherry is DsRed fluorescent protein derivative from Discosoma sp. Coral, Green Fluorescent Protein (GFP) is from the bioluminescent jellyfish Aequorea victoria, luciferase (e.g., Firefly and Gaussia luciferase).</td></tr>
<tr><td>Vectors to be used</td><td>BAC cDNA clone of mouse adapted SARS-CoV.</td></tr>
<tr><td>Expression of a foreign gene</td><td>Yes, mCherry, GFP, luciferase.</td></tr>
<tr><td>PI and lab staff trained</td><td>Yes, listed personnel are experts at reverses genetics and virology, BSL-3 aspects satisfactorily, a chart of staff members explaining the division of work is present.</td></tr>
<tr><td>Facilities and containment</td><td>BSL-3 and ABSL-3.</td></tr>
<tr><td>Applicable section of guidelines</td><td>II-A-3, Appendix C-1, II-A-3, III-D-1, III-D-2, III-D-3.</td></tr>
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</td></tr>
<tr><td>Occupational Health Representative Review (if applicable)</td><td>No change from parent application previously approved.</td></tr>
<tr><td>Discussion</td><td>The committee reviewed a five-year renewal protocol with no proposed changes from the original submissions (BSC21-021 and RDC21-021) (Hayhurst). Viral strains are properly documented in the inventory system, and no changes were identified in the risk assessment. Additional issues included discrepancies in personnel documentation between listed staff and their described experience, and questions about biosafety practices given the virus's approximately 10% mortality rate, particularly the rationale for using both BSL-3 and BSL-4 containment. There were also inconsistencies in treatment information. Although antivirals are reportedly available, the protocol states that no treatment exists, requiring clarification. Treatment decisions were noted to follow healthcare provider discretion, similar to SARS-CoV-2 or CDC guidance. Finally, concerns were raised regarding the equipment to be used, and overall clarification is needed in several areas of the protocol.</td></tr>
<tr><td>The following will require clarification</td><td>Several sections are unclear, including information on personnel, type of equipment to be used, availability of the medical treatment, and confirmation that the Tape Station is present to perform the required sample inactivation using the validated protocol.</td></tr>
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<table>
<tr><td>Overall risk determination</td><td>
<table>
<tr><td>Select the overall residual risk</td><td>☐<br>Very low</td><td>☐<br>Low</td><td>☒<br>Medium</td><td>☐<br>High*</td><td>☐<br>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>Vote count</td><td>13 Approve, 0 Against, 0 Abstain (see p.1 for the explanatory notes).</td></tr>
<tr><td>VI. Other business</td><td>Approval of the protocols affected by an administrative error<br>IBC is not allowed to collect votes by email per NIH guidelines and can only approve protocols and major amendments during a convened meeting where a quorum is present</td></tr>
<tr><td></td><td>BSCRDC21-017.5 – PI Name: Luis Martinez-Sobrido, Studies of influenza viruses, Amendment 5. Studies with influenza H5N1 in NHP/Preliminary evaluation of H5N1 pathogenesis in macaques & addition of Co-PI (votes collected through 27 August -12 September 2025).</td></tr>
<tr><td>Vote count</td><td>13 Approve, 0 Against, 0 Abstain (see p.1 for the explanatory notes).</td></tr>
<tr><td></td><td>BSCRDC22-014.10 & 23-009.9 – PI Name: Larry Schlesinger, Addition of M. tuberculosis reporter strain (previously voted on April 16, 2026).</td></tr>
<tr><td>Vote count</td><td>13 Approve, 0 Against, 0 Abstain (see p.1 for the explanatory notes).</td></tr>
<tr><td></td><td>BSCRDC22-016.2 - PI Name: Diako Ebrahimi CRISPR and stable transfection with pBABE vector systems (votes collected through 17 March -24 April, 2026).</td></tr>
<tr><td>Vote count</td><td>12 Approve, 0 Against, 1 Abstain (Conflict of interest) (see p.1 for the explanatory notes).</td></tr>
<tr><td></td><td>BSCRDC22-007.1&2 – PI Name: Luis Martinez-Sobrido, 1, Animal work with monkeypox virus and 2, generate recombinant reporter Monkeypoxvirus (previously voted on April 16, 2025).</td></tr>
<tr><td>Vote count</td><td>13 Approve, 0 Against, 0 Abstain (see p.1 for the explanatory notes).</td></tr>
<tr><td></td><td>BSC21-012.2 - PI Name: Luis Martinez-Sobrido, Amendment 2 BSC21-012. Add natural and recombinant forms of Bundibugyo virus (BDBV) (votes collected through June 6 - 11, 2026).</td></tr>
<tr><td>Vote count</td><td>13 Approve, 0 Against, 0 Abstain (see p.1 for the explanatory notes).</td></tr>
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| | **IBC24-021.3 - PI Name: Olena Shtanko, Amendment 3 to add Bundibugyo Ebolavirus (BDBV), Pathogenesis and drug efficacy studies of high-containment viruses (votes collected through May 28 - June 3, 2026).** |
| **Vote count** | **11 Approve, 0 Against, 1 Abstain (Conflict of Interest) (see p.1 for the explanatory notes).** |
| | **BC24-017.3 – PI Name: Viraj Kulkarni, Amendment 3 Adding Sri Lanka 2016 strain, Evaluate Pathogenicity of Dengue Viruses and Development of Interventions (votes collected through May 6 – 8, 2026).** |
| **Vote count** | **11 Approve, 0 Against, 1 Abstain (Conflict of Interest) (see p.1 for the explanatory notes).** |
| | **IBC24-017.1&2 – PI Name: Viraj Kulkarni, Amendments 1&2 Addition of NHP and personnel to Dengue for mRNA vaccine, Evaluate Pathogenicity of Dengue Viruses and Development of Interventions (on hold from 12-20, 2025, IBC meeting, votes collected through January 5, 2026).** |
| **Vote count** | **11 Approve, 0 Against, 1 Abstain (Conflict of Interest) (see p.1 for the explanatory notes).** |
| **NIH communication** | Discussion regarding NIH concerns about minutes provision (February, March, April of 2025) received on June 12, 2026. Communications of minutes to NIH for pre-review is returning to schedule. |
| **Reportable incidents.** | No incidents. |
| **VII. General discussion** | No discussion. |
| **VIII. Adjourn** | Meeting adjourned at 11:15 AM. |
| **Next meeting** | **7/16/2026 10:00 AM, Zoom.** |