UNM INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

Minutes
August 20, 2025
9:00 A.M. – 11:00 A.M.; Zoom Videoconference

Voting Members Present: (Quorum = 8)

☒ Coenraad Adema, PhD, UNM Department of Biology, IBC Co-Chair
☒ Steven Bradfute, PhD, HSC Department of Internal Medicine (Infectious Diseases)
☐ Tione Buranda, PhD, HSC Department of Pathology
☒ Eric Denkers, PhD, UNM Department of Biology
☒ Anastacia Griego-Fisher, PhD, NM SLD (Community Member)
☒ William 'Curt' Hines, PhD, HSC Department of Biochemistry and Molecular
☐ Julie In, PhD, HSC Department of Internal Medicine, Gastroenterology
☒ Tara Ooms Konecny, DVM, DACLAM, HSC Department of Pathology
☒ David N. Linsenbardt, PhD, HSC Department of Neurosciences
☒ Sharon Master, PhD, (Community Member)
☒ Tim Muller, MS, CBSP, HSC Office of Research, Biosafety Officer
☒ David Peabody, PhD, HSC Department of Molecular Genetics and Microbiology
☒ Graham Timmins, PhD, HSC College of Pharmacy, IBC Co-Chair
☒ Kevin Vlahovich, MD, HSC Department of Internal Medicine

Voting Members Absent:

Tione Buranda, PhD, HSC Department of Pathology
Julie In, PhD, HSC Department of Internal Medicine, Gastroenterology

Visitors & Non-Voting Members Present:

Virginia Severns, HSC Office of Research, Biosafety Specialist
Amanda Brothers, Animal Care Compliance Specialist
Brad Dolin, JD, UNM Health Sciences HRPP Director

1. **Call to Order:**
   - Dr. Coenraad Adema

   a. **Announcements**
   - None

2. **Approval of last meeting minutes:**
   - May 21, 2025

3. **Old Business:**

- None

4. **New Business:**

- The November IBC meeting has been rescheduled for November 12th. The original date was November 19th.
- Laboratory worker potential exposure to plasmids with gene inserts for CRISPR Cas 9 and gRNA(s) specific to Zebrafish.
- Posting of IBC Meeting Minutes

5. **Protocols Approved (Previously Reviewed):**

- 815 (KELLAL 24-11-01R A)
- 817 (SALIIR 25-05-01R)
- 818 (TUNCEL 23-08-01R D)
- 819 (VALECA 25-05-01R)
- 820 (FRIEKA 25-05-01)

6. **Protocols Pending (Contingencies)**

- 821 (DEREVO 25-05-01R)
- 822 (BRADST 23-02-01R E)
- 823 (BRADST 25-05-01R)
- 826 (BRADST 22-11-01 D)
- 827 (MILLER 25-05-01R)

7. **New Protocols for Review (requires IBC review and approval)**

IBC ID: 828 (BHASKI 25-08-01)
PI: Bhaskar
Title: Inflammasomes and Tau
Description: Our lab studies the accumulation of a protein called Tau and its effect on brain inflammation, specifically microglia, immune cells of the brain. Alzheimer's and other tauopathies progresses where tau becomes pathological and aggregates inside neurons. We use genetic mouse models and biochemical methods to study this interconnection between tau and brain inflammation, investigating the movement of that harmful protein through the brain and its effects relating to neuroinflammation and the pathways that are associated with Alzheimer's disease. We have also developed several vaccines based on Virus-Like Particles (VLP) platform, conjugated with various antibodies that make it specific to targeting tau or microglia with the aim of reducing neuroinflammation and therefore disease severity.
Agent: *Staphylococcus aureus* (LAC)
Human Material: No
Recombinant or Synthetic Nucleic Acid: N/A
Wild-type: Yes
Proposed BSL: A/BSL-2
Reviewer: Timmins

The Primary Reviewer provided a summary report. The committee decided that the safety precautions would mitigate the risks to lab personnel, the public, and the environment to an acceptable level if the following contingencies were adopted**. Protocol approved contingent upon completion of the following contingencies at A/BSL-2 practices:**

1. Ensure contact times for different disinfection/sterilization agents are detailed.
2. This is for the addition of *Staphylococcus aureus bacteria* to be used to induce skin infections via subcutaneous injections in mice. The routine surface cleaning PREempt RTU needs up to 3 minutes of wet contact time, depending on the virus, whereas PEROXigard and Quatracide TB only require 1 minute. Please update the protocol after clarifying with the BSO.
3. Section V, Bhaskar lab, emphasizes the worthiness of the research but provides no details on the experimental work that the Bhaskar lab will perform for this protocol. For clarification of the workflow, include a brief description of the procedure for initial VLP vaccination of the mice, indicate safety procedures and health considerations that address the risk of needle sticks.
4. Section V, Bhaskar lab, includes the following statement: "Peptides linked to or presented on the surface of these particles [VLPs] or non-pathogenic bacteriophage are presented in a multivalent array and can induce a strong antibody response. This type of vaccination has been proven safe in both humans and mice, and these components have been safely and successfully used by UNM faculty for several years." Provide a clear description of the vaccines used (only VLPs?)
5. Section V emphasizes that they will be pre-dosing the animals with the VLP vaccine. However, none of those details are included in the proposal. Should this be an addition to an existing proposal?

NOTE: Dr Linsenbardt was placed in a waiting room during the review of 831 (MCKESA 25-08-01R).

IBC ID: 831 (MCKESA 25-08-01R)
PI: McKenzie
Title: Investigation into the formation and propagation of neural synchrony in memory and disease
Description: Changes in the synaptic strength are thought to be the biological basis of memory. The pattern of coincident neural activity between pairs of cells is known to drive both increases and decreases in synaptic coupling. The rules relating spike timing and synaptic coupling are not well understood in vivo. To gain millisecond control of neural activity in specific types of neurons, I will deliver designer proteins (opsins) that convert light energy into changes in the excitability of the neurons. These opsins will be introduced to the neuron through commercially available adeno-associated viruses. To drive the opsin, all studies will require the implantation of fiber-optic stubs or recording optrodes that will allow us to use light to stimulate infected neurons and in the case of optrodes, record the activity of stimulated/inhibited cells.
Agent: AAV vector (AAV1,2,5,8,9; AAV-D, Retrograde AAV) with rNA inserts (CChannelrhodopsin-2 (ChR2), C1V1, ChrimsonR, eArchT 3.0, GFP, FRT-stop-FRT-Cre-GFP, GRABDA, GRABNE, GRABACH, CtACR, Jaws, eNpHR3.0, GCaMP6m, GCaMP6f, hM4Di, GRABDAmut, GRABNEmut, GRABACmut, Halorhodopsin, SOUL).
Human Material: No
Recombinant or Synthetic Nucleic Acid: III-E and III-D-4
Wild-type: No
Proposed BSL: A/BSL-1 with A/BSL-2 practices, for all gene inserts except for (FRT-stop-FRT-Cre-GFP). A/BSL-2 for AAV containing (FRT-stop-FRT-Cre-GFP).
Reviewer: Peabody

The Primary Reviewer provided a summary report. The committee decided that the safety precautions would mitigate the risks to lab personnel, the public, and the environment to an acceptable level if the following contingencies were adopted. **Protocol approved contingent upon completion of the following contingencies at A/BSL-1 with A/BSL-2 practices, for all gene inserts except for (FRT-stop-FRT-Cre-GFP). A/BSL-2 for AAV containing (FRT-stop-FRT-Cre-GFP).**

1. There are some typos. In section III, please edit "face bask" to "face mask". On page 12, in the table, rows 13 and 14, please edit "singling" to "signaling."
2. In section V (1), update the protocol to include the management of sharps (e.g., glass injector tips).
3. Update the protocol and provide a response for V(5)(b). Note: V(5)(a) covers routine surface and equipment disinfection/decontamination, and V(5)(b) covers BSC, centrifuge, and laboratory biological spill cleanup decontamination.
4. Updates to required biosafety training and update protocol with revised training dates.
5. Please ensure the presence of appropriate information/labels on the secondary container during transport.
6. Discuss appropriate use of disinfectants with BSO**.**

Note: Following the vote on 831 (MCKESA 25-08-01R), Dr. Linsenbardt returned to the meeting.

IBC ID: 834 (WHEECO 25-08-01)
PI: Wheeler
Title: Rapid Diagnostic Assay Development for SARS-CoV-2
Description: This protocol addresses the need to develop rapid and sensitive screening tests for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) that could be completed in less than 1 hour, use non-sophisticated relatively inexpensive laboratory approaches and equipment that could ultimately use crude human specimens such as sputum, saliva, and urine etc. instead of viral RNA or swab samples. Multiple amplification and detection methods could potentially meet this need such as Loop-mediated isothermal amplification (LAMP) technology. LAMP can then be carried out rapidly at a single temperature, generating millions of copies of a given target in less than an hour. We will perform assay development work with a non-infectious single-stranded DNA (ssDNA) molecule designed from specific nucleotide positions of the COVID-19 Wuhan-Hu-1 genome. We will design a rapid SARS-CoV-2 detection assay for application to human specimen sources that will be obtained under future approved IRB studies
Agent: Potential infection material, SARS-CoV-2 ssDNA fragments (ORF1ab-ssDNA spans nucleotide (NT) position 2941 – 3420, the 6 primers within this region are NT 3043 –3330, ORF1-ab ssDNA spans NT 15061 – 15480, the 6 primers within this region are NT 15182 – 15387, Envelope gene ssDNA spans NT 26130 – 26540, the 6 primers within this region are NT 26232 – 26441, Nucleocapsid gene ssDNA spans NT 29031 – 29420, the 6 primers within this region are NT 29136 – 29324); SARS-CoV-2 clinical samples (active and inactive); SARS-CoV-2 RNA fragments.
Human Material: Yes
Recombinant or Synthetic Nucleic Acid: III-E
Wild-type: Yes
Proposed BSL: BSL-2
Reviewer: Adema

The Primary Reviewer provided a summary report. The committee decided that the safety precautions would mitigate the risks to lab personnel, the public, and the environment to an acceptable level if the

following contingencies were adopted. **Protocol approved contingent upon completion of the following contingencies at BSL-2:**

1. Section (V) page 5, Background states SARS-CoV-2 as RG3. Please update the protocol where relevant according to the CDC https://www.cdc.gov/covid/php/lab/index.html update from March 27, 2025, that declares: (quote) "At a minimum, BSL-2 facilities, practices, and procedures are recommended for diagnostic research, anatomic pathology, environmental testing, and virus propagation utilizing SARS-CoV-2. At a minimum, ABSL-2 is recommended for work with these viruses in animal models.".
2. In the Lay protocol, clarify the meaning of the abbreviation "IRB" and how that relates to UNM-HSC Human Research Review Committee (HRRC) on page 7.
3. Integrate the information provided in form F (Significant modification) and form G (annual review) into the main document; do not use forms F and G in this 5-year renewal.
4. In Addendum D, section I, b. source of organism; complete source information using information for the non-activated SARS-CoV-2 BSL2 "remnant (nasopharyngeal) swabs, COVID-positive (RT-qPCR or sequenced) from Specimen.
5. Considering that LAMP assays are run in parallel … with RT-PCR (p6), provide a brief description of the method used to extract RNA from swab samples, and whether this method inactivates SARS-CoV-19 if present in the sample. Update protocol (e.g., section 6, pages 9-10) as relevant.
6. Considering that LAMP assays are run in parallel … with RT-PCR (p6), briefly describe details for swab-derived RNA samples (non-inactivated SARS-CoV-2) of transport of assembled RT-qPCR reaction tubes from BSC to thermal cycler, loading, running, and disposal of completed reactions. In case the RNA extraction method does not inactivate the samples, this information is not required.
7. Section 8. Please correct: for a 10% final concentration, 10 mL of bleach should be added to 90 mL of waste, not 100 mL.
8. Section II. Facility. Provide the number of BSCs.
9. Resolve laboratory inspection deficiencies.
10. Update expired webpage links within the protocol.
11. Section VI. Virus is being used in this protocol; uncheck the 'No' box and check the 'Yes' box.

8. Significant Modifications

IBC ID: 829 (BARTER 24-11-01R A)
PI: Bartee
Title: Oncolytic treatment of cancer
Description: This amendment covers 2 different items. Generation of randomly mutagenized myxoma virus: We would like to create a library of randomly mutagenized MYXV constructs which we can use to identify gene knockouts which display increased persistence in tumors in vivo. Generation of α(1,3)Galactosyltransferase expressing MYXV: We would like to generate a MYXV construct expressing the α(1,3)Galactosyltransferase enzyme. This enzyme creates Galactose-alpha-1,3 galactose (aGAL) which is a disaccharide motif found on the cell surface. Most mammalian species express α(1,3)Galactosyltransferase in all cells and are therefore immunologically tolerized against aGAL epitope.
Agent: Myxoma virus with rNA inserts (Sleeping Beauty Transposase, Puromycin R, Blastocidin R, Hydromycin R, Zeomycin R, Neomycin R, α(1,3)Galactosyltransferase).
Human Material: Yes

Recombinant or Synthetic Nucleic Acid: III-D-3-a and III-D-4
Wild-type: No
Proposed BSL: A/BSL-2
Reviewer: Bradfute

The Primary Reviewer provided a summary report. The committee decided that the safety precautions would mitigate the risks to lab personnel, the public, and the environment to an acceptable level if the following contingencies were adopted. **Protocol approved contingent upon completion of the following contingencies at A/BSL-2.**

1. Provide cited references that have previously used this mutagenicity approach (if it exists) in myxoma virus.
2. Provide details on the impact of mutagenesis on the virus genome: a) Provide several examples from scientific literature supporting the statement about the extent of awareness that every mutation ever (mutagenesis of the virus) has reduced pathogenicity in rabbits. b) What is the impact of the insertion of an antibiotic cassette on the genome of the virus? Indicate likely truncation of reading frames and disruption of the function of impacted viral genes. c) Indicate whether characterization of viral genomes will provide an indication for reduced pathogenicity.
3. Emphasize stringent adherence to methods from the mother protocol for safe storage, disinfection, inactivation, and disposal, specifically for the heterogeneous viral stock and any of the downstream selected mutants.
4. Indicate whether (like most mammalian species) also rabbits "express α(1,3)Galactosyltransferase in all cells and are therefore immunologically tolerized against the aGAL epitope".
5. Similarly, have previous studies been using viral vectors to express aGAL in mice?
6. There are 7 total products listed in addendum C/D, but only images of 3 are provided, and it's not immediately clear which ones they are for.
7. In Addendum C.I.1 – Is it sufficient to say, "Established human cancer cell lines of various kinds"? Should the specific identities of the cell lines be provided?
8. The lay summary in addendum F is highly technical—it should be moved to another section, and the lay summary should be simplified.
9. Please discuss whether additional safety concerns are involved with the heterologous expression of alpha-galactosyl transferase in humans. For example, could it somehow provoke alpha-gal syndrome by sensitizing a normal individual to alpha-Gal? Could it elicit an allergic response in an already alpha-Gal sensitive individual?

NOTE: Dr. Bradfute was placed in a waiting room during the review of 832 (BRADST 22-11-01 E).

IBC ID: 832 (BRADST 22-11-01 E)
PI: Bradfute
Title: Analysis of therapeutics and neutralizing antibody responses against non-select agent BSL-3 viruses
Description: Our current protocol is approved for the use of different strains of lymphocytic choriomeningitis virus (LCMV), including the Armstrong strain and new strains isolated from naturally infected wild-caught mice. In this addendum we request the addition of the WE strain of LCMV for our petri dish (in vitro) experiments. This strain has been shown to cause disease in monkeys, and we would like to see how it grows in cells in a petri dish, and how those cells respond to infection, compared to the other LCMV strains in our protocol. This will let us discover if the new LCMV strain we have found in wild-caught mice is more similar to the pathogenic WE strain or the more mild lab strains.

Agent: Lymphocytic choriomeningitis virus (arenavirus-WE)
Human Material: No
Recombinant or Synthetic Nucleic Acid: N/A
Wild-type: Yes
Proposed BSL: BSL-3
Reviewer: Muller

The Primary Reviewer provided a summary report. The committee decided that the safety precautions would mitigate the risks to lab personnel, the public, and the environment to an acceptable level. **The protocol was approved at BSL-3.**

Note: Following the vote on 832 (BRADST 22-11-01 E), Dr. Bradfute returned to the meeting.

IBC ID: 833 (ENDIJO 24-08-01R A)
PI: Endicott
Title: Regulation of chaperone-mediated autophagy in mammalian cells
Description: Viral expression vectors have been added to the protocol:
1. New expression vector for KFERQ-Dendra2 reporter – no major changes in procedures from before.
2. New expression vectors for wildtype and constitutively active receptor tyrosine kinases (RTKs) – for the first time, the lab will be expressing genes with oncogenic potential. This will help to achieve the aims of funded research projects. However, the lab already uses safety protocols that are sufficient to protect against exposure to lentiviral vectors. To help reduce risk, one BSL2 certified biosafety cabinet will be dedicated to lentiviral work, and one cabinet will be lentivirus free. We do not anticipate that personnel will be exposed to higher risk than before.

Agent: Lentiviral vector rNA inserts (EGFR,E GFRL858R,INSR, INSR Alpha variant, VEGFR, VEGFR C482R, PDGFRA, PDGFRA D842v).
Human Material: Yes
Recombinant or Synthetic Nucleic Acid: III-D-3-a
Wild-type: No
Proposed BSL: BSL-2
Reviewer: Linsenbardt

The Primary Reviewer provided a summary report. The committee decided that the safety precautions would mitigate the risks to lab personnel, the public, and the environment to an acceptable level if the following contingencies were adopted. **Protocol approved contingent upon completion of the following contingencies at BSL-2.**

1. Define all acronyms used within the protocol. For example, the acronym CMA is mentioned on page 4.
2. Please provide additional details on gene inserts. Some examples: "EGFR L858R refers to a specific mutation in the EGFR gene (epidermal growth factor receptor) that is commonly found in non-small cell lung cancer (NSCLC). This mutation, specifically a substitution of leucine to arginine at position 858 in exon 21 of the EGFR gene, makes cancer cells more sensitive to certain EGFR tyrosine kinase inhibitors (TKIs)."

   "The INSR Alpha variant" refers to a variant of the insulin receptor gene (INSR), which can lead to a range of insulin resistance syndromes, including Type A insulin resistance and, in severe cases, Donohue syndrome, which is a severe, rare, and often fatal condition. Patients with Donohue

syndrome experience extreme insulin resistance, growth retardation, and other serious health problems.

10. **Notifications (administrative approvals by BHC)**

Notifications simultaneous with initiation

- None

Personnel Addition / Removal

- 647 (DEREVO 21-05-01R); Removal
- 649 (YANGXU 21-05-01R); Removal
- 656 (IN00JU 21-05-01R); Addition
- 658 (LOKEER 21-05-01R); Addition/Removal
- 688 (BRINJE 22-05-01R); Removal
- 690 (ADAMSA 22-05-01R); Removal
- 701 (OZBUMI 22-08-01R); Addition
- 730 (LEE0DA 23-05-01R); Addition/Removal
- 733 (WEICJA 23-05-01R); Removal
- 740 (TUNCEL 23-08-01R); Addition
- 783 (HIGHKA 24-05-01); Addition/Removal
- 784 (LIU0ME 24-05-01R); Removal
- 785 (BURATI 24-05-01); Removal
- 815 (KELLAL 24-11-01R A); Addition
- 826 (BRADST 22-11-01 D); Addition/Removal

Room Changes

- 739 (SALIIR 23-08-01R)

Other Admin Changes

- None

11. **Protocol Closures-**

- 582 (BRADST 20-05-01)
- 599 (FRIEKA 20-05-01)
- 602 (BACAJU 20-05-01)
- 603 (VALECA 20-05-01R)
- 609 (BACAJU 20-05-02R)
- 611 (CANNJU 20-05-01R)
- 612 (DEREVO 20-05-01R)
- 613 (BRADST 20-05-02)

12. <u>Annual Reviews -</u>

- 646 (ZHANSI 21-05-01N)
- 647 (DEREVO 21-05-01R)
- 649 (YANGXU 21-05-01R)
- 652 (HURWIV 21-05-01R)
- 656 (IN00JU 21-05-01R)
- 658 (LOKEER 21-05-01R)
- 688 (BRINJE 22-05-01R)
- 690 (ADAMSA 22-05-01R)
- 726 (NEUMAA 23-05-01)
- 730 (LEE0DA 23-05-01R)
- 732 (FRIEKA 23-05-01R)
- 733 (WEICJA 23-05-01R)
- 735 (BRADST 23-05-01)
- 783 (HIGHKA 24-05-01)
- 784 (LIU0ME 24-05-01R)
- 785 (BURATI 24-05-01)
- 789 (PODDRA 24-05-01R)

13. <u>Adjourn</u> –10:55 am