

University of Wisconsin-Madison Institutional Biosafety Committee

Minutes of Regular Meeting Open Session

Date: 6/18/2025

Present: Peter Halfmann, Matt Reynolds, Dennis Halterman, Donna Neumann, Yevgenya Grinblat, Andrea Ladd, Warren Rose, Amita Kapoor, Ryan Stoffel, Marta Gaglia, Garret Suen, Joel Malak, Clint Morgan, Megan Spurgeon, Barak Blum, Sabine Pellett, Steve Garvis

Consultants: Tony McGrath, Lissa Koop, Darren Berger

OBS: Tony McGrath, TJ Whyte, David Dyer, Karen Demick, Andrea Ladd, Stephanie Kutz, Tara Schnell, Megan Dixon, Erin Plisch, Donald Busalacchi, Kathy Krasny

Guests: Sarah Johnson-Schlueter-CALS

Call to order: The meeting was called to order by Garret Suen, at Zoom at 1:30PM

Announcements: The IBC meeting is open to the public.

Review of Minutes: A motion to approve the open session minutes of the following IBC meetings was Unanimously adopted.

Institutional Biosafety Committee meeting on (6/4/2025)

Megan Spurgeon, abstain Peter Halfmann, abstain Steve Garvis, absent Warren Rose, absent Donna Neumann absent Barak Blum, absent Marta Gaglia, absent Joel Malak, absent Yevjenya Granblat, absent

Approval of Registered Protocols: A motion to approve registered protocols was null

Other business - open session

- Agenda Items - Documents For Open Session:
- IBCtraining_MinorActions_061825.pptx

Review of research protocols - open session

☐ B00001079

☐ B00001193

☐ B00000126-AM011

☐ B00000267-AM011

☐ B00000405-AM010

☐ B00000415-AM007

☐ B00000435-AM011

☐ B00000464-AM006

☐ B00000471-AM013

☐ B00000553-AM006

☐ B00000608-AM016

☐ B00000855-AM013

☐ B00000865-AM006

☐ B00001019-AM003

☐ B00001025-AM003

☐ B00001028-AM003

☐ B00001034-AM002

☐ B00001071-AM003

☐ B00001091-AM001

☐ B00001130-AM005

Announcements

null

The meeting adjourned 3:04 PM

- Bio Protocol Number: B00001079
PI Name: Manish Patankar
Protocol Title: OBGYN Tissue Collections and Processing Core Lab
Motion: IBC approved with contingencies
Motion Made By: Joel Malak
Motion Seconded By: Garret Suen
Committee Action: Adopted unanimously by voice vote
Nay Votes, Abstentions, Absentees: Steve Garvis, absent Marta Gaglia, absent
Biosafety Level: BSL1; BSL2; BSL2; BSL2; BSL1; BSL2
Containment Equipment: Not applicable; Not applicable; Biological safety cabinet (BSC); Biological safety cabinet (BSC); Biological safety cabinet (BSC); Not applicable;
Committee Review: The IBC has reviewed the locations, activities, and agents involved in the proposed work. The IBC considered agent characteristics including but not limited to pathogenicity, stability, and source and nature of recombinant and synthetic nucleic acids and their expressed products, as applicable.
Facilities: Facilities meet standards set by the IBC or additional controls are used effectively to mitigate risk caused by deviation from the standards.

Required Institutional Training: The PI and laboratory staff have completed required institutional biosafety training.

Lab-specific Training and Expertise: The training and expertise of personnel involved in the conduct of research deviate from standards set by the IBC. Revisions are required for approval.

PPE, Controls, and Practices: The PPE, engineering controls, and administrative controls deviate from the standards set by the IBC for the proposed materials and activities. Revisions are required for approval.

NIH Guidelines Requirements: Proposed work is not subject to the NIH Guidelines.

Administrative: Administrative revisions are required for approval (e.g., reorganizing information, removing extraneous text, correcting typos, spelling out acronyms).

NIH Guidelines: (III-D-1-a) (III-D-1-b); (III-E-1); (III-E-1); (III-F-8); (III-F-8);

Summary of IBC Review: This is a new protocol for a core facility at Meriter Hospital that focuses on processing research samples for the Department of Obstetrics and Gynecology. The IBC discussed lab-specific training for users of the core, access control, and sample handling.

- Bio Protocol Number: B00001193

PI Name: Andrew Alexander

Protocol Title: MRI of Brain Waste Clearance

Motion: IBC approved with contingencies

Motion Made By: Joel Malak

Motion Seconded By: Barak Blum

Committee Action: Adopted unanimously by voice vote

Nay Votes, Abstentions, Absentees: Steve Garvis, absent Marta Gaglia, absent

Biosafety Level: BSL2; Not applicable (non-laboratory area); BSL2; BSL2; BSL2;

Containment Equipment: Not applicable; Not applicable; Biological safety cabinet (BSC); Not applicable; Biological safety cabinet (BSC);

Committee Review: The IBC has reviewed the locations, activities, and agents involved in the proposed work. The IBC considered agent characteristics including but not limited to pathogenicity, stability, and source and nature of recombinant and synthetic nucleic acids and their expressed products, as applicable.

Facilities: Facilities meet standards set by the IBC or additional controls are used effectively to mitigate risk caused by deviation from the standards.

Required Institutional Training: The PI and laboratory staff have completed required institutional biosafety training.

Lab-specific Training and Expertise: The training and expertise of personnel involved in the conduct of research meets standards set by the IBC.

PPE, Controls, and Practices: The PPE, engineering controls, and administrative controls meet the standards set by the IBC for the proposed materials and activities or additional controls are used effectively to mitigate risk caused by deviation from the standards.

NIH Guidelines Requirements: Proposed work is not subject to the NIH Guidelines.

Administrative: Administrative revisions are required for approval (e.g., reorganizing information, removing extraneous text, correcting typos, spelling out acronyms).

NIH Guidelines:

Summary of IBC Review: This is a new protocol for the Alexander laboratory, which studies the role of waste product build-up in the brain in neurodegenerative diseases. They collect blood samples from participants in conjunction with MRI scans. There were no biosafety concerns, but some clerical corrections were identified.

- Bio Protocol Number: B00000126-AM011

PI Name: [REDACTED]

Protocol Title: Amendment/Renewal 011 for Lipid and Energy Metabolism

Motion: IBC approved protocol

Motion Made By: Sabine Pellett

Motion Seconded By: Garret Suen

Committee Action: Adopted unanimously by voice vote

Nay Votes, Abstentions, Absentees:

Biosafety Level: BSL2; ABSL2; ABSL2; BSL2; BSL1; ABSL1, BSL1; Not applicable (non-laboratory area);

Containment Equipment: Biological safety cabinet (BSC), Chemical fume hood, Other – bioBubble; Not applicable; Not applicable; Biological safety cabinet (BSC), Chemical fume hood; Chemical fume hood; Chemical fume hood; Not applicable;

Committee Review: The IBC has reviewed the locations, activities, and agents involved in the proposed work. The IBC considered agent characteristics including but not limited to pathogenicity, stability, and source and nature of recombinant and synthetic nucleic acids and their expressed products, as applicable.

Facilities: Facilities meet standards set by the IBC or additional controls are used effectively to mitigate risk caused by deviation from the standards.

Required Institutional Training: The PI and laboratory staff have completed required institutional biosafety training.

Lab-specific Training and Expertise: The training and expertise of personnel involved in the conduct of research meets standards set by the IBC.

PPE, Controls, and Practices: The PPE, engineering controls, and administrative controls meet the standards set by the IBC for the proposed materials and activities or additional controls are used effectively to mitigate risk caused by deviation from the standards.

NIH Guidelines Requirements: Proposed work meets the requirements set forth in the NIH Guidelines.

Administrative:

NIH Guidelines: (III-D-4)(III-D-4-a)(III-D-1-a)(III-D-1-b)(III-D-4-b); (III-D-4-a)(III-D-4-b); (III-D-1-a) (III-D-1-b); (III-D-3-a) (III-D-3-b) (III-D-3-e); (III-E-3); (III-E-3); (III-E); (III-E-1); (III-F-8); (III-F-8);

Summary of IBC Review: This laboratory uses recombinant DNA techniques, cell culture, and genetically modified mice to study the physiological functions of fat synthesis enzymes. In this amendment, they propose to add work with non-recombinant RG2 bacteria and a replication incompetent adenoviral vector. No biosafety concerns were identified.

- Bio Protocol Number: B00000267-AM011

PI Name: [REDACTED]

Protocol Title: Amendment/Renewal 011 for Pathogenesis, immunology and drug discovery related to fungal infections by *Blastomyces dermatitidis* and other fungi.

Motion: IBC approved with contingencies

Motion Made By: Sabine Pellett

Motion Seconded By: Warren Rose

Committee Action: Adopted unanimously by voice vote

Nay Votes, Abstentions, Absentees:

Biosafety Level: BSL2; BSL2; BSL2; ABSL2; ABSL2; BSL2; BSL2; BLS2; BSL2; Not applicable (non-laboratory area); BSL2; Other – BSL3 anteroom; BSL3; BSL2; Not applicable (non-laboratory area); ABSL2; Other – Anteroom; ABSL3; ABSL3; BSL2; BSL2; ABSL1;

Containment Equipment: Not applicable; Chemical fume hood; Biological safety cabinet (BSC); Biological safety cabinet (BSC), Ventilated HEPA-filtered housing or rack system; Biological safety cabinet (BSC), Ventilated HEPA-filtered housing or rack system; Biological safety cabinet (BSC), Chemical fume hood; Biological safety cabinet (BSC); Biological safety cabinet (BSC); Biological safety cabinet (BSC); Not applicable; Biological safety cabinet (BSC); Not applicable; Biological safety cabinet (BSC); Not applicable; Not applicable; Biological safety cabinet (BSC); Not applicable; Biological safety cabinet (BSC); Not applicable; Not applicable; Biological safety cabinet (BSC), Chemical fume hood; Not applicable;

Committee Review: The IBC has reviewed the locations, activities, and agents involved in the proposed work. The IBC considered agent characteristics including but not limited to pathogenicity, stability, and source and nature of recombinant and synthetic nucleic acids and their expressed products, as applicable.

Facilities: Facilities meet standards set by the IBC or additional controls are used effectively to mitigate risk caused by deviation from the standards.

Required Institutional Training: The PI and/or laboratory staff must complete required institutional biosafety training. Final approval will be withheld until required biosafety training is complete.

Lab-specific Training and Expertise: The training and expertise of personnel involved in the conduct of research deviate from standards set by the IBC. Revisions are required for approval.

PPE, Controls, and Practices: The PPE, engineering controls, and administrative controls deviate from the standards set by the IBC for the proposed materials and activities. Revisions are required for approval.

NIH Guidelines Requirements: Proposed work meets the requirements set forth in the NIH Guidelines.

Administrative: Administrative revisions are required for approval (e.g., reorganizing information, removing extraneous text, correcting typos, spelling out acronyms).

NIH Guidelines: (III-D-4-b); (III-D-2-a); (III-D-2-a); (III-D-4)(III-D-4-a)(III-D-1-a)(III-D-1-b)(III-D-4-b); (III-D-4-a)(III-D-4-b); (III-D-1-a) (III-D-1-b); (III-D-3-a) (III-D-3-b) (III-D-3-e); (III-E); (III-E-1); (III-E-1); (III-F-8); (III-F-8); (III-F-8); (III-F-8); (III-F-8); (III-F-1); (III-F-4) (III-F-5);

Summary of IBC Review: This laboratory studies immune responses to infection by dimorphic fungi with the goal of developing vaccines. In this renewal, completed projects have been removed and quaternary ammonium disinfectants have been added. The IBC discussed microcentrifuge use inside a BSC, lab-specific training for work with biological toxins, and handling cultures embedded in Matrigel outside of containment.

- Bio Protocol Number: B00000405-AM010

PI Name: Amita Kapoor

Protocol Title: Amendment/Renewal 010 for Biosafety protocol for Assay Services

Motion: IBC approved with contingencies

Motion Made By: Joel Malak

Motion Seconded By: Megan Spurgeon

Committee Action: Adopted unanimously by voice vote

Nay Votes, Abstentions, Absentees: Amita Kapoor, absent

Biosafety Level: BSL2; BSL2; BSL2; BSL2; BSL2; BSL2; BSL2; BSL2; BSL2;

Containment Equipment: Chemical fume hood; Chemical fume hood; Chemical fume hood; Chemical fume hood; Not applicable; Biological safety cabinet (BSC); Not applicable; Not applicable; Not applicable;

Committee Review: The IBC has reviewed the locations, activities, and agents involved in the proposed work. The IBC considered agent characteristics including but not limited to pathogenicity, stability, and source and nature of recombinant and synthetic nucleic acids and their expressed products, as applicable.

Facilities: Facilities meet standards set by the IBC or additional controls are used effectively to mitigate risk caused by deviation from the standards.

Required Institutional Training: The PI and laboratory staff have completed required institutional biosafety training.

Lab-specific Training and Expertise: The training and expertise of personnel involved in the conduct of research meets standards set by the IBC.

PPE, Controls, and Practices: The PPE, engineering controls, and administrative controls meet the standards set by the IBC for the proposed materials and activities or additional controls are used effectively to mitigate risk caused by deviation from the standards.

NIH Guidelines Requirements: Proposed work is not subject to the NIH Guidelines.

Administrative: Administrative revisions are required for approval (e.g., reorganizing information, removing extraneous text, correcting typos, spelling out acronyms).

NIH Guidelines:

Summary of IBC Review: This is the protocol for the Assay Services core facility at the Wisconsin National Primate Research Center. The core performs radioimmunoassays, enzyme immunoassays, electrochemiluminescence assays, bioassays and automated, quantitative high performance liquid chromatography (HPLC) and mass spectrometry (LC/MS). Major sample preparation techniques include Solid Phase Extraction, HPLC and celite chromatography. In this renewal, no changes to research materials or activities are proposed.

- Bio Protocol Number: B00000415-AM007

PI Name: Silvia Cavagnero

Protocol Title: Amendment/Renewal 007 for Mechanisms of Protein Folding in Vitro and in the Cell

Motion: IBC approved with contingencies

Motion Made By: Matt Reynolds

Motion Seconded By: Garret Suen

Committee Action: Adopted unanimously by voice vote

Nay Votes, Abstentions, Absentees:

Biosafety Level: BSL1; BSL1; BSL1; BSL1; BSL1; BSL1; BSL1; BSL1; BSL2; BSL1, BSL2; BSL1, BSL2; BSL1; BSL1, BSL2; BSL1; BSL2;

Containment Equipment: Not applicable; Not applicable; Not applicable; Not applicable; Not applicable; Not applicable; Not applicable; Not applicable; Not applicable; Not applicable; Chemical fume hood; Not applicable; Chemical fume hood; Not applicable; Biological safety cabinet (BSC), Chemical fume hood;

Committee Review: The IBC has reviewed the locations, activities, and agents involved in the proposed work. The IBC considered agent characteristics including but not limited to pathogenicity, stability, and source and nature of recombinant and synthetic nucleic acids and their expressed products, as applicable.

Facilities: Facilities meet standards set by the IBC or additional controls are used effectively to mitigate risk caused by deviation from the standards.

Required Institutional Training: The PI and/or laboratory staff must complete required institutional biosafety training. Final approval will be withheld until required biosafety training is complete.

Lab-specific Training and Expertise: The training and expertise of personnel involved in the conduct of research meets standards set by the IBC.

PPE, Controls, and Practices: The PPE, engineering controls, and administrative controls deviate from the standards set by the IBC for the proposed materials and activities. Revisions are required for approval.

NIH Guidelines Requirements: Proposed work meets the requirements set forth in the NIH Guidelines.

Administrative: Administrative revisions are required for approval (e.g., reorganizing information, removing extraneous text, correcting typos, spelling out acronyms).

NIH Guidelines: (III-E); (III-F-8);

Summary of IBC Review: The Cavagnero laboratory studies protein folding and misfolding using microbiological and biochemical approaches. In this renewal, they propose to continue ongoing work with mouse prions and prion-like bacterial proteins, as well as adding work with commercially sourced human urine and plasma. The IBC discussed proposed work outside of containment and inactivation procedures for prion-containing waste.

- Bio Protocol Number: B00000435-AM011

PI Name: [REDACTED]

Protocol Title: Amendment/Renewal 011 for Translational Studies of Gastrointestinal Cancers to Develop Personalized Treatment Strategies

Motion: IBC approved with contingencies

Motion Made By: Peter Halfmann

Motion Seconded By: Marta Gaglia

Committee Action: Adopted unanimously by voice vote

Nay Votes, Abstentions, Absentees:

Biosafety Level: BSL2; BSL2; BSL2; Not applicable (non-laboratory area); BSL2; Not applicable (non-laboratory area); BSL1; BSL2; BSL2; BSL2; BSL2; BSL2; BSL2; BSL2; BSL2; BSL2; BSL2; BSL2; BSL2; Not applicable (non-laboratory area); BSL2; BSL2; BSL2; ABSL2; BSL2; ABSL2; BSL2; ABSL2, BSL2; BSL2; ABSL1, ABSL2;

Containment Equipment: Biological safety cabinet (BSC); Biological safety cabinet (BSC); Not applicable; Not applicable; Not applicable; Not applicable; Not applicable; Not applicable; Biological safety cabinet (BSC); Not applicable;

Chemical fume hood; Biological safety cabinet (BSC); Biological safety cabinet (BSC); Not applicable; Not applicable; Biological safety cabinet (BSC); Not applicable; Not applicable; Biological safety cabinet (BSC), Chemical fume hood; Not applicable; Biological safety cabinet (BSC); Chemical fume hood; Biological safety cabinet (BSC); Ventilated HEPA-filtered housing or rack system; Chemical fume hood; Biological safety cabinet (BSC), Ventilated HEPA-filtered housing or rack system; Not applicable; Not applicable; Biological safety cabinet (BSC); Biological safety cabinet (BSC), Ventilated HEPA-filtered housing or rack system;

Committee Review: The IBC has reviewed the locations, activities, and agents involved in the proposed work. The IBC considered agent characteristics including but not limited to pathogenicity, stability, and source and nature of recombinant and synthetic nucleic acids and their expressed products, as applicable.

Facilities: Facilities meet standards set by the IBC or additional controls are used effectively to mitigate risk caused by deviation from the standards.

Required Institutional Training: The PI and/or laboratory staff must complete required institutional biosafety training. Final approval will be withheld until required biosafety training is complete.

Lab-specific Training and Expertise: The training and expertise of personnel involved in the conduct of research deviate from standards set by the IBC. Revisions are required for approval.

PPE, Controls, and Practices: The PPE, engineering controls, and administrative controls deviate from the standards set by the IBC for the proposed materials and activities. Revisions are required for approval.

NIH Guidelines Requirements: Proposed work meets the requirements set forth in the NIH Guidelines.

Administrative:

NIH Guidelines: (III-D-4-b); (III-D-2-a); (III-D-2-a); (III-D-4)(III-D-4-a)(III-D-1-a)(III-D-1-b)(III-D-4-b); (III-D-4-a)(III-D-4-b); (III-D-1-a) (III-D-1-b); (III-E-3); (III-E-1); (III-E-1); (III-F-8); (III-F-8); (III-F-8); (III-F-8); (III-F-1); (III-F-4) (III-F-5);

Summary of IBC Review: This laboratory studies gastrointestinal cancer using cell culture and transgenic mouse models. In this renewal, a new mouse model is proposed. The IBC discussed lab-specific training for genes with oncogenic potential and exposure response procedures.

- Bio Protocol Number: B00000464-AM006

PI Name: [REDACTED]

Protocol Title: Amendment/Renewal 006 for Mechanisms of cardiac arrhythmia and membrane excitability

Motion: IBC approved with contingencies

Motion Made By: Yevgenya Grinblat

Motion Seconded By: Donna Neumann

Committee Action: Adopted unanimously by voice vote

Nay Votes, Abstentions, Absentees:

Biosafety Level: BSL2; BSL2; BSL1; BSL1; BSL1; BSL1; BSL1; BSL1;

Containment Equipment: Biological safety cabinet (BSC); Biological safety cabinet (BSC); Not applicable; Not applicable; Not applicable; Not applicable; Not applicable; Not applicable;

Committee Review: The IBC has reviewed the locations, activities, and agents involved in the proposed work. The IBC considered agent characteristics including but not limited to pathogenicity, stability, and source and nature of recombinant and synthetic nucleic acids and their expressed products, as applicable.

Facilities: Facilities meet standards set by the IBC or additional controls are used effectively to mitigate risk caused by deviation from the standards.

Required Institutional Training: The PI and laboratory staff have completed required institutional biosafety training.

Lab-specific Training and Expertise: The training and expertise of personnel involved in the conduct of research meets standards set by the IBC.

PPE, Controls, and Practices: The PPE, engineering controls, and administrative controls meet the standards set by the IBC for the proposed materials and activities or additional controls are used effectively to mitigate risk caused by deviation from the standards.

NIH Guidelines Requirements: Proposed work meets the requirements set forth in the NIH Guidelines.

Administrative: Administrative revisions are required for approval (e.g., reorganizing information, removing extraneous text, correcting typos, spelling out acronyms).

NIH Guidelines: (III-D-1-a) (III-D-1-b); (III-E); (III-E-1); (III-E-1); (III-F-8); (III-F-8); (III-F-1);

Summary of IBC Review: This laboratory studies the molecular mechanisms underlying irregular heart rhythms. Replication incompetent AAV and adenoviral vectors are used in cell culture to express reporters and other genes that are not toxins or oncogenes. In this renewal, no changes to the research are proposed.

- Bio Protocol Number: B00000471-AM013

PI Name: Lloyd Smith

Protocol Title: Amendment/Renewal 013 for Understanding Proteins and Protein-Nucleic Acid Interactions

Motion: IBC approved protocol

Motion Made By: Steve Garvis

Motion Seconded By: Barak Blum

Committee Action: Adopted unanimously by voice vote

Nay Votes, Abstentions, Absentees:

Biosafety Level: BSL2; BSL2; BSL1; BSL2; BSL2; BSL2; BSL2; BSL2; BSL1;

Containment Equipment: Chemical fume hood; Chemical fume hood; Not applicable; Chemical fume hood; Chemical fume hood; Not applicable; Biological safety cabinet (BSC); Not applicable; Biological safety cabinet (BSC);

Committee Review: The IBC has reviewed the locations, activities, and agents involved in the proposed work. The IBC considered agent characteristics including but not limited to pathogenicity, stability, and source and nature of recombinant and synthetic nucleic acids and their expressed products, as applicable.

Facilities: Facilities meet standards set by the IBC or additional controls are used effectively to mitigate risk caused by deviation from the standards.

Required Institutional Training: The PI and laboratory staff have completed required institutional biosafety training.

Lab-specific Training and Expertise: The training and expertise of personnel involved in the conduct of research meets standards set by the IBC.

PPE, Controls, and Practices: The PPE, engineering controls, and administrative controls meet the standards set by the IBC for the proposed materials and activities or additional controls are used effectively to mitigate risk caused by deviation from the standards.

NIH Guidelines Requirements: Proposed work meets the requirements set forth in the NIH Guidelines.

Administrative:

NIH Guidelines: (III-D-2-a); (III-E); (III-E-1); (III-F-8); (III-F-8); (III-F-1); (III-F-4) (III-F-5);

Summary of IBC Review: The Smith laboratory studies protein modifications, protein-protein interactions, and protein-nucleic acid interactions using cell culture and in vitro methods. In this amendment, new work with BL21 strain of RG1 E coli is proposed.

- Bio Protocol Number: B00000553-AM006

PI Name: [REDACTED]

Protocol Title: Amendment/Renewal 006 for MAMMALIAN LACTATION PHYSIOLOGY

Motion: IBC approved with contingencies

Motion Made By: Barak Blum

Motion Seconded By: Peter Halfmann

Committee Action: Adopted unanimously by voice vote

Nay Votes, Abstentions, Absentees:

Biosafety Level: ABSL1; Not applicable (non-laboratory area); BSL1; BSL1; BSL2; BSL2; BSL1; BSL2; Not applicable (non-laboratory area); Not applicable (non-laboratory area);

Containment Equipment: Ventilated HEPA-filtered housing or rack system; Not applicable; Not applicable; Not applicable; Biological safety cabinet (BSC); Not applicable; Chemical fume hood; Biological safety cabinet (BSC); Not applicable; Not applicable;

Committee Review: The IBC has reviewed the locations, activities, and agents involved in the proposed work. The IBC considered agent characteristics including but not limited to pathogenicity, stability, and source and nature of recombinant and synthetic nucleic acids and their expressed products, as applicable.

Facilities: Facilities meet standards set by the IBC or additional controls are used effectively to mitigate risk caused by deviation from the standards.

Required Institutional Training: The PI and laboratory staff have completed required institutional biosafety training.

Lab-specific Training and Expertise: The training and expertise of personnel involved in the conduct of research meets standards set by the IBC.

PPE, Controls, and Practices: The PPE, engineering controls, and administrative controls deviate from the standards set by the IBC for the proposed materials and activities. Revisions are required for approval.

NIH Guidelines Requirements: Proposed work is not subject to the NIH Guidelines.

Administrative:

NIH Guidelines: (III-F-8); (III-F-8); (III-F-8);

Summary of IBC Review: This laboratory studies the physiology of mammalian lactation. They analyze milk and other biological samples from a variety of mammalian species including human. In this renewal, proposed changes include addition of fixed tissues and updates to procedures for handling raw milk. The IBC discussed spill procedures and the source of raw milk.

- Bio Protocol Number: B00000608-AM016

PI Name: [REDACTED]

Protocol Title: Amendment/Renewal 016 for Experimental manipulation of helminth parasites and model nematodes to understand parasite biology and validate parasite drug targets

Motion: IBC approved with contingencies

Motion Made By: Yevgenya Grinblat

Motion Seconded By: Dennis Halterman

Committee Action: Adopted unanimously by voice vote

Nay Votes, Abstentions, Absentees:

Biosafety Level: BSL1; BSL2, Other – ACL2; ABSL2, BSL2; BSL2; ABSL2, BSL2;

ABSL2, BSL2; BSL2; ABSL2, BSL2; Not applicable (non-laboratory area); Not applicable (non-laboratory area); BSL2; BSL2; BSL1; ABSL2, BSL2; BSL2; BSL2;

Containment Equipment: Not applicable; Other - For studies that require BL2 mosquito containment, animals will be housed in the large environmental chamber in this room; Biological safety cabinet (BSC), Chemical fume hood, Other -

Dedicated room. All mice on this protocol are housed in a separate room only housing our lab's animals.; Biological safety cabinet (BSC), Chemical fume hood, Other – bioBubble; Biological safety cabinet (BSC), Chemical fume hood, Ventilated HEPA-filtered housing or rack system; Not applicable; Not applicable; Biological safety cabinet (BSC), Chemical fume hood, Ventilated HEPA-filtered housing or rack system; Not applicable; Not applicable; Not applicable; Biological safety cabinet (BSC); Biological safety cabinet (BSC), Chemical fume hood; Not applicable; Not applicable; Biological safety cabinet (BSC);

Committee Review: The IBC has reviewed the locations, activities, and agents involved in the proposed work. The IBC considered agent characteristics including but not limited to pathogenicity, stability, and source and nature of recombinant and synthetic nucleic acids and their expressed products, as applicable.

Facilities: Facilities meet standards set by the IBC or additional controls are used effectively to mitigate risk caused by deviation from the standards.

Required Institutional Training: The PI and laboratory staff have completed required institutional biosafety training.

Lab-specific Training and Expertise: The training and expertise of personnel involved in the conduct of research meets standards set by the IBC.

PPE, Controls, and Practices: The PPE, engineering controls, and administrative controls meet the standards set by the IBC for the proposed materials and activities or additional controls are used effectively to mitigate risk caused by deviation from the standards.

NIH Guidelines Requirements: Proposed work meets the requirements set forth in the NIH Guidelines.

Administrative: Administrative revisions are required for approval (e.g., reorganizing information, removing extraneous text, correcting typos, spelling out acronyms).

NIH Guidelines: (III-D-4) (III-D-4-a) (III-D-4-b); (III-D-4)(III-D-4-a)(III-D-1-a)(III-D-1-b)(III-D-4-b); (III-E-1); (III-E); (III-F-8); (III-F-1);

Summary of IBC Review: This laboratory studies parasitic worms and the insects or snails that transmit them to discover better ways to diagnose, treat, and prevent spread of disease. The laboratory uses a combination of invertebrate and rodent animal models. In this amendment, the addition of two parasite vectors, fleas and snails, is proposed. The IBC considered containment and source of the new vectors.

- Bio Protocol Number: B00000855-AM013

PI Name: [REDACTED]

Protocol Title: Amendment/Renewal 013 for Genetics of blood disorders and cancer

Motion: IBC approved with contingencies

Motion Made By: Donna Neumann

Motion Seconded By: Barak Blum

Committee Action: Adopted unanimously by voice vote

Nay Votes, Abstentions, Absentees: Warren Rose, absent Steve Garvis, absent Marta Gaglia, absent

Biosafety Level: BSL2; BSL2; BSL2; BSL2; BSL2; BSL2; BSL2; ABSL2; ABSL2, BSL2; BSL2; ABSL1, ABSL2;

Containment Equipment: Biological safety cabinet (BSC); Not applicable; Chemical fume hood; Chemical fume hood; Chemical fume hood; Not applicable; Biological safety cabinet (BSC), Chemical fume hood; Biological safety cabinet (BSC), Chemical fume hood; Not applicable; Not applicable; Biological safety cabinet (BSC), Chemical fume hood, Ventilated HEPA-filtered housing or rack system;

Committee Review: The IBC has reviewed the locations, activities, and agents involved in the proposed work. The IBC considered agent characteristics including

but not limited to pathogenicity, stability, and source and nature of recombinant and synthetic nucleic acids and their expressed products, as applicable.

Facilities: Facilities meet standards set by the IBC or additional controls are used effectively to mitigate risk caused by deviation from the standards.

Required Institutional Training: The PI and laboratory staff have completed required institutional biosafety training.

Lab-specific Training and Expertise: The training and expertise of personnel involved in the conduct of research meets standards set by the IBC.

PPE, Controls, and Practices: The PPE, engineering controls, and administrative controls meet the standards set by the IBC for the proposed materials and activities or additional controls are used effectively to mitigate risk caused by deviation from the standards.

NIH Guidelines Requirements: Proposed work meets the requirements set forth in the NIH Guidelines.

Administrative: Administrative revisions are required for approval (e.g., reorganizing information, removing extraneous text, correcting typos, spelling out acronyms).

NIH Guidelines: (III-D-2-a); (III-D-1-a) (III-D-1-b); (III-D-3-a) (III-D-3-b) (III-D-3-e); (III-E-3); (III-E-3); (III-E-1); (III-E-1); (III-F-8); (III-F-8); (III-F-8); (III-F-8); (III-F-1); (III-F-4) (III-F-5);

Summary of IBC Review: This laboratory studies genetic changes that contribute to risk for blood disorders and cancer using cell culture and mouse models. Enhanced practices are used for work with replication incompetent lentiviral vectors expressing genes with oncogenic potential. In this renewal, no changes to the research are proposed.

- Bio Protocol Number: B00000865-AM006

PI Name: [REDACTED]

Protocol Title: Amendment/Renewal 006 for Immunotherapy in Malignant Glioma

Motion: IBC approved with contingencies

Motion Made By: Matt Reynolds

Motion Seconded By: Marta Gaglia

Committee Action: Adopted unanimously by voice vote

Nay Votes, Abstentions, Absentees:

Biosafety Level: BSL2; Not applicable (non-laboratory area); BSL2; ABSL1, ABSL2; BSL2; BSL2; BSL2;

Containment Equipment: Biological safety cabinet (BSC); Not applicable; Not applicable, Chemical fume hood; Not applicable; Not applicable; Biological safety

cabinet (BSC), Chemical fume hood; Biological safety cabinet (BSC), Ventilated HEPA-filtered housing or rack system;

Committee Review: The IBC has reviewed the locations, activities, and agents involved in the proposed work. The IBC considered agent characteristics including but not limited to pathogenicity, stability, and source and nature of recombinant and synthetic nucleic acids and their expressed products, as applicable.

Facilities: Facilities meet standards set by the IBC or additional controls are used effectively to mitigate risk caused by deviation from the standards.

Required Institutional Training: The PI and laboratory staff have completed required institutional biosafety training.

Lab-specific Training and Expertise: The training and expertise of personnel involved in the conduct of research meets standards set by the IBC.

PPE, Controls, and Practices: The PPE, engineering controls, and administrative controls deviate from the standards set by the IBC for the proposed materials and activities. Revisions are required for approval.

NIH Guidelines Requirements: Proposed work meets the requirements set forth in the NIH Guidelines.

Administrative: Administrative revisions are required for approval (e.g., reorganizing information, removing extraneous text, correcting typos, spelling out acronyms).

NIH Guidelines: (III-D-1-a) (III-D-1-b); (III-D-3-a) (III-D-3-b) (III-D-3-e); (III-E-1);

Summary of IBC Review: This laboratory studies malignant glioma using cell culture and transgenic mouse models. In this renewal, no changes to the research are proposed. The IBC discussed PPE and information provided about replication incompetent viral vectors used in the lab.

- Bio Protocol Number: B00001019-AM003

PI Name: Stephanie McGregor

Protocol Title: Amendment/Renewal 003 for SMPH WiscShare

Motion: IBC approved with contingencies

Motion Made By: Steve Garvis

Motion Seconded By: Donna Neumann

Committee Action: Adopted unanimously by voice vote

Nay Votes, Abstentions, Absentees: Amita Kapoor, absent

Biosafety Level: BSL2; Not applicable (non-laboratory area); BSL2; BSL2; BSL2; Not applicable (non-laboratory area);

Containment Equipment: Biological safety cabinet (BSC), Chemical fume hood; Not applicable; Not applicable; Biological safety cabinet (BSC); Biological safety cabinet (BSC), Chemical fume hood; Not applicable;

Committee Review: The IBC has reviewed the locations, activities, and agents involved in the proposed work. The IBC considered agent characteristics including but not limited to pathogenicity, stability, and source and nature of recombinant and synthetic nucleic acids and their expressed products, as applicable.

Facilities: Facilities meet standards set by the IBC or additional controls are used effectively to mitigate risk caused by deviation from the standards.

Required Institutional Training: The PI and/or laboratory staff must complete required institutional biosafety training. Final approval will be withheld until required biosafety training is complete.

Lab-specific Training and Expertise: The training and expertise of personnel involved in the conduct of research meets standards set by the IBC.

PPE, Controls, and Practices: The PPE, engineering controls, and administrative controls deviate from the standards set by the IBC for the proposed materials and activities. Revisions are required for approval.

NIH Guidelines Requirements: Proposed work is not subject to the NIH Guidelines.

Administrative:

NIH Guidelines:

Summary of IBC Review: This is a protocol for the School of Medicine and Public Health WiscShare, a centralized biorepository that serves to collect, process, store, and distribute human biospecimens. In this renewal, no changes to the research activities are proposed. The IBC discussed the laboratory spill protocol.

- Bio Protocol Number: B00001025-AM003

PI Name: Hara Levy

Protocol Title: Amendment/Renewal 003 for Molecular studies of GGCF family registry

Motion: IBC approved protocol

Motion Made By: Andrea Ladd

Motion Seconded By: Matt Reynolds

Committee Action: Adopted unanimously by voice vote

Nay Votes, Abstentions, Absentees: Steve Garvis, absent Warren Rose, absent Barak Blum, absent Marta Gaglia, absent

Biosafety Level: BSL2; BSL2; BSL2; Not applicable (non-laboratory area); BSL2; BSL2; BSL2; BSL2; BSL2; BSL2;

Containment Equipment: Not applicable; Biological safety cabinet (BSC); Not applicable; Not applicable; Not applicable; Not applicable; Not applicable; Biological safety cabinet (BSC); Not applicable; Biological safety cabinet (BSC);

Committee Review: The IBC has reviewed the locations, activities, and agents involved in the proposed work. The IBC considered agent characteristics including but not limited to pathogenicity, stability, and source and nature of recombinant and synthetic nucleic acids and their expressed products, as applicable.

Facilities: Facilities meet standards set by the IBC or additional controls are used effectively to mitigate risk caused by deviation from the standards.

Required Institutional Training: The PI and laboratory staff have completed required institutional biosafety training.

Lab-specific Training and Expertise: The training and expertise of personnel involved in the conduct of research meets standards set by the IBC.

PPE, Controls, and Practices: The PPE, engineering controls, and administrative controls meet the standards set by the IBC for the proposed materials and activities or additional controls are used effectively to mitigate risk caused by deviation from the standards.

NIH Guidelines Requirements: Proposed work meets the requirements set forth in the NIH Guidelines.

Administrative:

NIH Guidelines: (III-E-1); (III-F-8); (III-F-1);

Summary of IBC Review: The Levy laboratory studies the functions of genes involved in cystic fibrosis. Research activities include collection of human samples, cell and microbiological assays, and gene knockdown experiments in cell culture. In this renewal, procedural clarifications are provided but there are no changes to the research.

- Bio Protocol Number: B00001028-AM003

PI Name: Charlie Mo

Protocol Title: Amendment/Renewal 003 for Anti-phage defense mechanisms in bacteria

Motion: IBC approved with contingencies

Motion Made By: Warren Rose

Motion Seconded By: Sabine Pellett

Committee Action: Adopted unanimously by voice vote

Nay Votes, Abstentions, Absentees:

Biosafety Level: BSL2; BSL2; BSL2; BSL2; BSL2; BSL2;

Containment Equipment: Not applicable; Not applicable; Not applicable; Chemical fume hood; Not applicable; Biological safety cabinet (BSC);

Committee Review: The IBC has reviewed the locations, activities, and agents involved in the proposed work. The IBC considered agent characteristics including

but not limited to pathogenicity, stability, and source and nature of recombinant and synthetic nucleic acids and their expressed products, as applicable.

Facilities: Facilities meet standards set by the IBC or additional controls are used effectively to mitigate risk caused by deviation from the standards.

Required Institutional Training: The PI and laboratory staff have completed required institutional biosafety training.

Lab-specific Training and Expertise: The training and expertise of personnel involved in the conduct of research meets standards set by the IBC.

PPE, Controls, and Practices: The PPE, engineering controls, and administrative controls deviate from the standards set by the IBC for the proposed materials and activities. Revisions are required for approval.

NIH Guidelines Requirements: Proposed work meets the requirements set forth in the NIH Guidelines.

Administrative:

NIH Guidelines: (III-D-1-a) (III-D-1-b); (III-E); (III-F-8);

Summary of IBC Review: The Mo laboratory studies mechanisms that protect bacteria against phage infection. The laboratory uses a variety of RG1 and RG2 Staphylococcus strains including both methicillin-resistant and methicillin-sensitive strains. In this renewal, no changes to the research activities are proposed. The IBC discussed signage and post-exposure procedures for methicillin-resistant strains.

- Bio Protocol Number: B00001034-AM002

PI Name: Daniela Barbosa

Protocol Title: Amendment/Renewal 002 for DNA constructs for generation of transgenic fruit flies

Motion: IBC approved protocol

Motion Made By: Garret Suen

Motion Seconded By: Dennis Halterman

Committee Action: Adopted unanimously by voice vote

Nay Votes, Abstentions, Absentees:

Biosafety Level: BSL1; BSL1; BSL1; BSL1; BSL1; BSL1;

Containment Equipment: Not applicable; Not applicable; Not applicable; Chemical fume hood; Not applicable; Chemical fume hood;

Committee Review: The IBC has reviewed the locations, activities, and agents involved in the proposed work. The IBC considered agent characteristics including but not limited to pathogenicity, stability, and source and nature of recombinant and synthetic nucleic acids and their expressed products, as applicable.

Facilities: Facilities meet standards set by the IBC or additional controls are used effectively to mitigate risk caused by deviation from the standards.

Required Institutional Training: The PI and laboratory staff have completed required institutional biosafety training.

Lab-specific Training and Expertise: The training and expertise of personnel involved in the conduct of research meets standards set by the IBC.

PPE, Controls, and Practices: The PPE, engineering controls, and administrative controls meet the standards set by the IBC for the proposed materials and activities or additional controls are used effectively to mitigate risk caused by deviation from the standards.

NIH Guidelines Requirements: Proposed work meets the requirements set forth in the NIH Guidelines.

Administrative:

NIH Guidelines: (III-D-4-a) (III-D-4-b); (III-D-4) (III-D-4-a) (III-D-4-b); (III-F-8); (III-F-4) (III-F-5);

Summary of IBC Review: The Barbosa laboratory uses fruit flies to investigate how stem cells and their descendants alter their preference for different types of nutrients under normal or obese conditions. Fruit flies are modified using an approach that prevents gene drive. In this renewal, no changes to the research are proposed.

- Bio Protocol Number: B00001071-AM003

PI Name: [REDACTED]

Protocol Title: Amendment/Renewal 003 for Isolation, characterization, storage, and testing of food borne bacterial pathogens and efficacy testing of intervention and decontamination methods

Motion: IBC approved with contingencies

Motion Made By: Sabine Pellett

Motion Seconded By: Warren Rose

Committee Action: Adopted unanimously by voice vote

Nay Votes, Abstentions, Absentees:

Biosafety Level: ABSL2; BSL2; BSL2; BSL2; Not applicable (non-laboratory area); BSL2; Not applicable (non-laboratory area); BSL2; BSL2; BSL2; BSL2; BSL2; BSL2; BSL2; BSL2; Not applicable (non-laboratory area);

Containment Equipment: Not applicable; Not applicable; Not applicable; Not applicable; Not applicable; Not applicable; Not applicable; Biological safety cabinet (BSC), Chemical fume hood; Not applicable; Not applicable; Not

applicable; Not applicable; Not applicable; Not applicable; Not applicable; Not applicable;

Committee Review: The IBC has reviewed the locations, activities, and agents involved in the proposed work. The IBC considered agent characteristics including but not limited to pathogenicity, stability, and source and nature of recombinant and synthetic nucleic acids and their expressed products, as applicable.

Facilities: Facilities meet standards set by the IBC or additional controls are used effectively to mitigate risk caused by deviation from the standards.

Required Institutional Training: The PI and laboratory staff have completed required institutional biosafety training.

Lab-specific Training and Expertise: The training and expertise of personnel involved in the conduct of research deviate from standards set by the IBC. Revisions are required for approval.

PPE, Controls, and Practices: The PPE, engineering controls, and administrative controls deviate from the standards set by the IBC for the proposed materials and activities. Revisions are required for approval.

NIH Guidelines Requirements: Proposed work meets the requirements set forth in the NIH Guidelines.

Administrative: Administrative revisions are required for approval (e.g., reorganizing information, removing extraneous text, correcting typos, spelling out acronyms).

NIH Guidelines: (III-D-4-b); (III-D-4)(III-D-4-a)(III-D-1-a)(III-D-1-b)(III-D-4-b); (III-D-1-a)(III-D-1-b);

Summary of IBC Review: This laboratory studies the biology of foodborne pathogens. In this amendment, experiments in which recombinant *Salmonella* will be administered to swine are proposed. The recombinant modifications are not anticipated to alter pathogenicity of the bacteria. The IBC discussed containment during inoculation procedures, lab-specific training, and PPE.

- Bio Protocol Number: B00001091-AM001

PI Name: C. Rubinstein

Protocol Title: Amendment/Renewal 001 for UW Biotechnology Center Biogarage

Motion: IBC approved with contingencies (protocol must go back to IBC reviewers)

Motion Made By: Amita Kapoor

Motion Seconded By: Peter Halfmann

Committee Action: Adopted unanimously by voice vote

Nay Votes, Abstentions, Absentees:

Biosafety Level: BSL1; BSL1; BSL1; BSL1; BSL1;

Containment Equipment: Chemical fume hood; Not applicable; Biological safety cabinet (BSC); Not applicable; Not applicable;

Committee Review: The IBC has reviewed the locations, activities, and agents involved in the proposed work. The IBC considered agent characteristics including but not limited to pathogenicity, stability, and source and nature of recombinant and synthetic nucleic acids and their expressed products, as applicable.

Facilities: Facilities meet standards set by the IBC or additional controls are used effectively to mitigate risk caused by deviation from the standards.

Required Institutional Training: The PI and laboratory staff have completed required institutional biosafety training.

Lab-specific Training and Expertise: The training and expertise of personnel involved in the conduct of research meets standards set by the IBC.

PPE, Controls, and Practices: The PPE, engineering controls, and administrative controls deviate from the standards set by the IBC for the proposed materials and activities. Revisions are required for approval.

NIH Guidelines Requirements: Proposed work meets the requirements set forth in the NIH Guidelines.

Administrative:

NIH Guidelines:

Summary of IBC Review: This protocol is for the UW Biotechnology Center Biogarage core facility, which provides convenient and affordable access to instruments and laboratory space for molecular biology services such as nucleic acid extractions and genotyping. In this amendment, the addition of DNA extraction services from environmental samples is proposed. The IBC discussed containment for work with environmental samples.

- Bio Protocol Number: B00001130-AM005

PI Name: [REDACTED]

Protocol Title: Amendment/Renewal 005 for Center for Biomedical Swine Research and Innovation Animal & Cadaver Lab Biosafety Protocol

Motion: IBC approved with contingencies

Motion Made By: Yevgenya Grinblat

Motion Seconded By: Garret Suen

Committee Action: Adopted unanimously by voice vote

Nay Votes, Abstentions, Absentees: Steve Garvis, absent Marta Gaglia, absent

Biosafety Level: ABSL2; BSL2; ABSL2; ABSL1; ABSL1; BSL2; BSL2; BSL2; ABSL2, BSL2; BSL1, BSL2; BSL2; BSL1, BSL2; BSL2; ABSL2; BSL1, BSL2;

Containment Equipment: Not applicable; Not applicable; Biological safety cabinet (BSC), Chemical fume hood; Not applicable; Not applicable; Not applicable; Not applicable; Not applicable; Not applicable; Biological safety cabinet (BSC), Chemical fume hood; Biological safety cabinet (BSC); Biological safety cabinet (BSC); Not applicable; Chemical fume hood; Biological safety cabinet (BSC);

Committee Review: The IBC has reviewed the locations, activities, and agents involved in the proposed work. The IBC considered agent characteristics including but not limited to pathogenicity, stability, and source and nature of recombinant and synthetic nucleic acids and their expressed products, as applicable.

Facilities: Facilities meet standards set by the IBC or additional controls are used effectively to mitigate risk caused by deviation from the standards.

Required Institutional Training: The PI and laboratory staff have completed required institutional biosafety training.

Lab-specific Training and Expertise: The training and expertise of personnel involved in the conduct of research meets standards set by the IBC.

PPE, Controls, and Practices: The PPE, engineering controls, and administrative controls deviate from the standards set by the IBC for the proposed materials and activities. Revisions are required for approval.

NIH Guidelines Requirements: Proposed work meets the requirements set forth in the NIH Guidelines.

Administrative: Administrative revisions are required for approval (e.g., reorganizing information, removing extraneous text, correcting typos, spelling out acronyms).

NIH Guidelines: (III-D-4-b); (III-D-4) (III-D-4-a) (III-D-4-b); (III-D-4)(III-D-4-a)(III-D-1-a)(III-D-1-b)(III-D-4-b); (III-D-4-a)(III-D-4-b); (III-D-3-a) (III-D-3-b) (III-D-3-e); (III-D-4-c-(3)) (III-D-5) (III-D-8); (III-E-1); (III-F-1);

Summary of IBC Review: This protocol covers activities of the Center for Biomedical Swine Research and Innovation, which creates models of human disease in swine.

The laboratory also trains professional students in surgical techniques. In this amendment, various updates to experiments and practices are proposed. The IBC discussed PPE worn for cadaver work.

University of Wisconsin-Madison Institutional Biosafety Committee

Minutes of Regular Meeting Closed Session

Date: 6/18/2025

Present: Peter Halfmann, Matt Reynolds, Dennis Halterman, Donna Neumann, Yevgenya Grinblat, Andrea Ladd, Warren Rose, Amita Kapoor, Ryan Stoffel, Marta Gaglia, Garret Suen, Joel Malak, Clint Morgan, Megan Spurgeon, Barak Blum, Sabine Pellett, Steve Garvis

Consultants: Tony McGrath, Lissa Koop, Darren Berger

OBS: Tony McGrath, TJ Whyte, David Dyer, Karen Demick, Andrea Ladd, Stephanie Kutz, Tara Schnell, Megan Dixon, Erin Plisch, Donald Busalacchi, Kathy Krasny

Guests: Sarah Johnson-Schlueter-CALS

Call to order: The meeting was called to order by Garret Suen, at Zoom at 1:30PM

Announcements: The IBC meeting is closed to the public.

Review of Minutes: A motion to approve the closed session minutes of the following IBC meetings was Unanimously adopted.

Institutional Biosafety Committee meeting on (6/4/2025)

Megan Spurgeon, abstain Peter Halfmann, abstain Steve Garvis, absent Donna Neumann abstain Marta Gaglia, absent

Other business - closed session

- Agenda Items - Documents For Closed Session:

Review of research protocols - closed session

Review of research amendments - closed session

☐ B00000807-AM003

☐ B00000929-AM028

Announcements

null

The meeting adjourned 3:04 PM

- Bio Protocol Number: B00000807-AM003
PI Name: Vaishalee Kenkre
Protocol Title: Amendment/Renewal 003 for UW18095: Tisagenlecleucel versus standard of care in adult patients with relapsed or refractory aggressive B-cell non-Hodgkin lymphoma: A randomized, open label, phase III trial (BELINDA)
Motion: IBC approved with contingencies
Motion Made By: Joel Malak
Motion Seconded By: Matt Reynolds
Committee Action: Adopted unanimously by hand vote
Nay Votes, Abstentions, Absentees: Steve Garvis, absent Marta Gaglia, absent
Biosafety Level: BSL2; BSL2; BSL2; BSL2; BSL2; BSL2; BSL2;
Containment Equipment: Not applicable; Biological safety cabinet (BSC), Chemical fume hood; Biological safety cabinet (BSC) - 2 Biological safety cabinet (BSC) that are certified bi-annually.; Biological safety cabinet (BSC), Chemical fume hood - BSC is SterilGARD Baker Company; Fume hood is technically in Immunology, but that is also B4/220- the processing area does have access to it if needed; Not applicable; Biological safety cabinet (BSC); Chemical fume hood;
Committee Review: The IBC has reviewed the locations, activities, and agents involved in the proposed work. The IBC considered agent characteristics including but not limited to pathogenicity, stability, and source and nature of recombinant and synthetic nucleic acids and their expressed products, as applicable.
Facilities: Facilities meet standards set by the IBC or additional controls are used effectively to mitigate risk caused by deviation from the standards.
Required Institutional Training: The PI and laboratory staff have completed required institutional biosafety training.
Lab-specific Training and Expertise: The training and expertise of personnel involved in the conduct of research meets standards set by the IBC.
PPE, Controls, and Practices: The PPE, engineering controls, and administrative controls deviate from the standards set by the IBC for the proposed materials and activities. Revisions are required for approval.
NIH Guidelines Requirements: Proposed work meets the requirements set forth in the NIH Guidelines.
Administrative:
NIH Guidelines: (III-C-1);

Summary of IBC Review: This is a renewal for a clinical trial that uses modified T-cells to treat lymphomas. There were no changes to the research. The IBC reviewed and approved continuation of the PI status for Dr. Kenkre. The IBC discussed containment for aerosol-generating activities during sample processing.

- Bio Protocol Number: B00000929-AM028

PI Name: [REDACTED]

Protocol Title: Amendment/Renewal 028 for Studies of Viral Pathogenesis in the Bailey Laboratory

Motion: IBC approved with contingencies

Motion Made By: Megan Spurgeon

Motion Seconded By: Matt Reynolds

Committee Action: Adopted unanimously by hand vote

Nay Votes, Abstentions, Absentees: Steve Garvis, absent Marta Gaglia, absent

Biosafety Level: BSL2; BSL2; BSL3; ABSL3; BSL1; BSL1; Not applicable (non-laboratory area); BSL1; BSL1; BSL2; BSL2; BSL2; BSL2; BSL2; BSL1; ABSL2;

Containment Equipment: Biological safety cabinet (BSC), Chemical fume hood, Other – BioBubble; Not applicable; Biological safety cabinet (BSC); Biological safety cabinet (BSC); Not applicable; Not applicable; Not applicable; Not applicable; Not applicable; Biological safety cabinet (BSC); Biological safety cabinet (BSC); Not applicable; Biological safety cabinet (BSC), Chemical fume hood; Not applicable; Not applicable; Biological safety cabinet (BSC), Ventilated HEPA-filtered housing or rack system;

Committee Review: The IBC has reviewed the locations, activities, and agents involved in the proposed work. The IBC considered agent characteristics including but not limited to pathogenicity, stability, and source and nature of recombinant and synthetic nucleic acids and their expressed products, as applicable.

Facilities: Facilities meet standards set by the IBC or additional controls are used effectively to mitigate risk caused by deviation from the standards.

Required Institutional Training: The PI and laboratory staff have completed required institutional biosafety training.

Lab-specific Training and Expertise: The training and expertise of personnel involved in the conduct of research meets standards set by the IBC.

PPE, Controls, and Practices: The PPE, engineering controls, and administrative controls deviate from the standards set by the IBC for the proposed materials and activities. Revisions are required for approval.

NIH Guidelines Requirements: Proposed work meets the requirements set forth in the NIH Guidelines.

Administrative: Administrative revisions are required for approval (e.g., reorganizing information, removing extraneous text, correcting typos, spelling out acronyms).

NIH Guidelines: (III-D-2-a); (III-D-2-a); (III-D-2-a); (III-D-4)(III-D-4-a)(III-D-1-a)(III-D-1-b)(III-D-4-b); (III-D-4-a)(III-D-4-b); (III-D-1-a) (III-D-1-b); (III-D-3-a) (III-D-3-b) (III-D-3-e); (III-E-3); (III-E); (III-E-3); (III-E-1); (III-E-1); (III-F-8); (III-F-8); (III-F-8); (III-F-8);

Summary of IBC Review: This laboratory studies viral pathogenesis using a variety of RG2 and RG3 viruses. In this amendment, introduction of mouse-adapted mutations into a pegivirus is proposed to improve mouse models of infection. This amendment also proposes the addition of reporter genes or tags in recombinant arterivirus for use in small animal imaging. The IBC discussed supporting data for mouse-adapted strains and requested review of the new project by the DURC Subcommittee.