University of Kentucky
Institutional Biosafety Committee (IBC) Meeting

Date: 14JAN2026
Time: 12:02PM – 1:05PM
Location: Virtual Meeting via Zoom - https://uky.zoom.us/j/88085297311?pwd=xTD6CSbUp8KaEa5y4bJuaQr9DbpfeQ.1&from=addon

Minutes

Call to Order

The meeting was called to order by Douglas Harrison at 12:02PM EST.

Attendance

IBC Members Present

Maria Landron (Local, Non-Affiliated Member)

Thomas Chambers (Local, Non-Affiliated Member)

Doug Harrison (Chairperson)

Cheryl Haughton (Animal Containment Expert)

Carrie Shaffer (Institutional Member)

Delena Mazzetti (Biological Safety Officer)

Mike Mendenhall (Local, Non-Affiliated Member)

Brandy Nelson (Institutional Member)

Amelia Pinto (Institutional Member)

Carol Pickett (Local, Non-Affiliated Member)

Arthur Hunt (Plant Containment Expert)

Delphine Malherbe (Laboratory Staff Representative)

Jan Smalle (Plant Containment Expert)

Regrets

Yadi Wu (Institutional Member)

Guests

Elizabeth Brooks (Administrative Support Associate I)

Robert Hayman (Assistant Biological Safety Officer)

Jeff Howell (IBC Administrative Professional II)

Audra Strahl (IBC Administrative Professional II)

Melissa Hollifield (Animal Compliance Manager)

Kathryn Childress (Temporary STEPS Office and Clerical)

Quorum

Per the University of Kentucky Institutional Biosafety Committee By-Laws, at least 6 voting members shall constitute a quorum.

University of Kentucky
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Approval of Previous Month's Meeting Minutes

2025.12.03 IBC Meeting Minutes DRAFT.pdf

The previous month's minutes were approved. Thomas Chambers initiated the motion. Cheryl Haughton seconded the motion. All members present (13) voted in favor.

Old Business

None.

Protocol Review

Amendments

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PI: Douglas Andres
IBC Protocol Number: IBC-24-28
Protocol Title: Ras Family Protein Signaling
Protocol Type: Amendment
Amendment To: Genetic constructs, Manipulations planned, Laboratory Location(s)
Applicable Guidelines & Regulations: NIH Guidelines Section III-D-1, NIH Guidelines Section III-E-3, NIH Guidelines Section III-F-2, NIH Guidelines Section III-F-4, UK Administrative Regulation 6.9, OSHA Act of 1970 Clause 5(a)(1), NIH Guidelines Section IV-B-7, OSHA 29 CFR 1910.1030, UK Administrative Regulation 6.3
Maximum Containment Level: Biological Safety Level 2 - Enhanced (BSL2+), Animal Biological Safety Level 2 (ABSL2)
Primary Reviewers: C. Haughton, A. Pinto, C. Pickett

Brief Project Overview:

The Andres laboratory studies two novel families of RAS-related G-proteins and their roles in regulating cellular signaling. The first program investigates the role of the Rit and Rin proteins as regulators of pro-survival signaling pathways in neurons, and in the development of lung cancer. The death of neurons causes or contributes to various neurodegenerative disorders including stroke, epilepsy, and Alzheimer's disease. We believe that elucidation of the mechanisms that promote neuronal survival is of fundamental importance to the development of treatment strategies to these disorders. Specifically, we have found that loss of the Rin (RIT2) G-protein improves neuronal survival and promotes recovery following brain injury. Very recently, we have helped to prove that activating mutations in the Rit (RIT1) G-protein promote lung cancer. Thus, a greater understanding of Rit protein function may lead to new anti-cancer therapies. The second program investigates the molecular mechanisms of signal regulation of cardiac contraction by the novel RGK subfamily of GTPases (Rem, Rad and Rem2) in this process. Recent work in the Andres/Satin laboratories has identified a role for these proteins in regulating voltage-dependent Ca2+ channel function. These data provided evidence that Rem and Rad regulate calcium channel activity in cardiac and skeletal muscle. We hypothesize that modulating Rem/Rad/Rem2 protein levels may provide a unique therapeutic approach to treating heart disease. We are currently addressing these issues using a combination of approaches including the use of recombinant DNA, adenoviral gene transfer, and the production of transgenic mice either expressing activated

versions of these proteins or mice that fail to express these G-proteins. Transgenic animals are maintained in the animal facility in the BBSRB Research building.

We are utilizing mammalian cell lines, isolated primary cardiac myocytes, primary murine embryonic fibroblasts, and isolated primary neurons for our studies and use recombinant DNA and adeno/retro/lentiviral gene transfer to express genes of interest in these cells. Introduction of DNA into most of the cultured cell lines used in this work is done using standard laboratory transfection procedures. However, introduction of DNA into primary neurons (used to examine Rit/Rin effects in neurons) and cardiomyocytes (Rad/Rem) uses viral gene transfer to introduce DNA into these cells. The viruses have been tested and are not replication competent. Appropriate procedures will be followed to minimize risk and maintain a safe working environment.

Summary of Biohazard Materials & Manipulations:

Manipulations Planned: Bacterial culture, Cell culture, DNA/RNA isolation/purification, Immunohistochemistry, PCR/qRT-PCR, Transformation, Use of Infectious Agents, Use of Viral Vectors, Proteomics, Animal work (breeding, surgeries, etc.), Creation of Viral Vectors, Propagation of Infectious Agents, Transfection
Transport: Yes
Materials Transported: Animals, Biohazardous Materials
Infectious Agent(s)/Natural Host(s): Human Sourced Materials (RG2-cells, tissues, bodily fluids, organs, etc.)/Human
Source & Nature of Inserted Nucleic Acid(s) [Gene Information/Gene Source/Gene Category/Use of Construct/Host(s)/Vector(s)]: mTOR/Human/Regulatory/Silencing/Cell Culture/Mission RNAi/; Raptor/Human/Regulatory/Silencing/Cell Culture/Mission RNAi/;
Sin1/Human/Regulatory/Silencing /Cell Culture/Mission RNAi/; Rit (RIT1) GTPase/Mouse, Rat, Human/Signaling/Regulatory /Expression/Knockdown/Cells/Animals/Expression/RNAi/; Rin (RIT2)GTPase/Mouse,Human/Signaling/Regulatory/Expression/Knockdown/Cells/Animals/Expression/RNAi/; Rem GTPase/Rat,
Human/Regulatory/Expression/Silencing/Cells/Animals/Expression/RNAi/; Rad GTPase/Mouse, Human/Regulatory/Expression/Silencing/Cells/Animals/Expression/RNAi/; Rem2 GTPase/Mouse, Human/Regulatory/Expression/Silencing /Cells/Expression/RNAi/; Ca Channel CaV1.2/Mouse/Regulatory/Expression/Silencing /Cells/Animals/Expression/RNAi/; MAP Kinases/Human, Mouse/Regulatory/Expression/Silencing/Cells/Expression/RNAi/; GFP, YFP, RFP/Bacterial/Gene Tracking/Expression/Cells/Animals/Expression, AAV9/; Ras Family GTPases/Mouse/Oncogene and Signaling /Expression/Silencing /Cells/Expression/RNAi/; Myotubularin /Mouse/Regulatory/Expression/Knockdown/Cells/Expression/RNAi/; DLK/Human/Regulatory /Expression/Knockdown/Cells/Expression/RNAi/; Dopamine Transporter/Mouse/Membrane Protein/Expression/Cells/Expression/;
Enigma/Human/Scaffold/Expression/RNAi/Cells/Expression/RNAi/;
SARM1/Mouse/Scaffold/Expression/Silencing /Cells/Animals/Expression/RNAi/;
SMADs/Human/Regulatory /Expression/Cells/Expression/;
NMNAT2/Mouse/Metabolic/Expression/Silencing /Cells/Expression/RNAi/; RRAD/Mouse/Calcium Channel Regulator /Expression/Mouse/AAV9, Expression Vector and RNAi/; Toll-like receptor (TLR) oligocnucleotide ligands: Let7b, CpG ODN, and ssRNA40 and scrab=mbled oligo negative controls/Synthetic oligonuceoltide(s) different squeneces- but all act to bind TLR/Receptor ligand-activation of TLR signaling /TLR Activation /Primary neuron cultures and injection into mouse/NO

Vector - naked oligo /; PLC bet and eta/Human/Signaling Protein /Expression/Cell Line/Flag-tagged CMV Expression Vector /; LRRK2 /Human/Signaling Protein/Expression/Cell Line/MYC-tagged CMV Expression Vector /; mt-mKeima/Anthoza/Reporter/Monitor Mitophagy/Cells/Expression/; pLV-mitoDSred/Anthoza/Reporter/Monitor mitochondrial numbers/Cells/Expression/; LV-mCherry_mito_Grx1-roGFP2/Anthoza/Reporter/Biosensor for mitochondrial glutathione redox potential /Cells/Expression/; LV-mCherry_mito_roGFP2-Orp1/Aequorea victoria jellyfish/Reporter/Hydrogen Peroxide Biosensor /Cells/Expression/; RICTOR/Mouse/Signaling /Expression/Cells/Expression/; Cre recombinase/bacteriophage P1/Regulatory/Knockdown via cleavage at loxP sites /Mouse/vector pAAV.GFAP.Cre.WPRE.hGH (addgene)/
Vector(s) [Vector Category/Vector Technical Name]: Lentivirus/shERWOOD0UltramiR-lentiviral shRNA/; Plasmid/p3xFlag-CMV10/; Lentivirus/Mission shRNAi lentivirus /; Retrovirus/Retrovirus (GFAP-GFP developed from F. Gage GAG-GFP in addgene)/; Lentivirus/pHIV-dTomato/; Plasmid/pKH3/; Plasmid/pGEX4T-1/; Plasmid/PiggyBAC GFP/; Plasmid/PiggyBac Cumate switch/; Plasmid/pcDNA3.1/; Plasmid/pEBG/; Plasmid/pEFG-C1/; Plasmid/pCMV-Myc/; Adenovirus/pShuttle-CMV/Adtrack/; Plasmid/pET4A/; Plasmid/pSUPER-GFP/neo/; Plasmid/pcDNA3.1/; Plasmid/p3xFlag/; Plasmid/pGEM4Z/; Adeno-Associated Virus (AAV)/AAV9/; Plasmid/pCMV-Flag-APEX2/; Plasmid/pCMV-Flag-TuboID/; Lentivirus/pLV[FlexON] /; Plasmid/pET32A/; Adeno-Associated Virus (AAV)/pAAV.GFAP.Cre.WPRE.hGH
Cell line(s) Used [Cell Line Type/Cell Line Technical Name]: Human/293 HEK/; Human/HeLa T4/; Animal/NIH3T3/; Animal/MIN6/; Animal/PC6/; Animal/PC12/; Animal/COS/; Animal/HIT-T15/; Human/SHSY-5Y/; Human/tSA-201/; Animal/MEF/; Animal/Hippocampal and Cortical Neurons /; Animal/Cardiac Myocyte /; Human/NCI-H2110/; Human/NCI-H1299/; Human/A549/; Animal/MC3T3-E1/; Human/SK-N-DZ/; Human/ACHN/; Human/O786/; Human/Caki2
Animal Use: Yes
Materials introduced into Animals [Animal Host Species/Biohazardous Material/Route of Administration/Restraint/Animal Experimental Procedures/PPE/Animal Housing/Agent Shedding/Special Practices & Procedures]: Mouse/Viral Vector - Lentivirus/stereotactic injection/anasthesia/ABSL2/Lab Coat, Gloves, Eye Protection/ABSL2/No//; Mouse/Viral Vector - Retrovirus/stereotactic injection/anasthesia/ABSL2/Lab Coat, Gloves, Eye Protection/ABSL2/No//; Mouse/Viral Vector - Adeno-Associated Virus (AAV)/thoracic injection/ice bed/ABSL1/Lab Coat, Gloves, Eye Protection/ABSL1/No/Neonatal mice will be anesthetized by being placed on a bed of ice./; Mouse/Naked Nucleic Acid-r/sDNA/stereotactic, intravitreal, or intrathecal injection/Anaesthetized/ABSL1/Lab Coat, Gloves, Eye Protection/ABSL1/No//; Mouse/Viral Vector - Adeno-Associated Virus (AAV)/Intrathecal/anesthesia/ABSL1/Gloves, lab coat, eye protection/ABSL1/No//

Risk Assessment/Discussion:

Dr. Andres has submitted an amendment to his current IBC protocol to update genetic constructs, laboratory locations, and manipulations planned. Specifically, he has added a new project to administer AAV-Cre via intrathecal injection to anesthetized mice. Expression of Cre recombinase is drive by the astrocyte specific GFAP promoter to target glycogen synthase 1 (GYS1) knockdown in astrocytes. This work will be done using BSL1/ABSL1 containment. PPE required for ABSL1 work includes gloves, lab coat, and eye protection. The new AAV construct is obtained from Addgene. Dr. Andres current IBC protocol includes approval for work with other AAV constructs. The addition

of this new AAV-Cre does not significantly alter the biohazardous risks associated with this IBC protocol. There is an IBC hold on the corresponding IACUC protocol 2019-3402.

IBC Discussion & Vote:

The amendment to IBC-24-28 (version 18.0) was approved pending minor modifications as listed below:

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SCIENTIFIC SUMMARY – In the paragraph describing the details of this amendment, please strike the open-ended statement "However, this is a general approach, such that inject of PHP.eB could be used to target other cell types in the brain (for example neurons) by using recombinant PHP.eB virus with a different cell-specific promoter." If you elect to target other cell types using alternative cell specific promoters with PHP.eB, create a new amendment to describe those specific project goals.

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Carol Pickett initiated the motion. Amelia Pinto seconded the motion. All IBC members present (13) voted in favor of the motion.

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Conflicts of Interest: None

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PI: Eddy Yang
IBC Protocol Number: IBC-24-94
Protocol Title: Novel combination therapies to treat cancer
Protocol Type: Amendment
Amendment To: Genetic constructs, Manipulations planned
Applicable Guidelines & Regulations: NIH Guidelines Section III-D-4, NIH Guidelines Section III-E-1, NIH Guidelines Section IV-B-7, UK Administrative Regulation 6.9, UK Administrative Regulation 6.3, OSHA Act of 1970 Clause 5(a)(1), OSHA 29 CFR 1910.1030, NIH Guidelines Section III-F-1
Maximum Containment Level: Biological Safety Level 2 (BSL2), Animal Biological Safety Level 2 (ABSL2)
Primary Reviewers: M. Landron, A. Pinto, D. Malherbe

Brief Project Overview:

Triple-negative breast cancers (TNBCs) are highly aggressive, metastatic and recurrent. The standard chemotherapies and radiotherapies have marginal curative benefits but there is no efficacious targeted therapy. This project will develop and fully evaluate a new strategy, the combined dual-targeted mitochondrial luminoptogenetic gene therapy and synthetic lethality of poly (ADP-Ribose) polymerase inhibitor, to eliminate the metastatic and heterogeneous TNBCs.

08/10/2023 addition: We will evaluate the Calpain-5/CAPN5 protease as a potential target in cancer therapy in cell culture experiments. CAPN5 is a protease enzyme that is activated by calcium. Abnormally high calcium levels were reported in a variety of cancers. The high expression of CAPN5 mRNA results in a poor prognosis in endometrial cancer. Recurrent mutants of CAPN5

detected in cancer samples will be evaluated for their biochemical activity and cellular localization. Suspected substrates of CAPN5 that play roles in DNA mismatch repair will be tested in CAPN5 assay. The effect of the level and recurrent cancer mutations in CAPN5 will be tested on the viability and invasiveness of endometrial cancer cell lines, the levels of cancer-relevant CAPN5 substrates, and the ability of cancer cells to repair DNA damage.

11/12/2024 addition: We will expand our experiments to develop a preclinical mouse model for CAPN5-high endometrial cancer.

12/10/2024 addition: SFRT is short for Spatially Fractionated Radiotherapy. This is a treatment technique used in radiation therapy, in which the tumor isn't treated uniformly with radiation, but rather with a grid-pattern (this is typically referred to as GRID treatments) or with a lattice-pattern (this is typically referred to as Lattice therapy) of high and low dose. This project will investigate the different SFRT patterns and their effectiveness in killing cells. Materials used are immortal tumor cell lines (SCC2 and SCC6). We want to investigate the therapeutic gain of using different sized rods and different rod spacing for SFRT. This will be performed by first uniformly irradiating cell flasks at set doses (2Gy, 4Gy, etc.) and deriving a cell survival curve. We will then irradiate the cell flasks using a GRID pattern at set equivalent uniform dose (EUD) (2Gy, 4Gy, etc), and derive a corresponding cell survival curve. Comparisons will be made of the different GRID pattern cell survival curves determining which pattern results in the most effective treatment.

Summary of Biohazard Materials & Manipulations:

Manipulations Planned: Animal work (breeding, surgeries, etc.), DNA/RNA isolation/purification, Use of Viral Vectors, Immunohistochemistry, Imaging/Microscopy, Histology, Cell culture, Flow Cytometry/Cell Sorting, Bacterial culture, Genetics, PCR/qRT-PCR, Transformation, Transfection, Use of Human Source Material(s)
Transport: Yes
Materials Transported: Biohazardous Materials
Infectious Agent(s)/Natural Host(s): Human Sourced Materials (RG2-cells, tissues, bodily fluids, organs, etc.)/Human
Source & Nature of Inserted Nucleic Acid(s) [Gene Information/Gene Source/Gene Category/Use of Construct/Host(s)/Vector(s)]: Cas9n (D10A)/Streptococcus pyogenes/Endonuclease/Gene knockout/Human cell lines/Double Nickase Plasmid (sc-400011-NIC, sc-403881-NIC)/; Cell surface receptor Plexin-B2/PLXNB2/Homo sapiens/Receptor/Expression/Human cell lines/p3xFLAG-CMV14/; Renilla luciferase/Renilla reniformis/Luciferase/Reporter/Human cell lines/phRL-TK(Int-)/; Firefly luciferase/Photinus pyralis/Luciferase/Reporter/Human cell lines, mouse/pGL2-TATA-Inr, pGL4.17[luc2/Neo]/; Nanoluciferase NLuc/Oplophorus gracilirostris/Luciferase/Produces blue light to activate CoChR/mouse/pAAV-MCS/; Light-gated channelrhodopsin CoChR/Chloromonas oogama/Membrane protein/Light-gated channelrhodopsin, depolarizes the mitochondrial inner membrane/mouse/pAAV-MCS/; Calpain-5 CAPN5/Homo sapiens/Enzymatic protein, CRISPR guide RNA/Expression, knockout/Human cell lines/p3xFLAG-CMV14, pMK243, pEF1a-IRES-Neo, Double Nickase Plasmid (sc-403881-NIC)/; DNA mismatch repair gene MLH1/Homo sapiens/Tumor suppressor/Expression/Human cell lines/pCSF107mT-GATEWAY-3'-3HA, pGCS-N2(3xHA)/; DNA mismatch repair gene MSH2/Homo sapiens/Tumor suppressor/Expression/Human cell lines/pCSF107mT-GATEWAY-3'-3HA/; DNA-

dependent protein kinase catalytic subunit PRKDC/DNAPKcs/Homo sapiens/Enzymatic protein/Expression/Human cell lines/pCMV6/; Mismatch repair endonuclease gene PMS2/Homo sapiens/Tumor suppressor/Expression/Human cell lines/pCSF107mT-GATEWAY-3'-3HA/; Cas9/Streptococcus pyogenes /Endonuclease /Gene Editing/Expression/Human cell lines/Plasmid AAVS1 T2 CRIPR in pX330/; Estrogen receptor alpha ESR1/Homo sapiens/Transcription factor, shRNA, CRISPR guide RNA/Expression, knockdown, knockout/Human cell lines/pcDNA3.1 (+), Double Nickase Plasmid (sc-400011-NIC)/
Vector(s) [Vector Category/Vector Technical Name]: Plasmid/"Double Nickase Plasmid"/; Adeno-Associated Virus (AAV)/pAAV-MCS/; Plasmid/p3xFLAG-CMV14/; Plasmid/pGCS-N2(3xHA)/; Plasmid/pMK243/; Plasmid/pX330/; Plasmid/pCMV6/; Plasmid/pGL4.17[luc2/Neo]/; Plasmid/pGL2-TATA-Inr/; Plasmid/phRL-TK(Int-)/; Plasmid/pCSF107mT-GATEWAY-3'-3HA/; Plasmid/AAVS1 T2 CRIPR in pX330 (Cas9 and gRNA Source)/; Plasmid/pEF1a-IRES-Neo/; Plasmid/pcDNA3.1 (+)/
Cell line(s) Used [Cell Line Type/Cell Line Technical Name]: Animal/4T1/; Animal/EMT6/; Human/293T/; Human/HEC-1-A/; Human/Ishikawa/; Human/KLE/; Human/SCC2/; Human/SCC6/; Human/MCF7/; Human/T-47D
Animal Use: Yes
Materials introduced into Animals [Animal Host Species/Biohazardous Material/Route of Administration/Restraint/Animal Experimental Procedures/PPE/Animal Housing/Agent Shedding/Special Practices & Procedures]: Mouse/Viral Vector - Adeno-Associated Virus (AAV)/Tail vein/Isoflurane anesthesia/ABSL1/Lab coat, gloves, eye protection/ABSL1/No/N/A/; Mouse/Cells - Human, non-modified/Subcutaneous injection/Isoflurane anesthesia/ABSL2/Eye protection and sterile lab coat, gloves, mask/ABSL2/No/These experiments will be done with immunocompromised nude mice, requiring extra caution to maintain sterility during handling and injection./; Mouse/Cells - Human, genetically modified/Subcutaneous injection/Isoflurane anesthesia/ABSL2/Eye protection and sterile lab coat, gloves, mask/ABSL2/No/These experiments will be done with immunocompromised nude mice, requiring extra caution to maintain sterility during handling and injection

Risk Assessment/Discussion:
Dr. Yang has submitted an amendment to his current IBC protocol to update genetic constructs and manipulations planned. Specifically, Dr. Yang has added a project to validate Calpain-5/CAPN5 as a therapeutic target in cancer. They will utilize CRISPR technology to inactivate the ESR1 gene (Estrogen Receptor alpha) in Ishikawa endometrial cancer cells. The ESR1-null cells will be utilized to generate CAPN5 stable cells. They will generate expression plasmids for WT, C81A mutant, and recurrent cancer mutants of CAPN5 based on the pEF1a-IRES-Neo expression plasmid from Addgene. Only plasmid vectors will be utilized for transfection, no viral vectors will be utilized in this new project. They will compare the metabolic changes in Ishikawa endometrial cancer cells expressing WT or mutant CAPN5 compared to control cells using the Metabolism Core, Flow Cytometry and Immune Monitoring Core, and the Redox Metabolism Shared Resource Core. All materials will be transported from the PIs lab to core facilities sealed in a primary container and placed within a leak-proof, shatter-proof, secure-lidded secondary container. This new project will be conducted using BSL2 containment wearing a lab coat, disposable gloves, and eye protection. This new project is very similar to previously approved work and does not significantly alter the biohazardous risks associated with this IBC protocol.

IBC Discussion & Vote:

The amendment to IBC-24-94 (version 53.0) was approved pending minor modifications as listed below:
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GENERAL INFORMATION – Lay Summary: Please revise the lay summary text to incorporate amendment information and remove references to specific amendments.

SCIENTIFIC SUMMARY –

1. It is indicated that cells will be quenched in cold acetonitrile within the BSC before transport, which is inadvisable due to the volatile nature of acetonitrile. Please update this procedure such that this step is performed in a Chemical Fume Hood (CFH) instead of a BSC.
2. The standard PPE described while working in a BSC includes lab coat, disposable gloves, eye protection, and surgical mask. The surgical mask is not necessary and may be removed if the other PPE listed is being utilized while working in the BSC.

Amelia Pinto initiated the motion. Delphine Malherbe seconded the motion. All IBC members present (13) voted in favor of the motion.
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Conflicts of Interest: None
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PI: Xiaoqi Liu
IBC Protocol Number: IBC-24-114
Protocol Title: Plk1 in epigenetics of prostate cancer development and progression
Protocol Type: Amendment
Amendment To: Cells or tissues used in research, Personnel, Genetic constructs
Applicable Guidelines & Regulations: NIH Guidelines Section III-D-1, NIH Guidelines Section IV-B-7, UK Administrative Regulation 6.3, OSHA 29 CFR 1910.1030, UK Administrative Regulation 6.9, OSHA Act of 1970 Clause 5(a)(1), NIH Guidelines Section III-E, NIH Guidelines Section III-E-3, NIH Guidelines Section III-F, NIH Guidelines Section III-F-8, NIH Guidelines Section III-F-1, NIH Guidelines Section III-D-4
Maximum Containment Level: Biological Safety Level 2 - Enhanced (BSL2+), Animal Biological Safety Level 2 (ABSL2)
Primary Reviewers: C. Haughton, D. Malherbe, D. Harrison

Brief Project Overview:

We aim to understand the underlying mechanisms of cancer development and therapy resistance. Based on this, we will eventually develop new approaches to treat cancer. The approaches of our study cover standard cell culture and mouse work. Our work focuses on a gene called Polo-like kinase 1 (Plk1), a critical cell cycle regulator, whose expression is elevated in many cancers. To study the role of Plk1 in cancer progression and therapy resistance, we need to use various approaches (standard plasmid-based transfection, lentivirus-based infection to express or deplete

Plk1 or other genes in human cancer cell lines). The personnel in the protocol has sufficient experience to use these agents and well aware the potential danger-associated with these agents. We will work with your committee closely to ensure we strictly follow the rule.

Plk1 is well known as a protein kinase playing critical roles in cell cycle regulation. The lab studies how Plk1-associated kinase activity regulates functions of different substrates, including EZH2 and BRD4. EZH2 is a component of PRC2 complex, responsible for H3K27 trimethylation. BRD4 recognizes acetylated histones. In addition, our lab also aim to identify whether PlK1 can phosphorylates two transcription factors, ASCL1 and Neurod1. which are critical drivers to promote neuroendocrine prostate cancer development. PLK1 can also phosphorylate two key factors-Nanog and HOXB13, which contribute to stemness and prostate cancer progression. In addition, three transcription factors, TTF1(NKX2.1), NMYC and Oct4 also been identified as PLK1 phosphorylation substrates, and these phophorylation events can promote stemness and neuroendocrine development in prostate cancer.

Prostate cancer reconstitution model is well used to study on the development and differentiation of prostate cancer. Briefly, we will implant the new mouse cell line RB1/P53-DKO/myc-KI, which induces phenotype of neuroendocrine prostate cancer, into the kidney of NSG mice. The personnel in the protocol has sufficient experience to handle this procedure. We will work with your committee closely to ensure we strictly follow the rule.

Summary of Biohazard Materials & Manipulations:

Manipulations Planned: Animal work (breeding, surgeries, etc.), Bacterial culture, Cell culture, Histology, Genetics, PCR/qRT-PCR, Transformation, Propagation of Infectious Agents, Transfection, DNA/RNA isolation/purification, Creation of Viral Vectors, Use of Viral Vectors, Use of Human Source Material(s), Imaging/Microscopy, Immunohistochemistry
Transport: Yes
Materials Transported: Animals, Biohazardous Materials
Infectious Agent(s)/Natural Host(s): Human Sourced Materials (RG2-cells, tissues, bodily fluids, organs, etc.)/Human
Source & Nature of Inserted Nucleic Acid(s) [Gene Information/Gene Source/Gene Category/Use of Construct/Host(s)/Vector(s)]: Plk1 /Mouse and Human /Cell Cycle/Division/Expression or Knockdown /human cells: LNCaP , C4-2, 22Rv1 ,PC3, NHPrE, N2P1, N2P2, N2P3, NCI-H660, LAPSCPC-1, DU145/pLKO.1 and pLenti-GIIICMV-C-term-HA, FuCRW, pLV-puro or pLV-EF1a-IRES-Hygromycin/; EZH2/Mouse and Human /Oncogene /Expression or Knockdown /human cells: LNCaP , C4-2, 22Rv1 ,PC3, NHPrE, N2P1, N2P2, N2P3, NCI-H660, LAPSCPC-1, DU145 E.Coli/pLKO.1 and pLenti-GIIICMV-C-term-HA, pET-GST, pCDNA3.1, pLV-puro or pLV-EF1a-IRES-Hygromycin, FuCRW/; BRD4/Human /Oncogene /Expression or Knockdown /human PCa cells: LNCaP, C4-2, 22Rv1, DU145, PC3, NHPrE. Mouse prostate cancer cell: TRAMP-C2. E.Coli/pLKO.1 and pLenti-GIIICMV-C-term-HA,pCDNA3.1, tetpLKO-puro, pCW57-RFP-P2A-MCS, FuCRW, pET-GST, pLV-puro or pLV-EF1a-IRES-Hygromycin/; SPOP/Human /Tumor Suppressor /Expression or Knockdown /human PCa cells: LNCaP, C42, C4-2B, 22Rv1, DU 145, and PC3/pCDNA3.1, pLenti-CMVpuro,tet-pLKO-puro, pCW57-RFP-P2A-MCS, pLKO.1, FuCRW/; FGF10/mouse/Oncogene /Expression /mouse UGSM /FuCGW/; GFP/Jellyfish/Tag/Expression /human PCa cells: LNCaP, C42, 22Rv1, DU 145, and PC3/pGFP/; Luciferase/Firefly/Tag/Expression /human PCa cells: LNCaP,

C42, 22Rv1, DU 145, and PC3/pLV-Luc/; Rb1/Mouse and Human/Regulatory Gene/Knockdown /human PCa cells: LNCaP, mouse prostate epithelia cells (RB1/P53-DKO/myc-KI)/pLKO.1, FuCRW/; P53/Mouse and Human/Regulatory Gene/Knockdown /human PCa cells: LNCaP, mouse prostate epithelia cells (RB1/P53-DKO/myc-KI)/pLKO.1, FuCRW/; ASCL1/Mouse and Human/Oncogene /Knockdown or Expression /human PCa cells: LNCaP, LNCaP/AR/tet-sh-P53&Rb1, mouse prostate epithelia cells (RB1/P53-DKO/myc-KI)/pLKO.1, FuCRW, pLV-puro or pLV-EF1a-IRES-Hygromycin/; Neurod1/Mouse and Human/Oncogene /Knockdown or Expression /human PCa cells: LNCaP, LNCaP/AR/tet-sh-P53&Rb1, mouse prostate epithelia cells (RB1/P53-DKO/myc-KI)/pLKO.1, FuCRW, pLV-puro or pLV-EF1a-IRES-Hygromycin/; HOXB13/Mouse and Human/Oncogene/Knockdown or Expression /human PCa cells: LNCaP, mouse prostate epithelia cells (RB1/P53-DKO/myc-KI)/pLKO.1, FuCRW, pLV-puro or pLV-EF1a-IRES-Hygromycin/; Nanog/Mouse and Human/Oncogene/Knockdown or Expression /human PCa cells: LNCaP, mouse prostate epithelia cells (RB1/P53-DKO/myc-KI)/pLKO.1, FuCRW, pLV-puro or pLV-EF1a-IRES-Hygromycin/; NMYC/HUMAN/ONCOGENE/Expression or Knockdown/Human PCa cells: LNCaP , C4-2, 22Rv1 ,PC3, NHPrE, N2P1, N2P2, N2P3, NCI-H660, LAPSCPC-1, DU145/pLKO.1 and pLenti-GIIICMV-C-term-HA, pET-GST, pCDNA3.1, pLV-puro or pLV-EF1a-IRES-Hygromycin/; TTF1/Mouse and Human/Oncogene/Expression or Knockdown/Human PCa cells: LNCaP , C4-2, 22Rv1 ,PC3, NHPrE, N2P1, N2P2, N2P3, NCI-H660, LAPSCPC-1, DU145/pLKO.1 and pLenti-GIIICMV-C-term-HA, pET-GST, pCDNA3.1, pLV-puro or pLV-EF1a-IRES-Hygromycin/; OCT4/Mouse and Human/oncogene/Expression or Knockdown/Human PCa cells: LNCaP, 16D, C4-2, 22Rv1 ,PC3, NHPrE, N2P1, N2P2, N2P3, NCI-H660, LAPSCPC-1, DU145; mouse prostate epithelia cells (RB1/P53-DKO/myc-KI)/pLKO.1 and pLenti-GIIICMV-C-term-HA, pET-GST, pCDNA3.1, pLV-puro or pLV-EF1a-IRES-Hygromycin, FuCRW
SQ, IP, IV, orthotopic njection restrainer/gas anesthesia such as isoflurane/ABSL2/double-layered gloves, lab coats and eye protection/face mask/ABSL2/No/castration; sub-renal capsule implantation; Mouse Tissue - Human (ex. PDX tumor tissue)/SQ tumor implantation/gas anesthesia such as isoflurane/ABSL2/double-layered gloves, lab coats and eye protection/face mask/ABSL2/No/human tumor inoculation

Risk Assessment/Discussion:
Dr. Liu has submitted an amendment to update cells/tissues used in research, genetic constructs, and personnel. Specifically, Dr. Liu has added three new oncogenes (NMYC, TTF1, and Oct4) for expression or knockdown via lentivirus vectors in human prostate cancer cells. He has also updated the gene entries for ASCL1, Neurod1, HOXB1, and Nanog to include knockdown (previously approved for expression of these constructs via lentiviral vector in human prostate cancer cells). These new lentiviral vector constructs will be packaged/produced as previously described and approved. Lentivirus transduced cells will be administered to mice via subcutaneous injection as previously described and approved. These new experiments are very similar to previously approved experiments utilizing oncogene expressing/knockdown lentiviral vectors. Work with lentivirus will take place using BSL2+ containment and requires lab coat, disposable gloves, and eye protection. Work with lentivirus will take place exclusively in a BSC. Transduced cells will be administered to mice using ABSL2 containment. While the use of oncogene expressing lentivirus vectors presents risk of cancer through oncogenesis or insertional mutagenesis, Dr. Liu's laboratory has extensive experience working with oncogenic lentiviral

vectors. This new project does not significantly alter the biohazardous risks associated with his currently approved work.

IBC Discussion & Vote:

The amendment to IBC-24-114 (version 46.0) was approved pending minor modifications as listed below:

*
SCIENTIFIC SUMMARY: Please remove verbiage from the Laboratory Hazards description regarding use of antiretroviral agents. Please specify that potential exposures are reported immediately to the PI and UK Worker's Care.

Cheryl Haughton initiated the motion. Doug Harison seconded the motion. All IBC members present (13) voted in favor of the motion.
*
Conflicts of Interest: None
*
PI: Lutz Goehring
IBC Protocol Number: IBC-25-02
Protocol Title: Equid (alpha)herpesvirus epidemiology, transmission, pathophysiology, vaccinology, latency &reactivation
Protocol Type: Amendment
Amendment To: Laboratory Location(s), Manipulations planned, Organisms used in research, Personnel, Project Title
Applicable Guidelines & Regulations: NIH Guidelines Section III-D-2, NIH Guidelines Section III-D-4, NIH Guidelines Section IV-B-7, OSHA Act of 1970 Clause 5(a)(1), UK Administrative Regulation 6.3, UK Administrative Regulation 6.9, NIH Guidelines Section III-E-1
Maximum Containment Level: Animal Biological Safety Level 2 (ABSL2), Biological Safety Level 2 (BSL2)
Primary Reviewers: C. Haughton, T. Chambers, C. Shaffer

Brief Project Overview:

The laboratory will specialize on a group of horse viruses, Equid (alpha)herpesviruses, that are not contagious for humans. They are also not contagious for other animals except for horses, ponies, donkeys, zebras (Equidae). However, people can carry virus on their hands and clothes with a small risk of transferring virus from horse to horse. The laboratory will isolate virus from various specimen (nasal swabs, white blood cells, contaminated surfaces) collected during studies. The laboratory will isolate or propagate virus in cell culture in vitro. Most of the work will, however, focus on isolating DNA from a variety of formaldehyde fixed tissues. During the process of fixation, virus is completely inactivated (unable to infect again). The laboratory will use dilutions of a virus suspension to infect cells in vitro to study effects and gather information on the course of cell infection. The laboratory will also evaluate novel vaccine(s) (candidates) for protection against equid herpesvirus infections and disease. Herpesviruses will cause a chronic infection after initial acute infection. The chronic stage is a dormant or inactive 'sleeper' stage, also known as latency or latent infection, from which virus can reactivate and cause new rounds of infection (and spread). A

prime example is the recurrent 'cold sore' or lip blister after Herpes simplex-1 infection in people. In addition to the listed activities (see above), my laboratory wants to study latency and reactivation of the Equid (alpha)herpesviruses.

Summary of Biohazard Materials & Manipulations:

Manipulations Planned: Animal work (breeding, surgeries, etc.), Cell culture, DNA/RNA isolation/purification, Histology, PCR/qRT-PCR, Immunohistochemistry, Propagation of infectious agents, Use of infectious agents, Imaging/Microscopy, Viral culture
Transport: Yes
Materials Transported: Animals, Biohazardous Materials
Infectious Agent(s)/Natural Host(s): Equine Herpesvirus (RG1-virus)/Horse
Source & Nature of Inserted Nucleic Acid(s) [Gene Information/Gene Source/Gene Category/Use of Construct/Host(s)/Vector(s)]: glycoprotein D/Equid alphaherpesvirus 1/structural/immunogenic/equine/lipid nanoparticle; immediate early gene/Equid alphaherpesvirus 1/non-structural/immunogenic/equine/lipid nanoparticle; spike protein/Sars Corona 19/structural/immunogenic/equine/lipid nanoparticle; replicase/viral: Venezuelan Equine Encephalitis (VEE)/non-structural/replicase will multiply target RNA replication/equine/lipid nanoparticle
Vector(s) [Vector Category/Vector Technical Name]: Nanoparticle/Lipid Nanoparticle
Cell line(s) Used [Cell Line Type/Cell Line Technical Name]: Animal/RK13; Animal/eDERM; Animal/eEC; Animal/Neuro 2A
Animal Use: Yes
Materials introduced into Animals [Animal Host Species/Biohazardous Material/Route of Administration/Restraint/Animal Experimental Procedures/PPE/Animal Housing/Agent Shedding/Special Practices & Procedures]: Equine, Agricultural/Equine Herpesvirus (RG1-virus)/intrabronchial instillation and nebulization with (gold standard) nasopharyngeal instillation; 'skin scratch' intradermal/sedation/ABSL2/daily (washable) scrubs or coverall; individual disposable Tyvec Coverall (1 per entry into infectious area); (buffon) head cover); disposable gloves; rubber boots upon entry/ABSL2/Yes/Isolation Barn protocols; Equine, Agricultural/Nanoparticle-r/sDNA/IM/no/ABSL1/no/ABSL1/No/Administration of vaccine for immunogenicity only. Daily checks post admin.

Risk Assessment/Discussion:

Dr. Goehring has submitted an amendment to update laboratory locations, manipulations planned, organisms used in research, personnel, and project title. Specifically, Dr. Goehring has added a new project utilizing Equine Herpes Virus-3 (EHV-3) in an intradermal model to study EHV latency and reactivation and updated a previously approved project to study EHV-1 transmission. The new project seeks to induce latency of EHV-1 or EHV-3 in tributary sensory nerve dorsal ganglia. 2 horses will be utilized for this project. Horses will be infected with EHV-1/EHV-3 via skin scratch method and housed in the BSL2 Isolation Barn. Once the lesions have fully healed and confirmed via PCR to no longer be shedding, horses will be moved to a shared paddock without any contacts in adjacent fields. Ultimately, horses will be utilized and transported to UKVDL for necropsy. The transmission study has been updated to utilize both the Vulcan barn and BSL2 Isolation barn, which are adjacent to one another. Previously, the transmission study was approved in the Vulcan barn only. Equine Herpes Virus is not zoonotic and infects only horses, ponies,

donkeys, zebras (Equidae). The risks posed by both the new and updated studies are not significantly altered from previously approved work. PPE requirements, manure handling, etc. remain the same as previously approved. There is an IBC hold on the corresponding IACUC protocol 2025-4702.

IBC Discussion & Vote:

The amendment to IBC-25-02 (version 29.0) was approved pending minor modifications as listed below:

*
DISINFECTANTS, EMERGENCY RESPONSE, TRANSPORT, WASTE – Disinfectants: Please add Rescue to the Disinfectants table.
INFECTIOUS AGENTS – Infectious Agents Table: Please create separate entries for the different EHV serovars.
SCIENTIFIC SUMMARY –

1. Include a brief description of the differences among EHV serovars in use.
2. Please specify how intentionally infected carcasses are disposed of.

*
Tom Chambers initiated the motion. Carrie Shaffer seconded the motion. All IBC members present (13) voted in favor of the motion.
*
Conflicts of Interest: None
*

New Protocols

*

PI: Zabeen Mahuwala
IBC Protocol Number: IBC-25-19
Protocol Title: RNAC-MG-002 (AURORA): A Randomized, Double-Blind, Placebo-Controlled Phase 3 Trial of Descartes-08 in Patients with Generalized Myasthenia Gravis (MG)
Protocol Type: New Protocol
Amendment To: N/A
Applicable Guidelines & Regulations: NIH Guidelines Section III-C-1, UK Administrative Regulation 6.3, UK Administrative Regulation 6.9, OSHA 29 CFR 1910.1030, OSHA Act of 1970 Clause 5(a)(1), NIH Guidelines Section IV-B-7
Maximum Containment Level: Biological Safety Level 2 (BSL2)
Primary Reviewers: T. Chambers, D. Harrison, B. Nelson

Brief Project Overview:

This is a Phase 3 clinical study to determine the efficacy of Descartes-08, an engineered cell product made from a patient's own cells, that transiently expresses a BCMA (B-cell Maturation Antigen) CAR (Chimeric Antigen Receptor) by way of an introduced recombinant mRNA. This is being studied to ideally aid in the treatment of patients suffering from acetylcholine receptor

autoantibody (anti-nAChR) titer or anti-AChR cluster antibody positive generalized myasthenia gravis (gMG).

Summary of Biohazard Materials & Manipulations:

Manipulations Planned: Human Clinical Trial, Use of Human Source Material(s)
Transport: Yes
Materials Transported: Biohazardous Materials
Infectious Agent(s)/Natural Host(s): Human Sourced Materials (RG2-cells, tissues, bodily fluids, organs, etc.)/Human
Source & Nature of Inserted Nucleic Acid(s) [Gene Information/Gene Source/Gene Category/Use of Construct/Host(s)/Vector(s)]: CD8 transmembrane domain/Human/Signaling/Cytoplasmic Domain/Expression/Autologous Patient Cells/Descartes-08 CAR mRNA/; CD137 cytoplasmic domain/Human/Signaling/Cytoplasmic Domain/Expression/Autologous Patient Cells/Descartes-08 CAR mRNA/; CD3 cytoplasmic domain/Human/Signaling/Cytoplasmic Domain/Expression/Autologous Patient Cells/Descartes-08 CAR mRNA/; anti-BCMA CAR/Human/Chimeric Antigen Receptor/Expression/Autologous Patient Cells/Descartes-08 CAR mRNA
Vector(s) [Vector Category/Vector Technical Name]: Naked Nucleic Acid/Descartes-08 CAR mRNA
Cell line(s) Used [Cell Line Type/Cell Line Technical Name]: N/A
Animal Use: No
Materials introduced into Animals [Animal Host Species/Biohazardous Material/Route of Administration/Restraint/Animal Experimental Procedures/PPE/Animal Housing/Agent Shedding/Special Practices & Procedures]: N/A

Risk Assessment/Discussion:

Dr. Mahuwala has submitted a new IBC protocol for a clinical study entitled *RNAC-MG-002 (AURORA): A Randomized, Double-Blind, Placebo-Controlled Phase 3 Trial of Descartes-08 in Patients with Generalized Myasthenia Gravis (MG)*. This is a Phase 3 study utilizing Descartes-08, an autologous T-cell product transiently expressing a CAR directed against B-cell maturation antigen (BCMA) for targeting BCMA+ cells in patients with Generalized Myasthenia Gravis (MG). Autologous T-cells are modified by directly electroporating purified mRNA encoding a chimeric antigen receptor (CAR) into activated human T-cells. UK expects to enroll 3 study participants over the course of 3-4 years. After leukapheresis, cells will be shipped to the Sponsor for isolation and processing. Final product will be shipped back to the UK Cell Therapy Laboratory for storage and preparation. Product will be administered within 2 hours of thawing to patient in the Precision Medicine Center in UK Chandler Hospital. Clinical and post-infusion samples will be obtained in the PMC as well. Patient blood and urine samples will be processed for shipment back to the study sponsor by the UK CCTS laboratory. The risks of exposure to healthcare workers (HCW) handling the study product is not greater than that which they would likely encounter working in a hospital setting. Risks include potential exposure to human sourced materials and blood borne pathogens. UK HCW are trained on how to minimize potential risks of exposure via appropriate PPE requirements, waste handling, and emergency response. All study personnel will also complete study specific training provided by the study sponsor.

IBC Discussion & Vote:

The protocol IBC-25-19 (version 6.0) was approved.
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Doug Harrison initiated the motion. Brandy Nelson seconded the motion. All IBC members present (13) voted in favor of the motion.
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Conflicts of Interest: None
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Renewals

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PI: Daniel Howe
IBC Protocol Number: IBC-25-136
Protocol Title: Biology of Coccidian Parasites
Protocol Type: Renewal
Amendment To: N/A
Applicable Guidelines & Regulations: NIH Guidelines Section III-D-2, NIH Guidelines Section III-F-1, NIH Guidelines Section IV-B-7, OSHA 29 CFR 1910.1030, OSHA Act of 1970 Clause 5(a)(1), UK Administrative Regulation 6.3, UK Administrative Regulation 6.9
Maximum Containment Level: Biological Safety Level 2 (BSL2)
Primary Reviewers: C. Shaffer, C. Pickett, M. Landron

Brief Project Overview:

Coccidian parasites are a significant cause of human and animal disease worldwide. This class of intracellular protozoan parasites includes Toxoplasma gondii, Sarcocystis spp., and Neospora spp. In susceptible animals, these parasites can cause abortions or neurologic disease. The parasites are all obligate intracellular pathogens. As such, we propagate them in monolayers of host cells. The cultures are manipulated in biosafety cabinets, and all work is conducted under biosafety level 2 conditions. Neospora spp. and the species of Sarcocystis that we use (Sarcocystis neurona) are not infectious to humans. T. gondii propagated in cell culture exist in the tachyzoite stage, which is infectious to humans only via parenteral inoculation. Our work with T. gondii does not require needles, and manipulations of open cultures is conducted in a biosafety cabinet with the window lowered to the recommended height to prevent splashes of media into the eye. Our primary research emphasis is on the identification and characterization of virulence factors (genes and proteins) that enable these parasites to survive their parasitic life-styles. We have conducted a sequencing project on cDNA libraries from the equine pathogen Sarcocystis neurona, and we are currently exploring the database of gene sequences to identify putative parasite virulence factors. Likewise, we are examining sequence databases for T. gondii and N. caninum for related virulence factors. Candidate cDNAs are cloned into bacterial expression plasmids to produce recombinant forms of the parasite antigens. The recombinant proteins are subsequently used for several avenues of investigation, including immunization of animals for the production of antibodies against the parasite antigens. All immunizations of animals for antibody production will be done at a commercial facility (e.g., Cocalico Biologicals, Inc.); no antibody production work will be conducted at the University of Kentucky. Molecular genetic techniques (DNA transfection) will be utilized to generate recombinant parasite clones that lack a gene of interest (gene knockouts), that express a gene from one of the related parasites (heterologous expression), or that express a

marker molecule (green fluorescent protein or beta-galactosidase). Although unlikely, it is conceivable that expression of a Toxoplasma gene in Neospora or Sarcocystis could increase the virulence and/or host range of the recombinant parasites. However, the level of virulence/host range would not exceed that of T. gondii.

Summary of Biohazard Materials & Manipulations:

Manipulations Planned: Animal work (breeding, surgeries, etc.), Bacterial culture, Cell culture, DNA/RNA isolation/purification, Flow cytometry/Cell sorting, Imaging/Microscopy, Immunohistochemistry, PCR/qRT-PCR, Propagation of infectious agents, Transfection, Use of infectious agents
Transport: No
Materials Transported: N/A
Infectious Agent(s)/Natural Host(s): Neospora caninum (RG1-parasite)/Dog/cow/; Neospora hughesi (RG1-parasite)/Dog/cow/; Sarcocystis falcatula (RG1-parasite)/Variable/; Sarcocystis neurona (RG1-parasite)/Variable/; Toxoplasma gondii (RG2-protozoa)/Warm blooded animals/; Human Sourced Materials (RG2-cells, tissues, bodily fluids, organs, etc.)/Human
Source & Nature of Inserted Nucleic Acid(s) [Gene Information/Gene Source/Gene Category/Use of Construct/Host(s)/Vector(s)]: Dihydrofolate reductase/Toxoplasma gondii/Enzymatic protein/Expression in protozoa/Sarcocystis spp., Neospora spp., Toxoplasma gondii, and E. coli/pBluescript/; Hypoxanthine-xanthine-guanine-phosphoribosyl transferase (HXGPRT)/Toxoplasma gondii/Enzymatic protein/Expression in protozoa/Sarcocystis spp., Neospora spp., Toxoplasma gondii, and E. coli/pBluescript/; Green/yellow/red fluorescent proteins/Aequorea victoria/Tracking proteins/Expression in protozoa/Sarcocystis spp., Neospora spp., Toxoplasma gondii, and E. coli/pBluescript/; Beta-galactosidase/E. coli/Metabolic/Expression in bacteria and protozoa/Sarcocystis spp., Neospora spp., Toxoplasma gondii, and E. coli/pBluescript/; Cas9/Streptococcus pyogenes/Enzymatic protein/Expression in protozoa/Sarcocystis spp., Neospora spp., Toxoplasma gondii, and E. coli/pBluescript, CRISPR/Cas9/; Members of the SAG/SRS gene family of surface antigens/Coccidian parasites(Sarcocystis spp., Neospora spp., Toxoplasma gondii)/Surface proteins/Expression in cell culture, bacteria, and protozoa. Also targets for CRISPR/cas9 gene editing./Sarcocystis spp., Neospora spp., Toxoplasma gondii, and E. coli/pBluescript, pET22b, CRISPR/Cas9/; Members of the ROP gene family of rhoptry secretory proteins/Coccidian parasites(Sarcocystis spp., Neospora spp., Toxoplasma gondii)/Rhoptry proteins/Expression in cell culture, bacteria, and protozoa. Also targets for CRISPR/cas9 gene editing./Sarcocystis spp., Neospora spp., Toxoplasma gondii, and E. coli/pBluescript, pET22b, CRISPR/Cas9/; Members of the GRA gene family of dense granule secretory proteins/Coccidian parasites(Sarcocystis spp., Neospora spp., Toxoplasma gondii)/Dense granule proteins/Expression in cell culture, bacteria, and protozoa. Also targets for CRISPR/cas9 gene editing./Sarcocystis spp., Neospora spp., Toxoplasma gondii, and E. coli/pBluescript, pET22b, CRISPR/Cas9/; Members of the MIC gene family of microneme secretory proteins/Coccidian parasites(Sarcocystis spp., Neospora spp., Toxoplasma gondii)/Microneme proteins/Expression in cell culture, bacteria, and protozoa. Also targets for CRISPR/cas9 gene editing./Sarcocystis spp., Neospora spp., Toxoplasma gondii, and E. coli/pBluescript, pET22b, CRISPR/Cas9/; Members of the MFS gene family of transporter proteins/Coccidian parasites(Sarcocystis spp., Neospora spp., Toxoplasma gondii)/Major facilitator superfamily transporters/Expression in cell culture, bacteria, and protozoa. Also targets for CRISPR/cas9 gene

editing./Sarcocystis spp., Neospora spp., Toxoplasma gondii, and E. coli/pBluescript, pET22b, CRISPR/Cas9/; Uracil phosphoribosyltransferase (UPRT)/Coccidian parasites (Sarcocystis spp., Neospora spp., Toxoplasma gondii)/metabolic enzyme/Target for CRISPR/cas9 gene editing./Sarcocystis spp., Neospora spp., Toxoplasma gondii/CRISPR/Cas/
Vector(s) [Vector Category/Vector Technical Name]: Plasmid/pET22b; Plasmid/pBluescript; Plasmid/CRISPR/Cas9
Cell line(s) Used [Cell Line Type/Cell Line Technical Name]: Animal/Bovine Turbinate; Animal/COS-1; Human/Human foreskin fibroblast
Animal Use: Yes
Materials introduced into Animals [Animal Host Species/Biohazardous Material/Route of Administration/Restraint/Animal Experimental Procedures/PPE/Animal Housing/Agent Shedding/Special Practices & Procedures]: N/A

Risk Assessment/Discussion:

Dr. Howe has submitted a renewal of his IBC protocol entitled *Biology of Coccidian Parasites*. Dr. Howe's laboratory studies coccidian parasites, a class of intracellular protozoan parasites that include *Toxoplasma gondii*, *Sarcocystis* spp., and *Neospora* spp. *Sarcocystis* spp. and *Neospora* spp. are not infectious to humans, however *T. gondii* is a RG2 human pathogen. Work with all intracellular protozoa and their cell cultures will be completed using BSL2 containment. This includes wearing appropriate PPE (lab coat, eye protection, and disposable gloves) and restricting manipulations to a BSC. Needles and other sharps are strictly prohibited, which greatly minimizes the risk of exposure to personnel. Parasites will be genetically manipulated to knock out genes of interest and express protein mutants. Plasmid constructs will be constructed to drive transcription, and CRISPR/Cas9 system will be utilized to create gene knockouts. Genes targeted for disruption include the SAG/SRS surface antigens, rhoptry (ROP) proteins, dense granule (GRA) proteins, microneme (MIC) proteins, members of the major facilitator superfamily (*MFS*) of transporter proteins, uracil phosphoribosyltransferase (UPRT) enzyme, and the hypoxanthine-xanthine-guanine phosphoribosyltransferase (HXGPRT) enzyme. Reporter molecules (ex. GFP) will also be introduced. It is important to note that a mutant DHFR gene is used as a drug selection marker for making stable transgenic *T. gondii*, however this confers resistance to pyrimethamine, which is commonly used to treat *T. gondii* infections in humans. Pyrimethamine-resistant *T. gondii* remains sensitive to sulfonamides, clindamycin, azithromycin, and atovaquone. Tetracycline and arprinocid are alternative therapeutic options, although they have not been tested in vivo. Laboratory personnel are trained to follow incident response procedures and contact UK Worker's Care in the event of potential exposure. Human cells may be utilized for parasite propagation, which introduces potential risk of exposure to human source materials and bloodborne pathogens. All biohazardous waste is inactivated and/or disposed of according to UK Research Safety guidelines. Dr. Howe's current IBC protocol will expire on January 26, 2026.

IBC Discussion & Vote:

The protocol renewal IBC-25-136 (version 9.0) was approved.

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Carrie Shaffer initiated the motion. Carol Pickett seconded the motion. All IBC members present (13) voted in favor of the motion.

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Conflicts of Interest: None
*

PI: Carl Bradley
IBC Protocol Number: IBC-25-159
Protocol Title: Research on endemic plant pathogens of agronomic field crops in Kentucky
Protocol Type: Renewal
Amendment To: N/A
Applicable Guidelines & Regulations: NIH Guidelines Section IV-B-7, UK Administrative Regulation 6.3, UK Administrative Regulation 6.9, OSHA Act of 1970 Clause 5(a)(1)
Maximum Containment Level: Biological Safety Level 2 - Plants (BSL2-P)
Primary Reviewers: A. Hunt, J. Smalle, B. Nelson

Brief Project Overview:

My research involves work with plant pathogens of agronomic field crops (primarily soybean, wheat, barley, rye, and canola) that are endemic to the state of Kentucky. All plant pathogens that are worked with in this lab are fungi and bacteria commonly found in most fields throughout the state of Kentucky that are considered NIH Risk Group 1. Kentucky farmers manage these diseases in their fields through the use of crop rotation, tillage, planting resistant varieties, and with seed-applied, soil-applied, or foliar-applied fungicides. My research is focused on evaluating management practices to control the plant diseases they cause. This work is done in the field and laboratory.

Summary of Biohazard Materials & Manipulations:

Manipulations Planned: Bacterial culture, DNA/RNA isolation/purification, Field trial(s), Histology, Imaging/Microscopy, PCR/qRT-PCR, Plant work, Propagation of infectious agents, Use of infectious agents
Transport: Yes
Materials Transported: Biohazardous Materials
Infectious Agent(s)/Natural Host(s): Phoma terrestris (RG1-fungus)/Corn, others/; Exserohilum turcicum (RG1-fungus) /Corn, grain sorghum/; Septoria tritci (RG1-fungus)/Wheat/; Corynespora cassiicola (RG2-fungus)/Soybean, others/; Phytophthora sojae (RG1-fungus)/Soybean/; Colletotrichum graminicola (RG1-fungus)/Corn, others/; Rhizoctonia solani (RG1-fungus)/Soybean, others/; Pythium ultimum (RG1-fungus)/Soybean, others/; Pythium sylvaticum (RG1-fungus)/Soybean/; Septoria glycines (RG1-fungus)/Soybean/; Stagonospora nodorum (RG1-fungus)/Wheat/; Bipolaris maydis (RG1-fungus)/Corn/; Biopolaris zeicola (RG1-fungus)/Corn/; Cercospora sojina (RG1-fungus)/Soybean/; Cercospora zeae-maydis (RG1-fungus)/Corn/; Stenocarpella macrospora (RG1-fungus)/Corn/; Stenocarpella maydis (RG1-fungus)/Corn/; Fusarium graminearum (RG1-fungus)/Corn, wheat, barley, others/; Macrophomina phaseolina (RG1-fungus)/Soybean, others/; Sclerotinia sclerotiorum (RG1-fungus)/Soybean, canola, others/; Clavibacter michiganensis subsp. nebraskensis (RG1-bacteria)/Corn/; Fusarium virguliforme (RG1-fungus)/Soybean/; Phomopsis longicolla (RG1-fungus)/Soybean/; Bipolaris sorokiniana (RG1-fungus) /Rye/; Calonectria ilicicola (RG1-fungus) /Soybean, peanut/; Cercospora flagellaris (RG1-fungus) /Soybean/; Cercospora kikuchii (RG1-fungus) /Soybean/; Diaporthe aspalathi (RG1-fungus)/Soybean/; Diaporthe caulivora (RG1-fungus)/Soybean/; Phytophthora sansomeana (RG1-

fungus)/Soybean, corn, others/; Pythium aphanidermatum (RG2-fungus)/Soybean, corn, others/; Pythium irregulare (RG1-fungus)/Soybean, corn, others
Source & Nature of Inserted Nucleic Acid(s) [Gene Information/Gene Source/Gene Category/Use of Construct/Host(s)/Vector(s)]: N/A
Vector(s) [Vector Category/Vector Technical Name]: N/A
Cell line(s) Used [Cell Line Type/Cell Line Technical Name]: N/A
Animal Use: No
Materials introduced into Animals [Animal Host Species/Biohazardous Material/Route of Administration/Restraint/Animal Experimental Procedures/PPE/Animal Housing/Agent Shedding/Special Practices & Procedures]: N/A

Risk Assessment/Discussion:

Dr. Bradley has submitted a renewal of his IBC protocol entitled *Research on endemic plant pathogens of agronomic field crops in Kentucky*. Dr. Bradley's laboratory works with plant pathogens of agronomic field crops (such as soybean, wheat, barley, rye, and canola) that are endemic to the state of Kentucky. Dr. Bradley's collection of fungal and bacterial plant pathogens includes isolates that originated from states outside of Kentucky, requiring an APHIS PPQ 526 permit. Dr. Bradley's work takes place within a traditional laboratory environment and in the field. Fungal plant pathogens are tested in the laboratory for resistance to specific fungicide. In the field, Dr. Bradley's laboratory seeks to investigate management of various diseases of agronomic field crops. In many cases, the isolates utilized to inoculate field plants will have originated from UK Research Farm properties. The plant pathogens in use are not known to be pathogenic to humans, although fungal plant pathogens can become opportunistic pathogens in immunocompromised individuals. Personnel are trained on the pathogens in use and steps required to minimize the potential for spread. Farm equipment is dedicated for field infections and personnel are required to wear dedicated boots while on UK farm properties. BSL2-P containment is utilized. Dr. Bradley's current IBC protocol will expire on January 18, 2026.

IBC Discussion & Vote:

The protocol renewal IBC-25-159 (version 9.0) was approved pending minor modifications as listed below:

*

PLANTS – Field Trials: – Please verify whether the attached PDF depicting the field trial location for Robinson Center, Jackson, KY is still accurate.

SCIENTIFIC SUMMARY – Please make note of the Robinson Center, Jackson, KY location listed in the Field Maps attachment if this location is still being utilized.

*

Arthur Hunt initiated the motion. Jan Smalle seconded the motion. All IBC members present (13) voted in favor of the motion.

*

Conflicts of Interest: None
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PI: Julie Pendergast
IBC Protocol Number: IBC-25-166
Protocol Title: Misalignment of Circadian Rhythms
Protocol Type: Renewal
Amendment To: N/A
Applicable Guidelines & Regulations: NIH Guidelines Section III-D-4, NIH Guidelines Section III-E-1, NIH Guidelines Section III-F, NIH Guidelines Section III-F-1, NIH Guidelines Section IV-B-7, OSHA Act of 1970 Clause 5(a)(1), OSHA 29 CFR 1910.1030, UK Administrative Regulation 6.3, UK Administrative Regulation 6.9
Maximum Containment Level: Biological Safety Level 2 (BSL2), Animal Biological Safety Level 1 (ABSL1)
Primary Reviewers: C. Haughton, D. Malherbe, M. Mendenhall

Brief Project Overview:

Obesity has reached epidemic proportions. More than 40% of adults in the U.S. are obese or morbidly obese. The obesity epidemic has been largely attributed to contemporary lifestyles which are characterized by disruption of daily rhythms of sleeping and eating. Eating a diet high in fat also disrupts daily rhythms, in particular, the circadian rhythm in the liver. One goal of the proposed research is to determine how disrupting the timing of the liver circadian clock causes obesity. A new mouse model, in which the timing of the circadian clock in the liver is altered, will be used to determine how metabolism is dysregulated by disruption of circadian rhythms. These studies could reveal the liver circadian clock as a target for novel drug therapies for obesity. We are also interested in developing novel therapeutics for treating obesity and diabetes in humans. We will perform a clinical study to determine if there is a best time of day to exercise. For this study, we will collect metabolic and circadian measurements before and after 4 weeks of timed exercise.

Summary of Biohazard Materials & Manipulations:

Manipulations Planned: Animal work (breeding, surgeries, etc.), Cell culture, Use of Human Source Material(s), Use of infectious agents, Use of viral vectors, Immunohistochemistry, Imaging/Microscopy, PCR/qRT-PCR

Transport: Yes

Materials Transported: Biohazardous Materials

Infectious Agent(s)/Natural Host(s): Human Sourced Materials (RG2-cells, tissues, bodily fluids, organs, etc.)/Human

Source & Nature of Inserted Nucleic Acid(s) [Gene Information/Gene Source/Gene Category/Use of Construct/Host(s)/Vector(s)]: Cre recombinase/P1 bacteriophage enzyme/knockdown/mouse/AAV; GFP/Aequorea victoria/tracking gene/expression/mouse/AAV

Vector(s) [Vector Category/Vector Technical Name]: Adeno-Associated Virus (AAV)/AAV-Cre-GFP Vector Biolabs 7018; Adeno-Associated Virus (AAV)/AAV-GFP, Vector Biolabs 7006

Cell line(s) Used [Cell Line Type/Cell Line Technical Name]: Animal/tissues/organs dissected from mice in our animal facility

Animal Use: Yes

Materials introduced into Animals [Animal Host Species/Biohazardous Material/Route of Administration/Restraint/Animal Experimental Procedures/PPE/Animal Housing/Agent Shedding/Special Practices & Procedures]: Mouse/Viral Vector - Adeno-Associated Virus (AAV)/injection into brain/anesthesia/ABSL1/gown/lab coat, surgical gloves, hair cap, and safety glasses/ABSL1/No

Risk Assessment/Discussion:

Dr. Pendergast has submitted a renewal of her IBC protocol entitled *Misalignment of Circadian Rhythms*. Dr. Pendergast's laboratory utilizes AAV constructs purchased from Vector Biolabs to introduce Cre recombinase and GFP will be administered to anesthetized WT or floxed mice via stereotaxic injection. Mice will be allowed to recover from surgery and will be placed on different diets. Body weight and composition will be monitored, and mice will undergo various downstream assays. 1-7 weeks after AAV administration, mice will be euthanized and tissues will be extracted for imaging, biochemistry, and immunohistochemistry. This work will be completed using BSL1/ABSL1 housing and containment. Personnel will wear lab coat, disposable gloves, and eye protection. A second project in Dr. Pendergast's laboratory utilizes human saliva samples to analyze saliva melatonin levels. Subjects will be asked to chew on a salivette and spit the salivette into a centrifuge tube. This will take place in TH Morgan. The tube is centrifuged and shipped to a 3rd party vendor that will perform melatonin assay. Additionally, they will utilize human blood obtained in the UK CCTS outpatient clinic. Glucose will be measured in the CCTS outpatient facility. Remaining blood samples will be either sent to an external vendor (ex. Quest) for further analysis, analyzed by the CCTS BAL Lab, or be stored in TH Morgan. Work with human source materials will take place using BSL2 containment. The primary risk of working with human source materials includes potential exposure to bloodborne pathogens or other unknown infectious agents. These risks are minimized via use of appropriate PPE (lab coat, disposable gloves, eye protection) and appropriate waste handling. Dr. Pendergast's current IBC protocol will expire on January 30, 2026.

IBC Discussion & Vote:

The protocol renewal IBC-25-166 (version 8.0) was approved pending minor modifications as listed below:

*

GENERAL INFORMATION – Shipping Information: The Scientific Summary indicates the shipment of samples, but there is no information about shipping personnel and DOT/IATA training records. If there is a departmental employee responsible for shipping, please add their name and training date to the protocol.

ANIMAL RESEARCH – Purchase/Transfer of Transgenic Animals: Please add a checkmark to “This work involves the purchase or transfer of transgenic rodents.”

DISINFECTANTS, EMERGENCY RESPONSE, TRANSPORT, WASTE – Transport (Animals): The protocol indicates some body mass measurements of animals in a core facility. Please add the transcription of transport of these animals to and from the facility.

SCIENTIFIC SUMMARY:

1. Please edit the first paragraph to remove the last incomplete sentence, “In syringes.”
2. Include information about what procedures are happening in the laboratory versus the core.
3. Provide details about the risk of needle sticks, how these risks will be mitigated, and how needles are being safely processed for reuse.
4. Regarding the use of human sourced samples, please indicate the safety precautions in use during centrifugation. Does the centrifuge have safety cups?
5. Two sets of transgenic mice are described, one from Jackson lab and the other from Vanderbilt. Please briefly describe what breed/strains are being used and how they are relevant to the biohazardous materials in use.
6. Describe how accidents and accidental exposures are handled and reported.
7. Please clarify what procedures are being done within a BSC versus the open lab bench.

*

Michael Mendenhall initiated the motion. Delphine Malherbe seconded the motion. All IBC members present (13) voted in favor of the motion.

*

Conflicts of Interest: None
*

PI: Jan Smalle
IBC Protocol Number: IBC-25-167
Protocol Title: Plant growth regulation and secondary metabolites
Protocol Type: Renewal
Amendment To: N/A
Applicable Guidelines & Regulations: NIH Guidelines Section III-E-2, NIH Guidelines Section III-F-1, NIH Guidelines Section III-F-2, NIH Guidelines Section III-F-3, NIH Guidelines Section III-F-4, NIH Guidelines Section III-F-5, NIH Guidelines Section III-F-8, NIH Guidelines Section IV-B-7, OSHA Act of 1970 Clause 5(a)(1), UK Administrative Regulation 6.3, UK Administrative Regulation 6.9
Maximum Containment Level: Biological Safety Level 1 - Plants (BSL1-P)
Primary Reviewers: A. Hunt, D. Harrison, M. Mendenhall

Brief Project Overview:

My lab investigates the role of hormones in plant growth. We have recently discovered that the secondary metabolite trans-cinnamic acid (t-CA) promotes leaf growth at micromolar concentrations, suggesting that it acts hormonally on plant development. We aim to understand the mechanism that underpins this growth regulation by using a range of treatments aimed at differentiating between direct effects on leaf development or meristem function. We also analyze to what extent this leaf growth promotion effect occurs via interaction with other hormones involved in leaf growth.

In addition to its hormonal function, t-CA has anti-microbial activities which occur at higher concentrations of this compound. We aim to test if this activity could be used to help prevent decay of produce post-harvest, with a special focus on fruits.

Summary of Biohazard Materials & Manipulations:

Manipulations Planned: Plant work, Imaging/Microscopy, PCR/qRT-PCR
Transport: Yes
Materials Transported: Plants
Infectious Agent(s)/Natural Host(s): N/A
Source & Nature of Inserted Nucleic Acid(s) [Gene Information/Gene Source/Gene Category/Use of Construct/Host(s)/Vector(s)]: N/A
Vector(s) [Vector Category/Vector Technical Name]: N/A
Cell line(s) Used [Cell Line Type/Cell Line Technical Name]: N/A
Animal Use: No
Materials introduced into Animals [Animal Host Species/Biohazardous Material/Route of Administration/Restraint/Animal Experimental Procedures/PPE/Animal Housing/Agent Shedding/Special Practices & Procedures]: N/A

Risk Assessment/Discussion:

Dr. Smalle has submitted a renewal of his IBC protocol entitled *Plant growth regulation and secondary metabolites*. Dr. Smalle's laboratory studies the role of hormones in plant growth. Towards that aim, his laboratory utilizes an Arabidopsis model, as well as other plants (lettuce, dandelion, and tobacco), to determine the extent to which hormone functions are evolutionarily conserved. Plants are grown in tissue culture and on soil for genotype and phenotype assays, as well as crossing and seed harvesting. In a second project, Dr. Smalle's laboratory is working to investigate the potential of t-CA as a preservative to post-harvest produce. A range of organic fruits (strawberries, raspberries, blackberries) purchased from a grocery stored are treated with a variety of t-CA solutions. The effectiveness of treatments is determined by the rate of decay. Suppression of microbial growth will be assayed on tissue culture medium with colony counting. Dr. Smalle's laboratory does not work with any infectious agents. While it is possible that microbial growth from the second project may contain potential pathogens, this is unlikely. All work described in this IBC protocol will be completed using BSL1-P containment. Plants are grown in culture or in a growth chamber located in KTRDC 110B. Laboratory coat, disposable gloves, and eye protection are required for laboratory work. Dr. Smalle's current IBC protocol will expire on January 18, 2026.

IBC Discussion & Vote:

Jan Smalle left the meeting at 12:55pm during discussion of his IBC protocol

The protocol renewal IBC-25-167 (version 8.0) was approved pending minor modifications as listed below:

*

GENERAL INFORMATION – Manipulations Planned: PCR/qtPCR is marked but there is no description of this work in the Scientific Summary. Please update the Summary or remove the checkmark here if not applicable.

RECOMBINANT and/or SYNTHETIC NUCLEIC ACID MATERIALS - General: The question, “Does your research involve recombinant or synthetic nucleic acid molecules or organisms,” is marked YES but there is no information about the creation of transgenic plants. Please either update the section with the recombinant work being performed or change the answer to this question to NO.

SCIENTIFIC SUMMARY:

1. If PCR/qtPCR work is being performed, please include a brief description of this work.
2. Please clarify - If transgenic plants are being created, please include details in the Summary. If transgenic plants are being sourced and not created, please include this information in the Summary.

*

Doug Harrison initiated the motion. Mike Mendenhall seconded the motion. All IBC members present (12) voted in favor of the motion. Jan Smalle was not present for vote.

*

Conflicts of Interest: None
*

Incident Review

Nothing to report.

Protocol Issued Registration Numbers

Protocols issued registration numbers, including minor amendments. These protocols are exempt from IBC review and are registered with the UK Biological Safety Officer (BSO).

Stowe, Ann Neuroinflammation after stroke Renewal BSO 01/13/26 IBC-25-147 (v.14.0)

Gordon, Scott Lipoprotein Physiology in Metabolism and Atherosclerosis Amendment BSO 01/13/26 IBC-24-453 (v.33.0)

Feola, David Mechanisms of Alternative Macrophage Activation Amendment BSO 01/13/26 IBC-24-124 (v.32.0) Thibault, Olivier Constitutively active insulin receptors in the brain of rodents Amendment BSO 01/13/26 IBC-25-141 (v.18.0)

Bauer, John B22-4140-M: KCH Office of Pediatric Research Amendment BSO 01/08/26 IBC-24-309 (v.21.0)

Dutch, Rebecca Purification of Viral Vectors with Electrodialysis Using Ultrafiltration Membranes Amendment BSO 01/08/26 IBC-24-398 (v.39.0)

Voss, Stephen Randal Salamander Genome Project Amendment BSO 12/22/25 IBC-24-441 (v.27.0)

Suzuki, Yasuhiro Molecular and cellular mechanisms of host resistance against Toxoplasma gondii Amendment BSO 12/19/25 IBC-24-421 (v.17.0)

Tian, Changhai Intra- and Inter-organ communications by extracellular vesicles in the pathogenesis of cardiovascular and neurodegenertive disorders Amendment BSO 12/19/25 IBC-24-402 (v.34.0)

Harris, Hannah THE EFFECTS OF REPEATED CBD ADMINISTRATION ON CANNABIS ABUSE LIABILITY AND ANALGESIA: A HUMAN LABORATORY STUDY New BSO 12/19/25 IBC-25-182 (v.10.0)
Sheppard, Mary Mechanisms of Aortic Disease Amendment BSO 12/18/25 IBC-24-165 (v.25.0)
Weisleder, Noah Modifying gene expression in vitro and in vivo Amendment BSO 12/17/25 IBC-24-499 (v.64.0)

Wong, Lesley B23-3091: Breast Capsule Biobank Amendment BSO 12/16/25 IBC-24-26 (v.13.0)
Xiao, Xu Intracellular Cholesterol transport in metabolic diseases Amendment BSO 12/12/25 IBC-24-469 (v.47.0)

Pinto, Amelia Risk group two virus protocol Amendment BSO 12/11/25 IBC-24-83 (v.51.0)

Shaddox, Luciana 1. Analysis of Host-Biofilm Interactions: A Novel Polymicrobial model 2: Evaluation of different risk factors on periodontal disease and caries 3: COVID-19 testing using Saliva and Nasal swabs 4. Analyze and characterize the oral microbiome in the presence COVID-19 in the Saliva and Dental plaque samples 5. Understanding the association between buprenorphine and oral health outcomes 6. Advancing Salivary Biomarker Development and Utility in Periodontitis 7. Targeting Health Disparities: Engineering Antimicrobial and Remineralizing Dental Resins for Therapeutic and Preventive Care in Underserved Communities Amendment BSO 12/11/25 IBC-24-349 (v.61.0)

Gipson-Reichardt, Cassandra Glutamate, Neuroinflammation, Acetylcholine, and Addiction Amendment BSO 12/09/25 IBC-24-350 (v.76.0)

Protocols Meeting Registration Requirements

Protocols that have been approved by the IBC pending minor modifications that have met approval requirements.

Gerber, Anthony Epigenetic and transcriptional and mechanisms in ex vivo and cultured cell models of lung disease airway New IBC 01/09/26 IBC-25-143 (v.16.0)

Norian, Lyse Translational Immuno-oncology studies New IBC 01/05/26 IBC-25-137 (v.11.0)

Liu, Xiaoqi Plk1 in prostate cancer lineage plasticity New IBC 12/19/25 IBC-25-118 (v.14.0)

Patel, Samir Transplantation of transgenic-labeled mitochondria after spinal cord injury for neuroprotection. Mitochondrial transplantation combined with mitochondrial-targeted pharmaceuticals to treat spinal cord injury; Antioxidant therapy for spinal cord injury. Enhanced Mitochondrial Viability via Engineered Hydrogels for Intrathecal Spinal Cord Delivery. Renewal IBC 12/19/25 IBC-25-139 (v.14.0)

Piranavan, Paramarajan A Phase 2, open-label study to evaluate the efficacy and safety of rapcabtagene autoleucel in patients with active, refractory systemic lupus erythematosus (SLE) or active, refractory lupus nephritis (LN) Amendment IBC 12/17/25 IBC-24-422 (v.36.0)

Thibault, Olivier Constitutively active insulin receptors in the brain of rodents Renewal IBC 12/16/25 IBC-25-141 (v.12.0)

Stewart, Andrew Gene Therapy Approaches to Induce and Control Neuronal Growth in Rodents With Spinal Cord Injuries Amendment IBC 12/16/25 IBC-24-333 (v.90.0)

Zaytseva, Yekaterina The role of fatty acid metabolism in colorectal cancer Renewal IBC 12/16/25 IBC-25-156 (v.13.0)

Liu, Xia The mechanism of cancer metastasis Renewal IBC 12/15/25 IBC-25-144 (v.13.0)

Chen, Meifan B22-4076-M: Neural repair after injury to the central nervous system Renewal IBC 12/15/25 IBC-25-149 (v.13.0)

Geisler, Caroline Neuroendocrine Control of Systemic Metabolism and Energy Balance Amendment IBC 12/15/25 IBC-25-445 (v.34.0)

Tackenberg, Michael C. Genetic, molecular, and environmental determinants of circadian period length and output phase. New IBC 12/15/25 IBC-25-130 (v.13.0)

D'Orazio, Sarah Role of cell wall enzymes in the virulence of Streptococcus species Renewal IBC 12/11/25 IBC-25-133 (v.13.0)

Burgess, David B22-4115: Evaluation of gram negative and gram positive bacterial resistance mechanisms Renewal IBC 12/11/25 IBC-25-153 (v.10.0)

Plattner, Rina Role of Abl Family Kinases in Solid Tumors Amendment IBC 12/11/25 IBC-24-474 (v.25.0)

Papazoglou, Ioannis Neuronal response to hypoglycemia Amendment IBC 12/10/25 IBC-24-35 (v.45.0)

Emfinger, Christopher Unmasking conditional dependencies between key proteins influencing metabolic health. New IBC 12/08/25 IBC-25-103 (v.13.0)

Firestein, Bonnie Regulation of Dendritic Morphology and Function by Cypin, the Main Guanine Deaminase, and Other Proteins Amendment IBC 12/04/25 IBC-25-104 (v.17.0)

IBC Training

None. All current IBC members have completed training online via SciShield.

New Business

Delena Mazzetti provided a reminder that the Region 3 public listening session for NIH Modernizing and Strengthening Oversight of Biosafety is scheduled to take place on January 15, 2026.

Adjournment

Douglas Harrison moved to adjourn the meeting at 1:05PM. Arthur Hunt seconded the motion. All members present (12) voted in favor.