Minutes of the CWRU Institutional Biosafety Committee

IBC of record for the Louis Stokes Cleveland VAMC

Meeting Date: July 9, 2026

Members Present:

Charles Bark, Scott Becka (alternate VA rep*), Cheryl Cameron, Ronald Conlon, Suhrim Fisher (Veterinarian), Monica Montano (Vice Chair), Sophia Onwuzulike, Ivy Samuels (VA rep), Koen van Besien, Pamela Vanderzalm, Marissa Wolfe (alternate Veterinarian*), Andrew Young

Ex-Officio Members and Guests:

Colleen Karlo (ex-officio), Lorrie Rice

Abstained from voting since primary VA rep and veterinarian were present.

Meeting Convened: 3:00 PM via Zoom

The Vice Chair reminded all members that any conflicts of interest related to a submission must be declared prior to the start of the discussion. Members with a conflict will be temporarily moved to the virtual waiting room for the duration of the relevant discussion.

Approval of Minutes

The IBC Chair asked members for discussion or additional changes to the draft minutes. There were minor changes recommended.

Motion: Approval of the June meeting minutes with the additional, specific changes.
For: 10 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Safety and Incident Reporting - None

Old Business

The incident report for the Drosophila labs was submitted to the NIH Office of Science Policy. Dr. Crown's IBC protocol was reviewed last month and is pending approval. Today's agenda includes IBC submissions for the other labs included in the report.

Review of New Protocols:

Investigator: Abhinav Acharya
Project Title: Modifying metabolite levels in the gut using probiotics
IBC Protocol: #IBC-2026-579

Project Overview, Risk Assessment and Discussion:
The research will utilize plasmid vectors to genetically modify E. coli Nissle 1917 to express a gene from Aspergillus niger. These modified bacteria will be administered to animal models and the animals housed in a standard housing room. Work practices and procedures are appropriate for the planned research.

NIH Guidelines: III-D-2, III-D-4

Training and Facilities: There are a few individuals that need training and they will be notified to complete training. There were no concerns regarding the facilities to accommodate the safety and containment requirements of the proposed experiments.

Vote: Approve at BSL1 with minor edits and completion of training.
For: 10 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Investigator: Thomas Kelley
Project Title: Assessing CFTR deficiency in neuronal cells
IBC Protocol: #IBC-2026-580

Project Overview, Risk Assessment and Discussion:
This cell culture study involves recombinant genetic modifications utilizing a replication-incompetent lentivirus vector system in murine cells in culture. The lentivirus will deliver Cas9 and gRNAs to generate a gene knockout. Addition of safety measures for the use of centrifuges should be added. Other work practices, procedures, and facilities are consistent with BSL2 standards and appropriate for the planned research.

NIH Guidelines: III-D-1, III-D-3

Training and Facilities: There are a few individuals that need training and they will be notified to complete training. There were no concerns regarding the facilities to accommodate the safety and containment requirements of the proposed experiments.

Vote: Approve at BSL2 with minor edits and completion of training.
For: 10 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Investigator: Seungyup Lee
Project Title: Delivery Amplification of Adeno-Associated Viral Vectors
IBC Protocol: #IBC-2026-583

Project Overview, Risk Assessment and Discussion:
This protocol involves the use of replication incompetent recombinant adeno-associated viral (AAV) vectors to deliver reporter genes into an animal model. Discussion of the facilities for administration to the animals identified some changes needed to the study protocol. With those changes, work practices and procedures are appropriate for the planned research.

NIH Guidelines: III-D-4

Training and Facilities: Training in the NIH Guidelines is needed. There were no concerns regarding the facilities to accommodate the safety and containment requirements of the proposed experiments.

Vote: Approve at BSL1 with minor edits and completion of training.
For: 10 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Investigator: Jonathan Stamler
Project Title: A novel nitrosylase that prevents hypoglycemia and mediates insulin resistance
IBC Protocol: #IBC-2026-586

Project Overview, Risk Assessment and Discussion:
This study involves the use of non-exempt Escherichia coli to produce proteins to be used for cell assays. Plasmids expressing CRISPR/Cas9 components will be introduced into human and rat cell lines to generate stable gene knockout lines. Work practices and procedures are consistent with BSL2 standards and appropriate for the planned research.

NIH Guidelines: III-E

Training and Facilities: There are a few individuals that need training and they will be notified to complete training. There were no concerns regarding the facilities to accommodate the safety and containment requirements of the proposed experiments.

Vote: Approve at BSL2 upon completion of training
For: 10 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Investigator: Masashi Tabuchi
Project Title: Generation, Maintenance, and Experimental Use of Non-Gene-Drive Transgenic Drosophila melanogaster for Studies of Circadian Regulation of Sleep
IBC Protocol: #IBC-2026-584

Project Overview, Risk Assessment and Discussion:
This project involves the generation, maintenance, and experimental use of genetically modified Drosophila melanogaster. The research utilizes recombinant and synthetic nucleic acid molecules, including the GAL4/UAS and LexA/LexAop systems, to express fluorescent and enzymatic reporter genes and calcium indicators. Work practices, procedures, and facilities are appropriate for containment and disposal of the invertebrates.

NIH Guidelines: III-D-4

Training and Facilities: Individuals need training, and they will be notified to complete training. There were no concerns regarding the facilities to accommodate the safety and containment requirements of the proposed experiments.

Vote: Approve at BSL1 with minor edits and completion of training.
For: 10 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Investigator: Robert Ward
Project Title: Investigating mechanisms of tissue morphogenesis in Drosophila melanogaster
IBC Protocol: #IBC-2026-587

Project Overview, Risk Assessment and Discussion:
This research involves the use of Drosophila melanogaster and involves approximately 450 fly stocks, the majority of which contain recombinant or synthetic nucleic acid molecules. These genetic modifications include fluorescently tagged reporter genes, the UAS/GAL4 binary expression system, FLP/FRT recombinases, RNA

interference constructs, and CRISPR/Cas9 components used for gene knockdown and editing. Work practices, procedures, and facilities are appropriate for containment and disposal of the invertebrates.

NIH Guidelines: III-D-4

Training and Facilities: The Investigator and laboratory staff have completed training in the NIH Guidelines, lab safety, and biosafety. There were no concerns regarding the facilities to accommodate the safety and containment requirements of the proposed experiments.

Vote: Approve at BSL1 with minor edits.
For: 10 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Investigator: Jessica Fox
Project Title: Fox lab neurogenetics
IBC Protocol: #IBC-2026-588

Project Overview, Risk Assessment and Discussion:
This research involves the purchase of genetically modified fruit flies (Drosophila) containing recombinant nucleic acid molecules. The recombinant materials express foreign genes within the flies' neurons, specifically fluorescent proteins and light-activated ion channels. Work practices, procedures, and facilities are appropriate for containment and disposal of the invertebrates.

NIH Guidelines: III-D-4

Training and Facilities: Individuals need training, and they will be notified to complete training. There were no concerns regarding the facilities to accommodate the safety and containment requirements of the proposed experiments.

Vote: Approve at BSL1 with minor edits and completion of training.
For: 10 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Investigator: Andrew Dacks
Project Title: Dacks Lab standard operating procedures for working with Drosophila.
IBC Protocol: #IBC-2026-585

Project Overview, Risk Assessment and Discussion:

The research involves genetically modified Drosophila melanogaster expressing fluorescent and nanotag reporters, small interfering RNAs (siRNAs), and Cas9/gRNAs. Some fly crosses utilize binary expression systems, including expression of the light chain of botulinum toxin in a subset of neurons within the progeny. This is the enzymatically active component of the toxin; however, its expression is restricted within specific cells and lacks the heavy chain which mitigates risk of exposure to the toxin since it lacks the ability to cross the cell membrane. The flies from botulinum toxin crosses need to be autoclaved to inactivate the toxin. This experiment will be submitted to NIH OSP for approval under Section III-B. Work practices, procedures, and facilities are appropriate for containment and disposal of the invertebrates. PI should note export controls apply to the strain containing the botulinum toxin sequence.

NIH Guidelines: III-D-4

Training and Facilities: Individuals need training, and they will be notified to complete training. There were no concerns regarding the facilities to accommodate the safety and containment requirements of the proposed experiments.

Vote: Approve at BSL1 with minor edits, completion of training, and approval from NIH OSP
For: 10 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Review of Continuing Protocols:

Investigator: Alex Gifford
Project Title: An Open-label, Phase 1/2 Trial of Gene Therapy 4D-710 in Adults with Cystic Fibrosis
IBC Protocol: #IBC-2021-437

Project Overview, Risk Assessment and Discussion:
The study uses a recombinant AAV vector expressing human ACFTR gene for aerosol administration to research participants. Respiratory protection will be worn by researchers present during administration and the administration will be done in a negative pressure room.

NIH Guidelines: III-C

Training and Facilities: The investigators have completed training. There were no concerns regarding the facilities to accommodate the safety and containment requirements of the proposed experiments.

Vote: Approve at BSL1 with respiratory protection.
For: 10 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Dr. van Besien leaves the meeting.

Investigator: Robert Bonomo
Project Title: Novel Therapeutic Strategies to combat resistance in M. abscessus
IBC Protocol: #IBC-2023-479

Project Overview, Risk Assessment and Discussion:
This laboratory study involves the use of recombinant plasmid vectors in non-exempt strains of ***Escherichia coli*** for protein production and testing. The recombinant genetic materials code for enzymes derived from Mycobacterium abscessus. Work practices, procedures, and facilities are consistent with BSL2 standards and appropriate for the planned research. Disinfection procedures need to be revised to be consistent with regulations.

NIH Guidelines: III-D-2

Training and Facilities: Some training is needed and individuals will be notified. There were no concerns regarding the facilities to accommodate the safety and containment requirements of the proposed experiments.

Vote: Approve at BSL2 with minor edits and completion of training.
For: 9 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Investigator: Seth Field
Project Title: Regulation of intracellular signaling and membrane trafficking by phosphoinositides
IBC Protocol: #IBC-2020-376

Project Overview, Risk Assessment and Discussion:
This research project utilizes non-exempt E. coli bacteria for protein production, replication-defective retroviral and lentiviral vectors , and CRISPR/Cas9 plasmid vectors to express and alter genetic material (shRNA expression, gene knockout). These recombinant materials will be introduced into various human and murine cell lines maintained in cell culture. Additionally, the modified cancer cells will be administered into animals, and the animals will be housed in a standard housing room. Work practices, procedures, and facilities are consistent with BSL2 standards and appropriate for the planned research.

NIH Guidelines: III-D-1, III-D-3, III-D-4, III-E

Training and Facilities: A few individuals need training. There were no concerns regarding the facilities to accommodate the safety and containment requirements of the proposed experiments.

Vote: Approve at BSL2 upon completion of training.
For: 9 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Investigator: Christopher King
Project Title: Christopher L King : Defining targets of protective immunity in Plasmodium vivax using human monoclonal antibodies
IBC Protocol: #IBC-2020-366

Project Overview, Risk Assessment and Discussion:
This study utilizes recombinant plasmid DNA introduced into Escherichia coli bacteria (non-exempt) for production of proteins involved in immune response. The project also utilizes strains of the Plasmodium knowlesi that were previously modified by external investigators to alter or replace native genes with synthetic sequences from Plasmodium knowlesi or Plasmodium vivax. These laboratory experiments are designated as cell culture work only. Work practices, procedures, and facilities are consistent with BSL2 standards and appropriate for the planned research.

NIH Guidelines: III-D-1, III-D-2, III-E

Training and Facilities: Some training is needed and the individuals will be notified. Inspection of the facilities noted that the biosafety cabinet needs to be certified.

Vote: Approve at BSL2 upon completion of training.
For: 9 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Investigator: Anirban Sen Gupta
Project Title: Neutrophil-Targeted Nanomedicine for Treating Cancer Metastasis
IBC Protocol: #IBC-2023-485

Project Overview, Risk Assessment and Discussion:
The proposed study involves mouse and human cell lines genetically modified with recombinant DNA to be used in cell culture work and animal models The recombinant material consists of a firefly luciferase gene that functions as a luminescent reporter marker. No bacteria, viruses, or viral vectors are used in these procedures.

Work practices, procedures, and facilities are consistent with BSL2 standards and appropriate for the planned research. Animals will be housed in a standard housing room.

NIH Guidelines: III-D-4

Training and Facilities: Some training has expired and the individuals will be notified. There were no concerns regarding the facilities to accommodate the safety and containment requirements of the proposed experiments.

Vote: Approve at BSL2 with minor edits and completion of training.
For: 9 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Review of Amendments:

Investigator: Jeffrey Schelling
Project Title: Role of FATP2 in Regulating Alpha-Cell-Derived GLP-1 Synthesis and Secretion: Implications for Type 2 Diabetes Therapy
IBC Protocol: #IBC-2025-565

Project Overview, Risk Assessment and Discussion:
The approved protocol included the use of replication incompetent lentiviral vectors in cell culture experiments. The amendment adds the introduction of AAV into animal models which will be housed in a standard housing room. The viral vectors will deliver cDNA or shRNA for genes of interest. Work practices and procedures are consistent with BSL2 standards and appropriate for the planned research.

NIH Guidelines: III-D-1, III-D-3, III-D-4

Training and Facilities: The Investigator and laboratory staff have completed training in the NIH Guidelines, lab safety, and biosafety. There were no concerns regarding the facilities to accommodate the safety and containment requirements of the proposed experiments.

Vote: Approve at BSL2 with minor edits.
For: 9 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Ron Conlon leaves the meeting

Investigator: Ron Conlon
Project Title: Case Transgenic and Targeting Facility Core Protocol

IBC Protocol: #IBC-20080404

Project Overview, Risk Assessment and Discussion:
The committee reviewed the generation of new mouse models.

NIH Guidelines: III-E

Training and Facilities: The Investigator and laboratory staff have completed basic lab safety and biosafety training. There were no concerns regarding the facilities to accommodate the safety and containment requirements of the proposed experiments.

Vote: Approve at BSL1
For: 8 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Ron Conlon returns

Notes to Committee:

Administrative Amendments

IBC #	PI	Title	Amendment
IBC-2025-548	Clayton	Modulating glial cell state in vivo using viral gene expression and modulation	Personnel
IBC-2025-549	Clayton	Modulating glial cell state in vitro using viral gene expression and modulation	Personnel
IBC-2024-513	Farr	Production of EcoHIV	Personnel

Notices of Closed Protocols/Terminations

IBC #	PI	Title
IBC-2017-275	Xiong	Investigations of Neuromuscular junction regeneration, and the pathological mechanisms of Alzheimer' Disease and Osteoporosis
IBC -2023-484	Mahipal	A Phase 1b Study to Evaluate the Safety, Tolerability and Preliminary Efficacy of ATP150/ATP152, VSV-GP154 and Ezabenlimab (BI 754091) in Patients with KRAS G12D/G12V Mutated Pancreatic Ductal Adenocarcinoma
IBC-20110305	Hatzoglou	Regulation of gene expression during stress
IBC-2023-482	Jin	Extracellular vesicles and tumor progression and immunotherapy

Next Meeting: August 13, 2026

Meeting Adjourned: 4:10 PM.

IBC Meeting Minutes, July 9, 2026