Minutes of the CWRU Institutional Biosafety Committee

IBC of record for the Louis Stokes Cleveland VAMC

Meeting Date: November 13, 2025

Members Present:

Charles Bark, Scott Becka (alternate VA rep*), Cheryl Cameron, Ronald Conlon, John Durfee, Craig Hodges (Chair), Kenneth Matreyek, Monica Montano (Vice Chair), Sophia Onwuzulike, Reshmi Parameswaran, Alexander Rodriguez-Palacios, Ivy Samuels (VA rep), Aaron Severson, Koen van Besien, Pamela Vanderzalm, Andrew Young

Ex-Officio Members and Guests:

Colleen Karlo, Lorrie Rice

Abstained from voting since VA rep was present.

Meeting Convened: 3:01 PM via Zoom

The 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 October meeting minutes with the additional, specific changes.
For: 14 | Absent: 1 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Safety and Incident Reporting - None

Prior Business:

The January IBC meeting will be held on Thursday January 15, 2025. The IBC Charter has been approved by the Institutional Official and has been posted to the IBC website.

Review of New Protocols:

Investigator: Allison Kraus
Project Title: Defining cellular mechanisms that contribute to the initiation of and response to protein seeding, aggregation, and spread.
IBC Protocol: #IBC-2025-563

Project Overview, Risk Assessment and Discussion:
The investigator will be using replication incompetent lentiviral vectors (3 plasmid system) and AAV to modulate expression of proteins in cultures of human iPSC lines, either overexpressing with cDNA or knockdown using shRNA. Work practices, procedures, and facilities are consistent with BSL2 containment and appropriate for the planned research.

NIH Guidelines: III-D-1, III-D-3, 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 BSL2
For: 14 | Absent: 1 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Dr. van Besien arrives, Sophia Onwuzulike leaves the meeting.

Review of Continuing Protocols:

Investigator: Andrew Blum **VA Research**
Project Title: TGFbeta and Smad Signaling Components in Esophageal Adenocarcinoma
IBC Protocol: #IBC-2019-355

Project Overview, Risk Assessment and Discussion:
The lab is using replication incompetent lentiviral vectors for overexpression of human genes in human cancer cells and non-malignant control cells in culture. Other experiments include the expression of shRNA or CRISPR components for targeting genes of interest. Work practices, procedures, and facilities are consistent with BSL2 containment and appropriate for the planned research.

NIH Guidelines: III-D-1
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, however an incorrect room number is listed on the study application and needs to be updated.

Vote: Approve at BSL2 with minor edits.
For: 14 | Absent: 1 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Investigator: Krishna Guda
Project Title: Identifying Cancer-Related Genes and Signaling Pathways through Genome-scale Screens
IBC Protocol: #IBC-2019-344

Project Overview, Risk Assessment and Discussion:
The research involves the use of replication incompetent lentiviral vectors for expression of shRNA or CRISPR/Cas9 components for gene knockdown or gene knockout in human cell lines in culture. Work practices, procedures, and facilities are consistent with BSL2 containment and appropriate for the planned research.

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

Training and Facilities: The Investigator and laboratory staff have completed basic lab safety and biosafety training. Inspection of the facilities noted that the signage for the room needs to be updated, and there are biosafety cabinets that need to be certified.

Vote: Approve at BSL2 with minor edits
For: 14 | Absent: 1 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Sophia Onwuzulike returns to the meeting.

Investigator: Gina Lewin
Project Title: Probing Polymicrobial Synergy using High Throughput Genomics
IBC Protocol: #IBC-2022-463

Project Overview, Risk Assessment and Discussion:
The research includes the creation and analysis of gene knockouts, transposon mutant libraries, and fluorescently tagged risk group 2 bacterial strains to study gene function, expression, and spatial organization in

cultured cells and in infected animal models. Work practices, procedures, and facilities are consistent with BSL2 containment and appropriate for the planned research and animals will be housed at ABSL2.

NIH Guidelines: III-D-1

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 BSL2
For: 15 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Investigator: Peder Lund
Project Title: Microbial molecules as metabolic precursors and nuclear receptor ligands regulating gut homeostasis
IBC Protocol: #IBC-2022-462

Project Overview, Risk Assessment and Discussion:
Replication incompetent lentiviral vectors will be used for overexpression and shRNA knockdown experiments. Genetic knockouts with guide-RNA and purified Cas9 are also described. The work will be conducted in human and murine cells in culture. Work practices, procedures, and facilities are consistent with BSL2 containment and appropriate for the planned research.

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

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 BSL2
For: 15 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Investigator: Douglas Rhee
Project Title: [redacted]adenovirus and lentivirus[redacted]
IBC Protocol: #IBC-2013-166

Project Overview, Risk Assessment and Discussion:
The researchers are using replication incompetent adenoviral and lentiviral vectors to overexpress, knockdown or knockout human genes in cell culture and in animal models. Animals will be housed at ABSL2 for 7 days following introduction of viral vectors. Work practices, procedures, and facilities are consistent with BSL2 containment and appropriate for the planned research, but minor edits are needed for the description of their handling of waste.

NIH Guidelines: III-D-1

Training and Facilities: The Investigator and laboratory staff have completed basic lab safety and biosafety training. Inspection of the facilities noted that the biosafety cabinet needs to be certified.

Vote: Approve at BSL2 with minor edits
For: 15 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Investigator: John Tilton
Project Title: Intracellular protein delivery using viral like particles
IBC Protocol: #IBC-2016-247

Project Overview, Risk Assessment and Discussion:
The proposed experiments aim to develop methods to use virus-like particles (VLPs) to deliver proteins into cultured cells. The VLPs are based on lentiviral vectors and will be loaded with Cre recombinase or Cas9:guide RNA RNPs that target either loxP sites or a frame-shifted RFP transgene. The design of the VLPs has multiple safety features to generate non-infectious particles and to maximize their ability to incorporate and deliver functional proteins. Work practices, procedures, and facilities are consistent with BSL2 containment and appropriate for the planned research.

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

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 BSL2 with minor edits.
For: 15 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Investigator: Rui Wang
Project Title: Paracrine role of endothelial cells in solid tumors
IBC Protocol: #IBC-2020-358

Project Overview, Risk Assessment and Discussion:
Replication incompetent lentiviral vectors will be used in human and murine cells in culture to establish stable expression of shRNAs. These cells will be introduced into animal models for further investigation, and these animals can be housed in a standard housing room. Work practices, procedures, and facilities are consistent with BSL2 containment, and safe sharps practices and PPE are described.

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

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. The protocol needs an update to the research locations.

Vote: Approve at BSL2 with minor edits.
For: 15 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Craig Hodges leaves the meeting. Monica Montano takes over as Chair.

Review of Amendments:

Investigator: Craig Hodges
Project Title: Cystic Fibrosis correction through gene editing
IBC Protocol: #IBC-2019-346

Project Overview, Risk Assessment and Discussion:
The amendment adds a new AAV serotype and a helper dependent adenovirus (HDAd) vector system for delivery of gene editing components. It was noted that the HDAd is produced using a helper virus (first generation adenovirus) and the resulting HDAd product is likely to contain a low level of helper virus and animals should be housed at ABSL2. Work practices, procedures, and facilities are consistent with BSL2 containment and appropriate for the planned research.

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

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 BSL2 with minor edits.
For: 14 | Absent: 0 | Against: 0 | Conflict of Interest: 1 | Abstained: 1

Craig Hodges returns to the meeting and resumes as Chair. Reshmi Parameswaran leaves the meeting.

Investigator: Reshmi Parameswaran
Project Title: Regulation of Natural Killer cell function by NF-kB.
IBC Protocol: #IBC-2016-244

Project Overview, Risk Assessment and Discussion:
The amendment is adding the murine orthologs of genes that were previously approved, to be expressed using replication incompetent lentiviral vectors. These will be used to transduce murine cells in culture.

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

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 BSL2
For: 14 | Absent: 0 | Against: 0 | Conflict of Interest: 1 | Abstained: 1

Reshmi Parameswaran returns to the meeting.

Investigator: David Wald
Project Title: Genetic Modifications of NK cells
IBC Protocol: #IBC-2020-370

Project Overview, Risk Assessment and Discussion:

The amendment to the protocol for use of lentiviral vectors for NK and T cell modification adds new transgenes, which are not known to pose new biosafety risks. Work practices, procedures, and facilities are consistent with BSL2 containment and appropriate for the planned research, and animals should be housed at ABSL2 for 7 days.

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

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 BSL2
For: 15 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

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. There were no concerns regarding the procedures and facilities to accommodate the safety and containment requirements of the proposed experiments.

NIH Guidelines: III-E

Vote: Approve at BSL1
For: 14 | Absent: 0 | Against: 0 | Conflict of Interest: 1 | Abstained: 1

Ron Conlon returns to the meeting.

Notice of Administrative Amendments

IBC #	PI	Title	Amendment
2021-405	Wald	Cellular Therapy Testing in Cancer Model	Addition of personnel and research location
2023-484	Mahipal	A Phase 1b Study to Evaluate the Safety, Tolerability and Preliminary Efficacy of	Updated clinical protocol document with no changes to agent/risk assessment

		ATP150/ATP152, VSV-GP154 and Ezabenlimab (BI 754091) in Patients with KRAS G12D/G12V Mutated Pancreatic Ductal Adenocarcinoma	

Notice of Terminated Protocols

IBC #	PI	Title
2019-352	Zhou	Novel regulation of renal function by S-nitrosylation

Next Meeting: December 11, 2025

Meeting Adjourned: 3:57 PM.