Minutes of the CWRU Institutional Biosafety Committee

IBC of record for the Louis Stokes Cleveland VAMC

Meeting Date: February 12, 2026

Members Present:

Charlie Bark, Scott Becka (alternate VA rep*), Ronald Conlon, Suhrim Fisher, Craig Hodges (Chair), Kenneth Matreyek, Monica Montano (Vice Chair), Sophia Onwuzulike, Reshmi Parameswaran, Ivy Samuels (VA rep), Aaron Severson, Pamela Vanderzalm, Andrew Young

Ex-Officio Members and Guests:

Colleen Karlo, Marissa Wolfe

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 January meeting minutes with the additional, specific changes.
For: 12 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Safety and Incident Reporting - None

Review of Initial Protocols:

Investigator: Stanley Bazarek
Project Title: Peripheral Human Motor Neuron Transplantation to Enhance Functional Recovery following Neurological Injury

IBC Protocol: #IBC-2026-569

Project Overview, Risk Assessment and Discussion:
The research utilizes differentiated human stem cells expressing a reporter gene introduced into animal models. Work practices and procedures are consistent with BSL2 standards and appropriate for the planned research, and the animals will be housed in a standard housing room following the administration of the cells. The committee has asked for edits on the number of stem cell lines to be used and it was confirmed that the acquisition of the human cells is evaluated for human subject research requirements. The biohazard disposal procedure was reviewed.

NIH Guidelines: III-D-4

Training and Facilities: The Investigator and laboratory staff have completed 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: 12 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Review of Continuing Protocols:

Investigator: Evan Deneris
Project Title: Regulation of Serotonergic Genes by both an adult and early postnatal deletion using either AAV Cre virus or using a Cre-inducible AAV to label serotonergic neurons with a reporter or over expression using Lentivirus.
IBC Protocol: #IBC-2014-179

Project Overview, Risk Assessment and Discussion:
The lab uses replication deficient recombinant AAV and lentiviral vectors for delivery of reporter genes and genes of interest into animal models. Work practices, procedures, and facilities are consistent with BSL2 standards, and safe sharps practices and PPE are described. Animals receiving lentiviral vectors will be housed at ABSL2 for 7 days.

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 was discussion regarding the room used for stereotaxic injections, and the committee was

comfortable with the proximity of the room to safety shower/eye wash and sink. There were no other concerns regarding the facilities to accommodate the safety and containment requirements of the proposed experiments.

Vote: Approve at BSL2
For: 12 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Investigator: Mark Jackson
Project Title: Identifying breast cancer genes by validation based insertional mutagenesis (VBIM)
IBC Protocol: #20071201

Project Overview, Risk Assessment and Discussion:
The research will involve the use of replication deficient lentiviral vectors to transduce human and murine cells in culture. The vectors will be designed to overexpress or knockdown genes (shRNA), edit genes to generate knockouts using CRISPR/Cas9 and sgRNAs, for random insertional mutagenesis, or the generation of CAR-T cells. The transduced cells may be introduced into mouse models and housed in a standard housing room. The committee noted that the procedures for the animal experiments were not detailed enough to complete a risk assessment.

Vote: Table for additional information
For: 13 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Investigator: Qingzhong Kong
Project Title: In vitro and in vivo Studies of Prions and Prionoids
IBC Protocol: #20070305

Project Overview, Risk Assessment and Discussion:
The research uses recombinant AAV for delivery of genes of interest, reporter genes, shRNA for gene knockdown, or gene editing components in both cell culture and in animal models. Nanoparticles will also be used for delivery of non-viral DNA vectors to cells and tissues. Some of the animal models will require ABSL2 housing. The committee discussed the addition of animal procedure details from the IACUC protocol as it relates to risk mitigation. Work practices, procedures, and facilities are consistent with BSL2 standards and appropriate for the planned research.

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

Training and Facilities: The Investigator and laboratory staff have completed basic lab safety and biosafety training. Inspection of the facilities noted that signage for a room is needed, and a biosafety cabinet needs to be certified.

Vote: Approve at BSL2 with minor edits
For: 12 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Investigator: Shujun Liu
Project Title: Aberrant Epigenetics in Cancer Pathogenesis and Drug Resistance
IBC Protocol: #IBC-2022-465

Project Overview, Risk Assessment and Discussion:
Replication deficient lentiviral vectors, AAV vectors, and retroviral vectors are being used to overexpress and knockdown human genes of interest or express reporter genes. Nanoparticles will be used to deliver RNA. These experiments will be done in cell culture as well as in animal models. Work practices, procedures, and facilities are consistent with BSL2 standards, and safe sharps practices and PPE are described. Animals receiving viral vectors will be housed at ABSL2 for 7 days.

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

Training and Facilities: Three 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 BSL2 upon completion of training.
For: 12 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Investigator: Zheng-Rong Lu
Project Title: Gene Therapy Using Gene Augmentation Technology for LCA Treatment
IBC Protocol: #IBC-2014-178

Project Overview, Risk Assessment and Discussion:
The research includes the use of recombinant AAV and nanoparticles in culture of human cell lines. rAAV is used for the delivery of a reporter gene, and nanoparticles are used for the delivery of plasmid DNA or proteins for gene expression or CRISPR/Cas gene editing. Work practices and procedures are consistent with BSL2 standards for handling human cells and appropriate for the planned research.

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

Training and Facilities: One individual needs 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 upon completion of training.
For: 12 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Investigator: Xin Qi
Project Title: Investigation of mitochondrial activity using AAV
IBC Protocol: #IBC-2020-365

Project Overview, Risk Assessment and Discussion:
The research uses replication deficient recombinant AAVs expressing rodent genes of interest or reporter genes. The AAVs will be administered to animal models. The transgenes to be expressed do not carry any additional risks and animals will be housed in a standard housing room. Work practices and procedures are consistent with BSL2 standards and appropriate for the planned research.

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

Training and Facilities: One individual needs 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 upon completion of training
For: 12 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Investigator: Ashleigh Schaffer
Project Title: Pathological mechanisms of pediatric neurodegenerative disorders
IBC Protocol: #IBC-2017-256

Project Overview, Risk Assessment and Discussion:
The protocol is being transferred to Dr. Helen Miranda, with no concern for her to serve as PI . Sendai virus or plasmid transfection will be used for iPSC reprogramming of cells in culture. Plasmids or replication

incompetent lentiviral vectors will be used for gene expression, Cas9 gene editing, or si/shRNA knockdown in human cells in culture. Work practices, procedures, and facilities are consistent with BSL2 standards and appropriate for the planned research.

NIH Guidelines: NIH Guidelines: III-D-1, III-D3

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

Vote: Approve at BSL2
For: 12 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Investigator: David Wald **VA Research**
Project Title: Targeting metabolism in AML VA title: Development of a kinase inhibitor for AML
IBC Protocol: #IBC-2020-359

Project Overview, Risk Assessment and Discussion:
The continuing research uses established human cancer cell lines expressing a reporter gene in animal models. Work practices, procedures, and facilities are consistent with BSL2 standards, and safe sharps practices and PPE are described. Animals will be housed in a standard housing room. Minor edits are needed regarding the disinfection of reusable sharps.

NIH Guidelines: 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: 12 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Ron Conlon leaves the meeting.

Review of Amendments:

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: 11 | Absent: 1 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Notes to Committee:

No administrative amendments or terminations were submitted

Next Meeting: March 12, 2026

Meeting Adjourned: 4:01 PM.