Draft Minutes of the CWRU Institutional Biosafety Committee

IBC of record for the Louis Stokes Cleveland VAMC

Meeting Date: April 9, 2026

Members Present:

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

Ex-Officio Members and Guests:

Colleen Karlo (ex-officio), Hibeh Fatteh and Priscah Norwood (bioethics students)

Abstained from voting since VA rep was present.

Meeting Convened: 3:00 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 March meeting minutes with the additional, specific changes.
For: 10 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Safety and Incident Reporting - None

Review of Continuing Protocols:

Investigator: Ann Harris
Project Title: Regulation of CFTR gene expression
IBC Protocol: #IBC-2017-262

Project Overview, Risk Assessment and Discussion:
The researchers will use mammalian expression vectors and synthetic RNAs, such as CRISPR/Cas9 systems, to deliver recombinant nucleic acids into cells. These recombinant materials consist of human genes, nucleases and reporter genes, and will be introduced into human epithelial cell cultures. Disinfection of liquid waste needs to be updated to be consistent with institutional recommendations (15% bleach for 30 min). Work practices, procedures, and facilities are consistent with BSL2 standards and appropriate for the planned research.

NIH Guidelines: III-E

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: 10 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Investigator: Christopher Hubert
Project Title: Studies of brain tumor cellular diversity and therapeutic sensitivities.
IBC Protocol: #IBC-2023-475

Project Overview, Risk Assessment and Discussion:
The research will use non-replicating lentiviral vectors to deliver modified genetic material into cells. The recombinant nucleic acids consist of genes encoding human proteins, markers, and CRISPR editing enzymes. Researchers will first introduce these genetic modifications into brain tumor cells in cell culture. The following experiments will introduce the stably modified tumor cells into animal models, which will be housed in a standard housing room.

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

Training and Facilities: A few personnel are due for retraining. 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: 1

Investigator: Tae Hun Kim
Project Title: Investigating transcription and DNA damage repair in the context of nucleosomes
IBC Protocol: #IBC-2023-476

Project Overview, Risk Assessment and Discussion:
This protocol uses recombinant DNA plasmids to produce specific proteins inside E. coli bacterial cells. The synthetic genetic materials encode humans, rodents, yeast, and bacteria structural histones, endonucleases, and DNA repair molecules. Work practices, procedures, and facilities are appropriate for the planned research.

NIH Guidelines: III-E

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: 1

Investigator: Pushpa Pandiyan
Project Title: Human Immunodeficiency Virus in vitro infection protocol
IBC Protocol: #IBC-2023-473

Project Overview, Risk Assessment and Discussion:
The proposed study involves the generation of HIV-1 infectious viral particles expressing a reporter gene. Researchers will use human cell lines (HEK-293T) to generate the virus and will infect primary human cells grown in cell culture. The committee discussed additional centrifuge safety measures to be added to the protocol. Work practices, procedures, and facilities are consistent with BSL2 standards with added BSL3 practices (Tyvek suits, double gloves) and appropriate for the planned research.

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

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: 10 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Investigator: Peng Zhang
Project Title: Investigating Molecular and Cellular Mechanisms of Synapse Development
IBC Protocol: #IBC-2020-368

Project Overview, Risk Assessment and Discussion:
This research project uses viral vectors, specifically adeno-associated viruses (AAVs) and lentiviruses, alongside antisense oligonucleotides and CRISPR/Cas9 gene-editing tools. These tools will deliver specific genetic material, including human and rodent genes, as well as guide RNAs and fluorescent reporter proteins to rodent neuron cultures and animal models. Animals will be housed in a standard housing room. Work practices, procedures, and facilities are consistent with BSL2 standards, and safe sharps practices and PPE are described.

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. Inspection of the facilities noted that the signage for the room needs to be updated, and the biosafety cabinet needs to be certified.

Vote: Approve at BSL2.
For: 10 | Against: 0 | Conflict of Interest: 0| Abstained: 1

Scott Becka leaves the meeting.

Review of Amendments:

Investigator: Robert Bonomo **VA Research**
Project Title: Bonomo Studies
IBC Protocol: #IBC-2020-383

Project Overview, Risk Assessment and Discussion:
The laboratory uses recombinant DNA containing genes from several bacteria species, inserted into plasmids and introduced into E. coli bacterial cell cultures to generate proteins. The amendment adds additional E. coli strains, laboratory locations, and bacterial genes to be investigated. Work practices, procedures, and facilities are consistent with BSL2 standards and appropriate for the planned research.

NIH Guidelines: NIH Guidelines: III-D-2

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

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

Investigator: Arne Rietsch
Project Title: Pseudomonas aeruginosa virulence
IBC Protocol: #IBC-2018-297

Project Overview, Risk Assessment and Discussion:
This study involves creating and using recombinant Pseudomonas aeruginosa and E. coli bacteria. The amendment adds plans to genetically modify bacteriophage and updates in personnel and funding. The PI provided additional risk assessment information regarding the planned modifications to the committee via email, and the committee stipulated that this information needs to be added to the study application. Work practices, procedures, and facilities are consistent with BSL2 standards and appropriate for the planned research.

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

Training and Facilities: Two 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 approved with minor edits
For: 10 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Ron Conlon moved to the waiting room.

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: 9 | Against: 0 | Conflict of Interest: 1 (***Conlon***) | Abstained: 0

Ron Conlon returns to the meeting.

Notes to Committee:

Administrative Amendments

IBC #	PI	Title	Amendment
IBC-2025-560	Gan	Elucidating Novel PRMT Regulatory Mechanisms And Their Roles in Tumorigenesis	Update personnel
IBC-2018-296	Rietsch	Pseudomonas aeruginosa type III secretion system function	Update personnel
IBC-2023-471	Langel	Maternal immunization for generation of potently neutralizing antibodies in breast milk	Update personnel
IBC-2023-498	Gates	The role of metabolism in regulating chromatin and gene expression	Update personnel

Notices of Closed Protocols/Terminations

IBC #	PI	Title
IBC-2022-438	Park	Quality control test for GMP grade lenti viral vector
IBC-2022-467	Gryder	Therapeutically Targeting Super Clusters at Genes Driving Childhood Sarcoma
IBC-2023-495	Deng	Phase 1b Multicenter, Open-label, Study of JNJ-90009530, an Autologous Anti-CD20 CAR-T Cell Therapy in Adult Participants with Relapsed or Refractory B-cell Non- Hodgkin Lymphoma

Other Business:

C. Karlo presented a new document, IBC Researcher Manual, to be provided as a resource to the research community. The committee had no concerns, and the document will be taken to the Institutional Official for review and posted to the website once finalized.

Next Meeting: May 14, 2026

Meeting Adjourned: 3:45 PM.