



## **Minutes of the CWRU Institutional Biosafety Committee**

IBC of record for the Louis Stokes Cleveland VAMC

**Meeting Date: January 15, 2026**

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### **Members Present:**

Scott Becka (alternate VA rep\*), Cheryl Cameron, Ronald Conlon, Suhrim Fisher, Craig Hodges (Chair), Kenneth Matreyek, Monica Montano (Vice Chair), Sophia Onwuzulike, Reshmi Parameswaran, Alexander Rodriguez-Palacios, 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.*

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### **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.

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### **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 December meeting minutes with the additional, specific changes.

For: 13 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

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### **Safety and Incident Reporting - None**

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*Scott Becka leaves the meeting (waiting room).*

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### **Review of Continuing Protocols:**

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Investigator: Robert Bonomo

VA Research

Project Title: Targeting Burkholderial  $\beta$ -lactamases: Structure, function, and regulation

IBC Protocol: #IBC-2020-364

Project Overview, Risk Assessment and Discussion:

The research will utilize the BL21 strain of *E. coli* to express *Burkholderia multivorans* proteins for use in downstream assays. The lab will receive *Burkholderia* mutant strains to conduct a phenotypic assessment. The committee requested minor edits to clarify that the lab is not generating the bacterial mutant strains. Work practices, procedures, and facilities are consistent with BSL2 standards and appropriate for the planned research, however the research locations listed in the protocol need to be updated.

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

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

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Investigator: Robert Bonomo

VA Research

Project Title: Exploring the activity of cefepime-VNRX-5133 and ceftibuten-(VNRX-7145->VNRX-5236) against multi-drug resistant pathogens

IBC Protocol: #IBC-2020-363 10

Project Overview, Risk Assessment and Discussion:

The research will utilize the BL21 strain of *E. coli* to express *Burkholderia multivorans* and *Pseudomonas aeruginosa* proteins for use in downstream assays. Work practices, procedures, and facilities are consistent with BSL2 standards and appropriate for the planned research, however the research locations listed in the protocol need to be updated.

NIH Guidelines: III-D-2

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

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*Scott Becka returns to the meeting.*

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Investigator: Helen Miranda

Project Title: Stem cell modeling of neurological diseases

IBC Protocol: #IBC-2019-348

Project Overview, Risk Assessment and Discussion:

The research uses replication incompetent lentiviral vectors for expression of a reporter gene in human cells in culture, and plasmids will be used for gene editing. 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-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: 13 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

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Investigator: Sanjay Rajagopalan

Project Title: Inflammatory pathways in cardiovascular disease

IBC Protocol: #IBC-2018-315

Project Overview, Risk Assessment and Discussion:

The research will use a replication incompetent AAV for gene expression in animal models. Work practices, procedures, and facilities are consistent with BSL1 standards and appropriate for the planned research. Animals will be housed in a standard housing room.

NIH Guidelines: III-D-4



Training and Facilities: Two lab members 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 upon completion of training

For: 13 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

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Investigator: Jiri Safar

Project Title: Structural mechanisms forming prion and tau protein strains in neurodegenerative diseases.

IBC Protocol: #IBC-2022-464

Project Overview, Risk Assessment and Discussion:

The laboratory expresses prion and tau proteins and their fragments in E. coli for reference and substrates for protein studies. Work practices, procedures, and facilities are consistent with BSL2 standards and appropriate for the planned research.

NIH Guidelines: III-D-2

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

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Investigator: Julian Stelzer

Project Title: Rescue of cardiac myosin binding protein-C deficient hearts by gene transfer

IBC Protocol: #20110502

Project Overview, Risk Assessment and Discussion:

The research involves the generation of purified proteins resulting from introduction of expression plasmids in BL21 E. coli. In addition, the laboratory will utilize replication incompetent lentivirus and AAV in animal models. Animals used in lentivirus experiments will be housed at ABSL2 for 7 days. Work practices, procedures, and facilities are consistent with BSL2 standards for handling viruses, and safe sharps practices and PPE are described.



NIH Guidelines: III-D-1, III-D-3, 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 upon completion of training.

For: 13 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

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Investigator: Phoebe L Stewart

Project Title: Molecular mechanisms of adenovirus neutralization

IBC Protocol: #IBC-2023-469

Project Overview, Risk Assessment and Discussion:

The laboratory uses cryo-electron microscopy to visualize human adenovirus type-5 complexes, investigating both wild-type and modified Ad5 variants. Work practices, procedures, and facilities are consistent with BSL2 standards 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.

Vote: Approve at BSL2

For: 13 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

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### **Review of Amendments:**

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 amendment contains additional cell lines expressing recombinant DNA to be introduced into animal models. Work practices and procedures are consistent with BSL2 standards for handling human cells and appropriate for the planned research. Animals will be housed in a standard housing room.

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NIH Guidelines: III-D-4

Training and Facilities: The research team will be notified regarding training that is due. There were no concerns regarding the facilities to accommodate the safety and containment requirements for the amendment.

Vote: Approve at BSL2

For: 13 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

### Notice of Administrative Amendments

IBC #	PI	Title	Amendment
2024-527	Ignatz-Hoover	A phase 1 single arm, open label study to evaluate the safety of UF-KURE-BCMA cells in patients with relapsed or refractory Multiple Myeloma	Update personnel
2022-448	Deng	A phase 1 single arm, open-label study to evaluate the safety of UF-KURE19 cells in patients with relapsed or refractory B cell non-Hodgkin lymphomas	Update personnel
2021-395	Methany	Phase II Trial of O6-benzylguanine (BG) and Temozolomide (TMZ) therapy of glioblastoma multiforme (GBM) with infusion of autologous P140KMGMT + hematopoietic progenitors to protect hematopoiesis	Update personnel
2013-150	Wynshaw-Boris	Mouse and Cellular Models of Human Neurogenetic Diseases	Update personnel

### Notice of Terminated Protocols

IBC #	PI	Title
2022-448	Deng	A phase 1 single arm, open-label study to evaluate the safety of UF-KURE19 cells in patients with relapsed or refractory B cell non-Hodgkin lymphomas
2022-448	Deng	A phase 1 single arm, open-label study to evaluate the safety of UF-KURE19 cells in patients with relapsed or refractory B cell non-Hodgkin lymphomas

### Other business:

The committee provided feedback on additional facility questions to be added to the IBC continuing review form in response to trends noted in inspections (BSC certification and laboratory signs).

Researcher training in the NIH Guidelines will be added to SpartaLearn and required for all individuals on an IBC protocol. Communications are being prepared to inform the research community.

**Next Meeting:** February 12, 2026

**Meeting Adjourned:** 3:45 PM.

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