



Minutes of the CWRU Institutional Biosafety Committee

IBC of record for the Louis Stokes Cleveland VAMC

Meeting Date: October 9, 2025

Members Present:

Charles Bark, Scott Becka (alternate VA rep*), Ronald Conlon, Craig Hodges (Chair), 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, 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 September meeting minutes with the additional, specific changes.

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

Safety and Incident Reporting - None

Review of Continuing Protocols:

Investigator: Qingzhong Kong

Project Title: Development of gene and cell therapies for cancer, diabetes and neurodegenerative diseases

IBC Protocol: #IBC-2016-246

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Project Overview, Risk Assessment and Discussion:

The research will use plasmid or DNA vectors or recombinant adeno-associated vectors for transfection or transduction in human or murine cells in culture to express a therapeutic or reporter protein or shRNA to knock down gene expression. The recombinant vectors and cells modified in culture may also be introduced into animal models. Some of the animal models require ABSL2 housing. Work practices, procedures, and facilities are consistent with BSL2 containment, and safe sharps practices and PPE are described.

NIH Guidelines: III-D-4, 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: 10 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Reshmi Parameswaran is moved to the waiting room for a conflict of interest.

Investigator: Leland Metheny

Project Title: 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

IBC Protocol: #IBC-2021-395

Project Overview, Risk Assessment and Discussion:

The clinical study involves autologous hematopoietic stem cells transduced with a replication incompetent lentiviral vector to express a gene that protects cells from the toxic effects of chemotherapy. The manufacturing of the cells will be done locally, and the cell product administered to research participants after passing the release testing. Work practices, procedures, and facilities are consistent with BSL2 containment and appropriate for the planned research.

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

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



Vote: Approve at BSL2

For: 9 | Absent: 0 | Against: 0 | Conflict of Interest: 1 | Abstained: 1

Reshmi Parameswaran returns to the meeting.

Notice of Administrative Amendments

IBC #	PI	Title	Amendment
2019-347	Kraus	Ultrasensitive assays for protein aggregates	Updates to personnel, research location
2021-437	Gifford	An Open-label, Phase 1/2 Trial of Gene Therapy 4D-710 in Adultswith Cystic Fibrosis	Updates to clinical protocol, no change in study agent

Notice of Terminated Protocols

IBC #	PI	Title
2023-474	Konczal	A Phase 1/Phase 2, open-label, dose-escalation, and dose expansion study to evaluate the safety, tolerability, and efficacy of SAR444836, an adeno-associated viral vector-mediated gene transfer of human phenylalanine hydroxylase, in adult participants with phenylketonuria
2022-455	Luna	Cellular stress responses during SARS-CoV-2 replication

Other Business:

C. Karlo proposed a change to the meeting date for the January IBC meeting due to the holiday break. A poll will be sent to the committee members to verify their availability.

Overview slides from the first NIH Listening Session regarding the NIH initiative to modernize and strengthen biosafety oversight were shared with the committee members. The NIH widget to receive feedback on the initiative has been added to the CWRU IBC website.

Procedures for review of amendments to approved IBC protocols were presented for committee consideration and will be discussed at an upcoming meeting.

Next Meeting: November 13, 2025

Meeting Adjourned: 3:20 PM.

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