Minneapolis VA Health Care System
IBC (Institutional Biosafety Committee)

MEETING MINUTES

May 23, 2023

TEAMS

The meeting was called to order on May 23, 2023 at 5:00 PM and a quorum was present.

ATTENDANCE

Voting Members Present:

[redacted]	Deputy Heatlthcare Epidemiologist
[redacted]	Community Member
[redacted]	Chair
[redacted]	Attending Veterinarian
[redacted]	Community Member

Non-Voting Attendees, Staff and Guests Present:

Recording:

[redacted]	IBC Coordinator

ITEMS

1 **Welcome and Opening Remarks**

Two new members were introduced: [redacted]., and [redacted], Associate Director of Research of Geriatric Research, Education and Clinical Center (GRECC),will serve as the IBC Chair, and [redacted], Deputy Healthcare Epidemiologist, will serve as a voting member. Their expertise in Recombinant DNA and Infectious Disease, respectively, will be valuable additions to the IBC.

2 **Amendments**

2.1 **[redacted] Evaluation of Novel Devices, Techniques and Therapies for the Treatment of Vascular Disease Using a Swine Model**

PI:	Krista Walkowiak
Sponsor:	Pathway
Submission Type:	Amendment/Modification

Review Type: Full Committee Review
Action: Approved
Effective Date: May 23, 2023
Vote: Total = 5; For = 5; Opposed = 0; Abstained = 0;
Primary Reviewer: [redacted]

Discussion and Remarks:

The overall goal of this project is to evaluate the safety and efficacy of diagnostic and interventional procedures, devices, and/or techniques and therapies, in Swine, prior to use in humans, for the treatment of heart and vessel disease. The animal experiments will acutely and chronically evaluate the functionality of varying devices and/or techniques for the sole purpose of eventual use in humans.

The amendment is to address techniques required for a new potential *future* therapy for cardiovascular disease using recombinant DNA. As a first step, the PI plans to test an empty AAV vector for feasibility and safety of delivery of the empty AAV in heart tissue.

Of note is that the AAV viral vector is empty. It does not contain an insert, which is needed so the encoded genes can replicate within cells, and therefore it is not replication competent as it does not possess the required enzymatic machinery to do so. Based on this, it is not expected to cause any hazard or risk to VMU staff who are housing or caring for injected animals. The animals are housed in standard BSL1 conditions. No special PPE is required. In addition, the AAV will not be created in Building 49, and as such, the VMU, its staff and study personnel will not be exposed to AAV during this stage.

This renders the use of this empty AAV in the NIH risk group 1 category, which covers studies not associated with disease in healthy adult humans. These Exempt Experiments include synthetic nucleic acids that can neither replicate nor generate nucleic acids that can replicate in any living cell (e.g., oligonucleotides or other synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA polymerase).

Based on the above observations and after discussion, this study was deemed free of safety concerns for the VMU, staff and study personnel. A motion was made to approve that it does not require IBC oversight as it is a study that falls into the NIH risk group 1 category.

The committee also agreed that studies falling into the NIH risk group 1 category do not require full IBC committee review in the future, but rather, could be reviewed by one committee member.

3 Closures

3.1 [redacted] Impairment and recovery of CD4 T cell-dependent B cell responses after sepsis

PI: Thomas Griffith, Ph.D.
Reference Number: [redacted]
Submission Type: Closure/Final Report

Review Type: Administrative Review
Action: Closed
Effective Date: May 23, 2023
Project Status: Closed

Discussion and Remarks:

Project is closed. Bench work and sample analysis are completed, samples are not stored, and there are no security/safety incidents to report in the past year.

3.2 **[redacted] Orexin and serotonin interactions to promote physical activity and prevent obesity**

PI:	Catherine Kotz
Reference Number:	[redacted]
Sponsor:	Department of Veterans Affairs
Submission Type:	Closure/Final Report
Review Type:	Administrative Review
Action:	Closed
Effective Date:	May 23, 2023
Project Status:	Closed

Discussion and Remarks:

This study is closed - no hazards are in use and no samples are stored onsite. There have been no Safety/Security incidents to report from the past year.

4 **Adjourn**

The meeting adjourned on May 23, 2023 at 5:20 PM.

[redacted]