

PRESENT

Matt Finley, MBA, PhD (Chairman, Biological Safety Officer)
Talulla Palumbo, MS, LIMR Safety Officer (Alternate IBC Member)
Anthony Ashton, PhD (IBC Member)
Lauren Merlo, PhD (IBC Member)
Bindu Kumar, MD (IBC Member)
Andrea Sipple (Community Member)
Gwen Gilliard (Community Member)
Judy Daviau, VMD, (Veterinary Consultant)

NOT PRESENT

John Medendorp, MS, BSN, RN, CIP, Director ORP (IBC Member)
Kamila Bedelbaeva, PhD (IBC Member)

STAFF

Elene Mironidis
R. Brannon Claytor, MD, FACS
Grace Tolan, MD

Quorum = 8

The IBC January 14, 2025 meeting began at 2:03pm with the Chair reviewing the administrative action approval items listed below that were approved between September 2024 to present time of January 14th, 2025.

ADMINISTRATIVE ACTIONS:

1. **B24-3063:** Wallon - Pilot study of glutathione recycling capacity as predictive marker for new onset post-operative atrial fibrillation among patients undergoing heart surgery.
Protocol Approved via DMR (Sept. 30, 2024)
 2. **B22-2918:** Viatour - Molecular and cellular mechanisms of tumorigenesis upon disruption of the Rb pathway
Protocol Approved via DMR (Dec. 4, 2024)
- ❖ **Minutes:** The minutes for the September 10, 2024 meeting were reviewed and approved unanimously by a vote of 7 for, 0 against, and 1 abstaining.

MOTION TO APPROVE: Matt Finley, MBA, PhD

SECOND: Anthony Ashton, PhD

ABSTAIN: Judy Daviau, VMD

NEW BUSINESS

1. **R. Brannon Claytor, MD, FACS – New Protocol (B24-3064)** – At 2:04pm, Dr. Claytor and his Research Fellow, Grace Tolan, shared the details of his new protocol with the Committee to provide all members present the opportunity to engage and ask questions in real time. These are the new protocol points they stated:

At 2:06pm, Gwendolyn Gilliard joined the meeting.

- Surgery to be conducted at Bryn Mawr Hospital Operating Room; tissue samples transported to Lankenau Hospital for analysis.

- Extraction of tissue samples conducted by infusing tumescent fluid along with a small dose of epinephrine and a little lidocaine while patient is asleep to draw out fat (standard liposuction technique to be utilized)
- Grace Tolan to oversee transportation and initial processing of samples. Research aims to explore the impact of remote ischemic preconditioning on fat cell survivability.
- Second extraction of samples conducted with use of standard tourniquet method on patient's leg where Dr. Claytor is blowing it up for ten minutes and then letting it down for up to ten minutes
- Patients voluntarily participate, receiving reduced fees for liposuction procedures
- Double-bagged and temperature-controlled transport of tissue specimens.
- Analysis conducted over several days before sample destruction.

Following Dr. Claytor's overview of his new protocol, the Chair then opened the floor to the IBC to ask their questions and/or raise concerns to be clarified by Dr. Claytor.

- Dr. Kumar inquired with Grace of her role capacity within Main Line Health and her parameters she can work in.
- Grace confirmed she is cleared to be under the role of a shadower under 40 hours working.
- Dr. Kumar also inquired of whether Grace will enter the operating room as well and if she has completed the necessary training required for this research protocol. Grace confirmed that she indeed has completed such and LIMER's IBC has her certificates on file accordingly.
- Anthony Ashton granted feedback for Specify biosafety procedures for tissue processing, disposal, and protection of staff.

Dr. Claytor and Grace were excused from the meeting at 2:27pm to allow the Committee to continue discussion of the items raised.

➤ The stipulation points listed below are requested for revision:

- 1) Revise Section 5 to include appropriate checkmarks
- 2) Revise Section 6 to clarify transportation logistics and post-arrival processing
- 3) Inclusion of biosafety measures, including masks and protective equipment for personnel.
- 4) Confirm training and responsibilities of technicians at Lankenau Hospital.
- 5) Expand details of post-arrival processing of specimens in the protocol.
- 6) Approval Coordination:
 - Engage with IRB and legal teams to finalize consent and protocol details.

Additional Notes/Observations:

- General Sentiment: Cooperative and constructive, with strong attention to safety and compliance.
- Concerns: Highlighted the importance of addressing incomplete protocol sections and safety gaps to ensure readiness for IRB approval.
- IRB and Legal Considerations:
 - Discuss legal requirements for including consent language addressing patient testing in case of accidental exposure.
 - Clarify patient eligibility and associated consent protocols.

The Chair made a motion for final approval to be administratively granted – pending proper clarification and/or revisions made of the points raised above.

MOTION TO APPROVE: Matt Finley, MBA, PhD
SECOND: Lauren Merlo, PhD

The motion was approved by a vote of 8 for, 0 against and 0 abstaining.

With no further business, the Committee adjourned at 2:40pm.



Matt Finley, MBA, PhD.
Chair, Institutional Biosafety Committee

Date

LANKENAU ANIMAL CARE and USE COMMITTEE

Final Audit Report

2025-12-10

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