

Vitalant Research Institute (VRI)

Institutional Biosafety Committee (IBC) Meeting Minutes

Friday, May 02, 2025, 11:00 AM PT / 12:00 PM PT

- **Members Present:** Graham Simmons, Satish Pillai, Clara Di Germanio, Marcus Muench, Jing Jin, Mohamed Bouzidi, Rachel Martinelli, and Steve Sweet (non-voting VRI member) , Rachael Jackman, PhD
- **Members Online:** Krystyna Kozakiewicz (Community Member), Nora Hirschler (Community Member), Dr. Philip J. Norris
- **Members Absent:** Laura L Flores, and Patrick Roberts (non-voting VRI member).
- **Public Present:** NA

Start Time: Dr. Graham Simmons, IBC Chair, called the meeting to order at 11:05 AM PT, and quorum was noted.

1. **Announcements:** Dr. Graham Simmons reported the following to the IBC members:

- a. **Update to NIH Meeting Procedures:** Dr. Lyric Jorgenson, the NIH Associate Director for Science Policy notifying institutions subject to the NIH Guidelines that, for all IBC meetings taking place on, or after June 1, 2025, the approved minutes from those meetings must be posted publicly on an institutional website. In addition, on June 1, 2025, NIH will post IBC rosters on the publicly available list of IBCs registered with the NIH Office of Science Policy (OSP) through the [IBC-Registration Management System](#). The roster will include all members identified by name and role on the committee. In addition, NIH will be posting the contact information for the IBC Chair, Biological Safety Officer, and IBC Contact. The following [Guide Notice](#) has been issued regarding these changes. Updated guidance on [IBC meetings and minutes](#) is also available. (See DHHS Attachment).
- b. **Public Posting of 5/2/25 IBC Meeting:** Dr. Graham Simmons noted that the IBC Meeting of the meeting was publicly posted.
- c. **Rachel Martinelli** - accepted Biosafety Officer position.
- d. **New Community Member to the VRI IBC:** Our new biosafety member from OSI for the IBC will be Michael Checkai. Externa member, Brian Diethorn has moved out of state, community members need to reside in the metro area to be an active VRI IBC member. Additionally, Laura Flores will step down as a community member. The VRI IBC is currently taking names to consider for additional external community members.
- e. **Welcome to Dr. Nora Hirschler**, IBC Community Member. Formerly the COO of the Blood Systems of the West, currently retired.
- f. **IBC CITI Certification updates** for NIH Submission – Some IBC Members are still pending.
- g. **NIH Registration IBC-RMS submission has been accepted** on 04/25/2025.
 - i. NIH Guidelines require IBCs to file an annual membership report with OSP, this is due on 04/25/2026. Patrick Roberts is tasked to submit the next annual report.

2. Old Business

- a. **Review of March 21, 2024, Meeting Minutes:** No objection or concern. The VRI IBC Committee voted unanimously to approve the 03-21-2024 meeting minutes.

3. New Business / New IBC Applications

- a. **PN-001-2025. Parvovirus B19V infectivity analyses.**

Principal Investigator, Philip Noris, MD / Co-Investigator, Pamela Milani, PhD, Marcus Muench, PhD.

Protocol Review: Dr. Graham Simmons provided a pre-discussion review prior to this IBC Meeting. This is a project in collaboration with Cerus, funded by the DoD. The first part of the project will be to reestablish a real time highly sensitive PCR assays for virus detection/quantification, replication, and incubated infection. The project will be using synthetic chunks of Parvovirus B19 ([B19V](#)) for the protocol which is a newer infectious agent being brought into the institute. There are some concerns, Parvovirus B19 is known to cause erythema infectiosum (fifth disease) in children and may lead to aplastic crises in patients with hematologic disorders and hydrops fetalis in pregnant women. However, if using small chunks of B19, it is exempt, if they're not being amplified, and if you are putting them into plasma to make the proper component DNA; it is exempt from having to be reported. The second part of the project, the optimization of the assay is exempt. We'll also test whether the virus can spread from one group of infected cells to another (called "passaging"). Finally, we'll figure out how small an amount of virus each test can still detect when mixed into blood plasma.

All the biosafety cabinet certifications are attached and are current. All Lab staff CITI certification has been reviewed and are current.

Suggested Edits to the Application:

- i. Kristina Kozakiewicz and Dr. Simmons suggest that the deactivation of the virus contact time be included in the application and followed in the protocol. 10-mins is the standard test time using CaviCide1 for disinfection in the BSL2 and BSL3 – for emerging diseases.
 - ii. Dr. Simmons noted that on page 14.3, the deposal/decontamination will need to be updated to include CaviCide1.
 - iii. Dr. Simmons noted that on page 12.3, the disinfectant will need to be updated with the proper name and concentration for cell inactivation, 1% formaldehyde.
 - iv. **The Committee voted unanimously to approve this application pending minor clarifications noted above. Once the amended application is submitted to the IBC an approval letter will be generated and sent to Dr. Norris.**
- b. **RJ-001-2025. Factors Influencing Platelet Alloimmunization.**
Principal Investigator, Rachael Jackman, PhD / Co-Investigator, Marcus Muench, PhD, Graham Simmons,

PhD.

Protocol Review: Dr. Satish Pillai and Dr. Clara Di Germanio provided a pre-discussion review prior to this IBC Meeting. This study includes animal work and is about alloimmunization, which is the immune response against foreign donor antigens. Dr. Jackman's lab will use an established murine mouse model to simulate how the immune system reacts to a transfusion transplantation. They are especially looking at immunomodulation of the degraded complex; they don't understand the cell's immune response, so they will develop a mouse model to simulate how transfusion reaction in infected mice, in different phases.

Overall, the study doesn't need IBC approval, however, there are a couple of parts of the study that do need IBC oversight. 1) establishing the infectious model in the mice using acute [dengue virus](#), 2) and the use of chemotherapy in combination of cytarabine pill and doxorubicin designed to mimic induction chemotherapy used to treat acute myeloid leukemia. There is no use for a recombinant synthetic nucleic acid. The dengue virus will be acquired from UC Davis, however there are no notes on how shipment of these agents will be managed, a copy of the Material Transfer Agreement (MTA) may be needed. It is unsure if the agent is already in-house. Dr. Simmons noted that the agents are onsite and are in the lab freezer. Most of the study will be in the BSL2+ and the BSL3, which is appropriate. All unused vectors and euthanized mice will be discarded in the autoclave in line with BSL3 waste. Prior to removal of all serum, samples will be inactivated, and the cells will stain in the flowcytometry disinfected for fifteen minutes prior to removal.

All the biosafety cabinet certifications are attached and are current. All Lab staff CITI certification has been reviewed and are current.

Suggestions for updates/edits:

- i. Noted that if the agent(s) is a non-commercial laboratory, provide a copy of the Material Transfer Agreement. None was provided in the application. The IBC will need a copy of the MTA on file prior to the project start.
- ii. Questions/Concerns provided to Dr. Jackman by Krystyna Kozakiewicz, related to the use of dengue virus and animal models, Krystyna found a protocol at Cornell University that recommends animal biosafety at level 2. Is there a need to, decided by the IBC, that we would go to level 3.
 1. VRI doesn't have a proper BSL2. It is preferred that viruses not be present in the vivarium; therefore (and due to limited space) we prefer to manage this type of work in the BSL if it isn't too inconvenient.
- iii. Questions/Concerns provided to Dr. Jackman by Krystyna Kozakiewicz, related to waste. Is there an autoclave that is process out of the BSL3. This information should be included in the application, noting the shedding of the virus and the bedding. A small sentence should be included for outside reviewers and outside members or add the published reference showing that heat activation is sufficient for shedding into BSL3 waste.
- iv. **The Committee voted unanimously to approve this application pending minor modifications noted above. Once the amended application is submitted to the IBC an approval letter will be generated and sent to Dr. Jackman.**

IBC Members Action Items:

- Steven Sweet will work with Patrick Roberts to post all the VRI IBC Meeting Minutes onto the VRI website.
- Patrick Roberts will update the NIH IBC Roster and add our new biosafety community member from Occupational Services, Inc. (OSI), Michael Checkai, MPH, CSP.