Agenda/Minutes

The Institutional Biosafety Committee (IBC) Meeting
Albany Medical College

September 11, 2025

Time: 2:00PM-4:00PM
Webex

IBC Members Present:

Member Name	Type	Voting
Kevin Pumiglia, Ph.D., IBC Chair, Department of Regenerative and Cancel Cell Biology	☒ Affiliated ☐ Unaffiliated ☐ Scientist ☐ Nonscientist ☐ Alt	☒ Yes ☐ No
David M. Chico, VMD, MPH, DACVPM, NYS Department of Agriculture and Markets, Division of Animal Industry	☐ Affiliated ☒ Unaffiliated ☐ Scientist ☐ Nonscientist ☐ Alt	☒ Yes ☐ No
Danielle Deloughery, MT (ASCP), CIC, Infection Preventionist II, Epidemiology	☒ Affiliated ☐ Unaffiliated ☐ Scientist ☐ Nonscientist ☐ Alt	☒ Yes ☐ No
Carlos de Noronha, Ph.D., ARO, Department of Immunology and Microbial Disease	☒ Affiliated ☐ Unaffiliated ☐ Scientist ☐ Nonscientist ☐ Alt	☒ Yes ☐ No
John Lamar, Ph.D., Assistant Professor, Department of Molecular and Cellular Physiology	☒ Affiliated ☐ Unaffiliated ☐ Scientist ☐ Nonscientist ☐ Alt	☒ Yes ☐ No
Anthony May, D.V.M., DACLAM, Director, Animal Resources Facility	☒ Affiliated ☐ Unaffiliated ☐ Scientist ☐ Nonscientist ☐ Alt	☒ Yes ☐ No
Nil McManus, RO, IBSO, Assistant Director, Environmental Health and Safety	☒ Affiliated ☐ Unaffiliated ☐ Scientist ☐ Nonscientist ☐ Alt	☒ Yes ☐ No

Julia Nalwalk, Instructor, Department of Neuroscience and Experimental Therapeutics	☒ Affiliated ☐ Unaffiliated ☐ Scientist ☐ Nonscientist ☐ Alt	☒ Yes ☐ No
Cara T. Pager, Ph.D., Associate Professor, Department of Biological Sciences, The RNA Institute, University at Albany - SUNY	☐ Affiliated ☒ Unaffiliated ☐ Scientist ☐ Nonscientist ☐ Alt	☒ Yes ☐ No

Quorum:

The IBC has eleven (11) voting members of whom Nine (9) were present when the meeting convened at 2:04PM. Quorum was maintained throughout the business of the meeting.

Other Individuals in Attendance: None

Call to Order: The IBC Chair called the meeting to order at 2:04PM

1. **Introduction of new committee/community member Dr. Cara Pager, University at Albany – SUNY.**

2. **Review and approval of Meeting Minutes of** June 12, 2025
   Note: The July 10 and August 14 meetings were cancelled.
   A motion was made and seconded to Approve

Vote: Total 9; Yes 9; No 0; Abstain 0

3. **Conflicts of Interest** - The Chair will ask the members to disclose any potential or actual conflict of interest with any registration to be reviewed at today's meeting.
   ☒No conflicts were disclosed.
   ☐One or more conflicts were disclosed.

4. **New IBC Registrations and Amendments for Review: Two**

Registration #203

PI Name(s): *Caitlin Hill, Ph.D., Neural Stem Cell Institute*

Registration Number/Title: *(IBC #203) Assessment of bifunctional intrabodies against alpha-synuclein for spinal cord injury repair (BSL-1)*

Project Overview: Spinal cord injury (SCI) shares histopathological features with other neurological injuries and diseases – including protein aggregation, inflammation, and cell death. Recently, α-syn, a key mediator of neurodegeneration, was shown to accumulate in injured human spinal cords and is linked to pathology following SCI. The Butler laboratory at the NSCI has developed a series of intracellular antibodies (intrabodies) delivered by adeno-associated virus (AAV), that effectively reduced intracellular levels of α-syn. They are in preclinical development for evaluation for their suitability for various neurological conditions. This research project leverages Dr. Butler's expertise

in developing intrabodies and his knowledge of α-syn in the context of disease modification and Dr. Hill's laboratory's expertise in SCI preclinical studies to evaluate AAV delivery of an a-syn intrabody and reporter constructs. In a prior initial evaluation, they identified that 1.5 x 1010 viral genomes (VG) resulted in detection of the HA-tag included in the intrabody construct but did not identify substantial a-syn reduction within the spinal cord. In these follow-up pilot experiments they will evaluate when the intrabody needs to be delivered following SCI and which axonal populations need to be targeted to reduce α-syn levels in the spinal cord. Four experiments are proposed. Completion of these studies is needed to establish the extent to which a-syn contributes to spinal cord pathology. They will also establish if a-syn intrabodies warrant further development as a possible therapeutic for SCI repair.

NIH Guidelines Section: IIA, IIID4, and Appendix B1

Risk Assessment and Discussion:

3. Recombinant DNA:

- Inserts and proposed vector system (helper-free AAV) are appropriate for biocontainment level proposed, ABSL1.
- 3.E.7 States virus will be stored at 150 New Scotland Ave. but not how it will be transported to AMC. This should be detailed as even BSL1 requires DOT approved transport, e.g. leak proof sealed containers, double containment. etc. during transport.
- 3.E.11 The contract research organization vendor who will provide the vector preparation and purification was not identified and while this is not a requirement, it would be helpful to be able to track reagents back to specific companies in case of any issues.
- 3.E.13.2 During transport absorbent padding should be used to absorb any spilled liquid. Disposed to red bag waste. Containers can be decontaminated with bleach solution.

9. Floor Plan of Laboratories for Project:

- A map should represent the area in the AMC ARF where the active AAV infections will be performed and immediately housed.

Training: Required training completed

Occupational Health Representative review (if applicable): NA

Biosafety Level Assignment: Appropriately designed as ABSL-1

IBC Vote: A motion was made and seconded to Approved pending changes

Vote: Total 9; Yes 9; No 0; Abstain 0 Conflict(s) of Interest: *None*

Registration #204

PI Name(s): *Peter McKenney, Ph.D.*

Registration Number/Title: *(IBC #204) Modulation of C. difficile Virulence by Enterococci (BSL-2)*

Project Overview: Vancomycin-resistant Enterococcus (VRE) species are the most common co-isolated pathogens from Clostridioides difficile Infection (CDI) human patients. The presence of

VRE increases the susceptibility of humans to CDI and the severity of disease in mouse models of infection. In this work Dr. McKenney and his lab will explore the molecular genetics of enterococci and *C. difficile* in this interaction using in-vitro bacterial culture and a mouse model of infection. They use *Enterococcus faecalis* OG1RF as a model system in certain in vitro experiments due to genetic tractability and the arrayed whole genome transposon library available in their lab. In the future, they may utilize the collection of non-pathogenic isolates from the human gut microbiota to screen for other bacteria that affect the *C. difficile* life cycle. They will screen an arrayed transposon library of mutants in the strain *Enterococcus faecalis* OG1RF for disruptions that modulate the frequency of sporulation by *C. difficile* when the two microbes are cultured together in the same liquid medium. They will then attempt to complement those OG1RF transposon insertions by cloning the gene of interest with its native promoter into the vector pLZ12-Spec. Currently they are generating complementation strains for the following OG1RF genes: the manganese importer *mntE*, the peptidoglycan hydrolase *salA*, the biofilm associated pilus *ebpABC*, and the uncharacterized genes *OG1RF_12481* and *OG1RF_11154*. Complemented OG1RF strains will then be co-cultured with *C. difficile* to determine their effect on sporulation.

NIH Guidelines Section: IIA, IIID1, Appendix B1

Risk Assessment and Discussion:

2. Project Information:

- Both of the organisms in use are RG2 and pathogenicity screens will be disruptive NOT gain of function.
- Please provide a more detailed explanation of the proposed experiments and how the recombinant DNA and the organisms interact.
- In section D, the box regarding ACUP protocol submission should be checked if it has been, if not it will require IACUC approval.

3. Recombinant DNA:

- All acceptable standard fare. It is unclear from the description if these are maintained as plasmids or integrated into the genome. For clarity it would be good to include this information.

4. Infectious Agents, Toxins, or Prions (Select Agents A/C Patriot Act):

- The role of the larger collections is unclear as originally written (note: project overview above has been amended to reflect enhanced detail).
- Please submit completed PI Self-Assessment for Dual Use Research of Concern to the DURC committee for review.

8. Biosafety Checklist:

- Training dates are missing or incomplete.

9. Floor Plan of Laboratories for Project:

- Absent, please provide.

Training: Dates are missing or incomplete

Occupational Health Representative review (if applicable): NA

Biosafety Level Assignment: Appropriately designed as BSL-2

IBC Vote: A motion was made and seconded to Approved pending changes

Vote: Total 9; Yes 9; No 0; Abstain 0 Conflict(s) of Interest: *None*

5. **Review of Prior Business:**

   Qualtrics Mandatory Annual BSL-2 Biosafety Training update. – Ms. Meg Riddle said there were fifty-one (51) individuals yet to complete the training and would follow up with each of them.

6. **New Business/Additional Topics:**

   - Revise IBC SOP to allow electronic voting for the following: – Dr. Kevin Pumiglia said they would like to revise the SOP to allow for electronic voting on the following items.
     1. Cancelling meetings.
     2. Reviewing and voting on meeting minutes to expedite posting to AMC internet according to the new NIH guidelines.
     3. Revisions to the IBC registration form and amendment form.

   IBC Vote: A motion was made and seconded to approve electronic voting on the three (3) above items.
   Vote: Total 9; Yes 9; No 0; Abstain 0

   - Dr. Kevin Pumiglia said an email from NIH was forwarded to the committee. It stated that over the next year, NIH will be launching a new Biosafety Modernization Initiative to strengthen biosafety policies, practices, and oversight. It's a four-phase project commencing in the fall and will include public forums held across the country. We are in region 1 and NIH will send an additional email as to where and when the forum will be held.

   - Ms. Nil McManus informed the committee that Dr. Anthony May, Director of the Animal Resources Facility, has been approved for the Select Agent Induction Program as a second Alternative Responsible Officer (ARO) and is currently in the process of training/onboarding. Additionally, another Assistant Director of Environmental Health & Safety will go through this program in the future.

   - Ms. Nil McManus said the BSL-3 is currently in its planned review cycle for lab safety and hopefully will be completed by October or November. This would be completed before a possible CDC site visit later in the year.

7. **Review of Incidents:** NA
8. **Inspections/Ongoing Oversight:** NA
9. **IBC Training:** NA
10. **Public Comments:** None

The Following Items are Informational Only:

11. Registrations/Significant Amendments Approved, Conditionally Approved, Disapproved, Tabled, or Terminated:

(IBC #150) ACTHAR gel for cutaneous sarcoidosis: An open label trial (BSL-2)...*Request for Termination*: **Terminated and Archived on 08/04/25.**

(IBC #203) Assessment of bifunctional intrabodies against alpha-synuclein for spinal cord injury repair (BSL-1)...**Approved pending changes on 09/11/2025.**

(IBC #204) Modulation of C. difficile Virulence by Enterococci (BSL-2)... **Approved pending changes on 09/11/2025.**

12. Annual Updates/Amendments Approved by Chair and Biological Safety Officer:

(IBC #185) Morphologic, Immunohistochemical and Molecular Evaluation of Genitourinary Disease (BSL-2)...*Request for Continuation*: **Approved on 06/12/25.**

(IBC #172) Anatomy Plastination Laboratory (BSL-2)... *Request for Continuation*: **Approved on 06/12/25.**

(IBC #49) Signal Transduction and Angiogenesis (BSL-2)...*Request for Continuation:* **Approved on 06/19/25.**

(IBC #77) Role of extracellular protein vitronectin in cell invasion (BSL-2)...*Request to Amend Registration to* include personnel: **Approved on 06/19/25.**

(IBC #162) Study of Myelination in Animals and Primary Cultures (BSL-2)...*Request for Continuation and to Amend Registration to* include personnel*:* **Approved on 06/19/25.**

(IBC #44) Adhesion-Dependent Signaling (BSL-2)...*Request for Continuation and to Amend Registration to* include personnel*:* **Approved on 06/19/25.**

(IBC #54) Regulation of Fibronectin Matrix Assembly (active) (BSL-2)...*Request for Continuation and to Amend Registration to* include personnel*:* **Approved on 06/19/25.**

(IBC #55) Fibronectin Effects on Signal Transduction (active) (BSL-2)...*Request for Continuation and to Amend Registration to* include personnel*:* **Approved on 06/19/25.**

(IBC #51) Matrix Mediators of Wound Healing (BSL-2)...*Request for Continuation and to Amend Registration to* include personnel*:* **Approved on 06/26/25.**

(IBC #192) Morphologic, Immunohistochemical and Molecular Evaluation of Hematolymphoid Tumors (BSL-2)...*Request for Continuation and to Amend Registration to* include personnel: **Approved on 07/01/25.**

(IBC #36) Regulation of Inducible Nitric Oxide Synthase by Reactive Oxygen Species (BSL-2)...*Request for Continuation and to Amend Registration to* include personnel: **Approved on 07/09/25.**

(IBC #79) Molecular mechanisms of smooth muscle function (BSL-2)...*Request for Continuation*: **Approved on 07/09/25.**

(IBC #88) CaMKII in arterial injury (BSL-2)...*Request for Continuation and to Amend Registration to* include personnel: **Approved on 07/09/25.**

(IBC #145) Pathological Glutamate Release in Stroke and Hyponatremia (BSL-2)...*Request to Amend Registration to* include personnel: **Approved on 07/09/25.**

(IBC #183) Project 1: The impact of aging on the functional and anatomical coupling between brainstem noradrenergic neurons and upper airway muscles (BSL-1)...*Request to Amend Registration to* include personnel: **Approved on 07/09/25.**

(IBC #38) Role of Alpha3 Beta 1 Integrin in EMT and Tumor progression (BSL-2)...*Request to Amend Registration to* include personnel: **Approved on 08/07/25.**

(IBC #116) Endothelial Functions of MEF2A and MEF2C in Cardiovascular Development (BSL-1)...*Request for Continuation*: **Approved on 08/07/25.**

(IBC #59) Analysis of HIV-1 Vpr Function (BSL-2)...*Request for Continuation and to Amend*

Registration to include personnel: **Approved on 08/15/25.**

(IBC #77) Role of extracellular protein vitronectin in cell invasion (BSL-2)…*Request for Continuation*: **Approved on 08/15/25.**

(IBC #131) Inflammation and Immunity in Genetically Modified Animals (BSL-2)…*Request for Continuation*: **Approved on 08/15/25.**

(IBC #202) Targeted degradation of intracellular tau (BSL-1)…*Request to Amend Registration to* include personnel: **Approved on 08/15/25.**

(IBC #115) Otitis Media-associated pneumococcal genes (BSL-2)…*Request for Continuation*: **Approved on 08/18/25.**

(IBC #175) Neuroendocrine Regulation of Puberty and Reproduction (BSL-2)…*Request for Continuation and to Amend Registration to* include personnel: **Approved on 08/18/25.**

(IBC #103) Development of quantum dot based applications (BSL-2)…*Request for Continuation and to Amend Registration to* include personnel, Host-Vectors, Cell Lines Used: **Approved on 09/03/25.**

(IBC #159) Kinematics and Mechanics of the ReVeal Cervical Plating System (BSL-2)…*Request for Continuation*: **Approved on 09/03/25.**

(IBC #197) Determining Risk Factors for Aspergillus fumigatus infection using animal models of aspergillosis (BSL-2)…*Request for Continuation and to Amend Registration to* include personnel, Cell Lines Used: **Approved on 09/03/25.**

Adjournment: The IBC Chair moved to adjourn the meeting at 2:33PM. The next meeting scheduled is for October 9, 2025 via Webex.