

Agenda/Minutes
The Institutional Biosafety Committee (IBC) Meeting
Albany Medical College

February 12, 2026

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	<input checked="" type="checkbox"/> Affiliated <input type="checkbox"/> Unaffiliated <input type="checkbox"/> Scientist <input type="checkbox"/> Nonscientist <input type="checkbox"/> Alt	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
David M. Chico, VMD, MPH, DACVPM, NYS Department of Agriculture and Markets, Division of Animal Industry	<input type="checkbox"/> Affiliated <input checked="" type="checkbox"/> Unaffiliated <input type="checkbox"/> Scientist <input type="checkbox"/> Nonscientist <input type="checkbox"/> Alt	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Danielle Deloughery, MT (ASCP), CIC, Infection Preventionist Sr., Epidemiology	<input checked="" type="checkbox"/> Affiliated <input type="checkbox"/> Unaffiliated <input type="checkbox"/> Scientist <input type="checkbox"/> Nonscientist <input type="checkbox"/> Alt	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Carlos de Noronha, Ph.D., ARO, Department of Immunology and Microbial Disease	<input checked="" type="checkbox"/> Affiliated <input type="checkbox"/> Unaffiliated <input type="checkbox"/> Scientist <input type="checkbox"/> Nonscientist <input type="checkbox"/> Alt	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
John Lamar, Ph.D., Assistant Professor, Department of Molecular and Cellular Physiology	<input checked="" type="checkbox"/> Affiliated <input type="checkbox"/> Unaffiliated <input type="checkbox"/> Scientist <input type="checkbox"/> Nonscientist <input type="checkbox"/> Alt	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Anthony May, D.V.M., DACLAM, Director, Animal Resources Facility	<input checked="" type="checkbox"/> Affiliated <input type="checkbox"/> Unaffiliated <input type="checkbox"/> Scientist <input type="checkbox"/> Nonscientist <input type="checkbox"/> Alt	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Nil McManus, RO, IBSO, Assistant Director, Environmental Health and Safety	<input checked="" type="checkbox"/> Affiliated <input type="checkbox"/> Unaffiliated <input type="checkbox"/> Scientist <input type="checkbox"/> Nonscientist <input type="checkbox"/> Alt	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

Cara T. Pager, Ph.D., Associate Professor, Department of Biological Sciences, The RNA Institute, University at Albany - SUNY	<input type="checkbox"/> Affiliated <input checked="" type="checkbox"/> Unaffiliated <input type="checkbox"/> Scientist <input type="checkbox"/> Nonscientist <input type="checkbox"/> Alt	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
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Quorum:

The IBC has eleven (11) voting members of whom 8 were present when the meeting convened at 2:02PM. 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 2:02PM

1. Meeting Minutes of September 11, 2025 were Approved on October 3, 2025

Note: the October, November, December 2025 and January 2026 meetings were cancelled.
(Approval of minutes is conducted electronically via email)

Vote: Total 11 Yes 11 No 0 Abstain 0

2. 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. *N/A*

3. New IBC Registrations and Amendments for Review: None

<p>PI Name(s): <i>Dr. Adrien Bernstein, Urology Department</i></p> <p>Registration Number/Title: <i>(IBC #205) RESQ132EX-NMIBC: Expanded Access Use of Recombinant Bacillus Calmette-Guérin in Nonmuscle Invasive Bladder Cancer (BSL-1)</i></p> <p>Project Overview: <i>The PI is a urologist with extensive experience but has not used the agent previously. The agent to be used is Mycobacterium bovis (M. bovis) BCG strain (Bacillus Calmette-Guérin). It is commonly used in the treatment of bladder cancer where it is highly effective in triggering an immune response against cancer cells. In this capacity, it is instilled into the bladder. The difference in this trial is two genetic modifications to the bacteria. One is the addition of a gene encoding Listeriolysin O, a protein that perforates phagosomes into which they are enveloped by mammalian cells. The escape into the cytoplasm promotes the MHC I pathway, which is efficient at cell killing. The second change is inactivation of BCG urease C, a change that skews pH in favor of Listeriolysin O function. Thus, the agent to be used here is a genetically modified organism.</i></p> <p>NIH Guidelines Section: <i>CDC/NIH BMBL (6th Ed.) and the April 2024 NIH Guidelines: NIH Guidelines Appendix B-II-A, BMBL 6th Ed. Section II, NIH Guidelines Section III-C-1, BMBL 6th Ed. Appendix N (Clinical Laboratory Biosafety), NIH Guidelines Section IV-B-1, BMBL 6th Ed. Section IV, (Biosafety Level 2), BMBL 6th Ed. Section IV. Table 3, BMBL 6th Ed. Appendix A,</i></p>
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Risk Assessment and Discussion: *It appears that all recommended BSL-1 procedures are in place to protect the patients, the healthcare workers, and the environment from the agent. An important concern raised by the IBC is whether the modified BCG is in fact a BSL-1 organism. BCG is generally handled under BSL-2 conditions and while the modifications to the agent to be used here may reduce its fitness, this is no documentation to indicate that it can be considered a BSL-1 pathogen under the US regulatory regime, despite classification at this level in Europe. Existing protocols are in place in Urology for BSL2 containment for the use of rBCG and the panel believed continuance under existing rBCG protocols at BSL2 is in order until such time as formal reclassification of the agent is made.*

Training: *The PI and 17 healthcare workers included on this registration have completed BSL-2 safety training (initial and annual). The registration states that the PI and research staff will receive specialized training from the study sponsor, ImmunityBio, Inc., through the Investigator Brochure (which was provided) and in person as well as remote training. Additional training requirements: Bloodborne Pathogen Standard (OSHA) annual training, protocol-specific training with spill and accidental exposure, demonstrate competency in proper donning/doffing of PPE, aseptic reconstitution technique, use of Biological Safety Cabinet (BSC), spill response procedures, and post-exposure reporting procedures.*

Occupational Health Representative review (if applicable): *A member of the Department of Epidemiology evaluated the application to assess exposure risks to patients as well as health care workers. These issues will also be addressed by parallel IRB review.*

Biosafety Level Assignment: *BSL-1 proposed, however IBC recommends BSL-2, to commensurate with other existing rBCG work.*

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

Vote: Total 8; Yes 8; No 0; Abstain 0

Conflict(s) of Interest: **None**

4. Review of Prior Business: N/A

5. New Business/Additional Topics:

Lab Safety Program:

- **EH&S provided 2 Lab Safety Program (informational) Training in December to the college.**
- **EH&S provided the end-of-year Lab Safety report to the labs.**

BSL-3 Program:

- **We completed all our training and 3 drills & exercises for the BSL-3 program.**

6. Review of Incidents:

BSL-3 Program: We had 4 incidents that we used as a live drill & exercises:

(1) Non-BSL-3 personnel (suspicious activity) unscheduled request to enter MS20 to tag capital equipment during an unscheduled ARF visit.

(2) 1 freezer bag tore inside in the -20 freezer with freezer door open during IACUC Semiannual Inspection (no PPE breach).

(3) -20 Mtb freezer unit out of temp requiring storage in -80 freezer for select agent (involve multi agent cross-contamination scenario).

(4) During the extremely cold weather the air handler was affected causing the humidifier sensor to malfunction and create too much steam which resulted in a lot of condensation in the room. This required the lab to be temporarily shut down for clean-up and equipment repairs. A concern was the exhaust filters being oversaturated and not properly functioning, but pressure readings were taken and there was no deviation from prior readings so there was no breach.

All incidents were responded to appropriately. The torn freezer bag was reported to CDC and NIH OSP as “non-exposure” per AMC occupational exposure policy (Epi). Forms were submitted to CDC and NIH OSP, and we are working to close out those reports. The humidifier sensor has also been reported to CDC and we are waiting to hear back from them..

7. Inspections/Ongoing Oversight:

BSL-3 Labs: CDC will conduct a site visit March 23-26.

8. IBC Training: N/A

9. Public Comments: N/A

The Following Items are Informational Only:

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

(IBC #203) Assessment of bifunctional intrabodies against alpha-synuclein for spinal cord injury repair (BSL-1)...**Approved on 10/03/2025.**

(IBC #204) Modulation of C. difficile Virulence by Enterococci (BSL-2)... **Approved on 10/07/2025.**

(IBC #198) Hippocampal effects of GLP-1R agonists (BSL-1)... **Terminated and Archived on 12/04/2025.**

(IBC #205) RESQ132EX-NMIBC: Expanded Access Use of Recombinant Bacillus Calmette-Guérin in Nonmuscle Invasive Bladder Cancer (BSL-2) ...**Approved Pending Changes on 02/12/2026.**

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

(IBC #75) Crawford rDNAs and cell lines (BSL-2)...*Request for Continuation and to Amend Registration* to include cell lines used: **Approved on 09/08/25.**

(IBC #152) Hippo Pathway Regulation of Gene Expression and its Impact on Human Disease (BSL-2)...*Request to Amend Registration* to include personnel: **Approved on 09/08/25.**

(IBC #89) Molecular Biology of NLR Proteins in Innate Immunity and Molecular Regulation of CIITA Function by GTP Binding (BSL-2)...*Request for Continuation and to Amend Registration* to

include personnel: **Approved on 09/11/25.**

(IBC #149) Anatomical Simulation Center (BSL-2)...*Request for Continuation*: **Approved on 09/11/25.**

(IBC #38) Role of Alpha3 Beta 1 Integrin in EMT and Tumor progression (BSL-2)...*Request to Amend Registration* to include personnel: **Approved on 09/24/25.**

(IBC #185) Morphologic, Immunohistochemical and Molecular Evaluation of Genitourinary Disease (BSL-2)...*Request to Amend Registration* to include personnel: **Approved on 09/24/25.**

(IBC #196) Morphologic, Immunohistochemical and Molecular Evaluation of Breast Disease (BSL-2)...*Request to Amend Registration* to include personnel: **Approved on 09/24/25.**

(IBC #77) Role of extracellular protein vitronectin in cell invasion (BSL-2)...*Request to Amend Registration* to include personnel: **Approved on 10/07/25.**

(IBC #151) Is COPD Exacerbation Associated to Dysfunctional Muscle Satellite Cells? (BSL-2)...*Request for Continuation*: **Approved on 10/07/25.**

(IBC #156) Logue BSL-2 Registration (BSL-2)...*Request to Amend Registration* to include personnel: **Approved on 10/07/25.**

(IBC #165) Role of Aromatase in Vascular Cognitive Impairment in Prediabetic Mice (BSL-2)...*Request to Amend Registration* to include personnel: **Approved on 10/07/25.**

(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 11/13/25.**

(IBC #200) A Phase 3b, Randomized, Controlled Trial of Nadofaragene Firadenovec vs. Observation in Subjects with Intermediate Risk Non-Muscle Invasive Bladder Cancer (IR NMIBC) (BSL-2)... *Request for Continuation and to Amend Registration* to include personnel: **Approved on 11/13/2025.**

(IBC # 201) EG70-101 A Phase ½ Study of EG-70 as an Intravesical Administration to Patients with BCG-unresponsive Non-Muscle Invasive Bladder Cancer (NMIBC) and High-Risk NMIBC Patients who are Naïve or Received Incomplete BCG Treatment (BSL-1) ... *Request for Continuation and to Amend Registration* to include personnel: **Approved on 11/13/2025.**

(IBC #126) Transition from Replication to Virus Production in the Flaviviridae Family of Viruses (BSL-2)...*Request for Continuation and to Amend Registration* to include host-vector system and personnel: **Approved on 12/01/25.**

(IBC #165) Role of aromatase in vascular cognitive impairment in prediabetic mice (BSL-2)...*Request to Amend Registration* to include personnel: **Approved on 12/01/25.**

(IBC #142) HBV Vaccines and Therapy (BSL-2)...*Request for Continuation and to Amend Registration* to include personnel: **Approved on 12/08/25.**

(IBC # 197) Determining Risk Factors for Aspergillus fumigatus infection using animal models of aspergillosis (BSL-2)...*Request to Amend Registration* to include personnel and change of PI: **Approved on 01/05/26.**

(IBC #122) Infection-induced HSPC activation (BSL-2)...*Request for Continuation and to Amend Registration* to include personnel: **Approved on 01/08/26.**

(IBC #152) Hippo Pathway regulation of Gene Expression and its impact on Human Disease (BSL-2)...*Request for Continuation and to Amend Registration* to include cell lines used: **Approved on 01/08/26.**

(IBC #188) Enhanced immunity to bacterial and viral pathogens by anti-human FcγRI targeting approach (BSL-2)...*Request for Continuation*: **Approved on 01/08/26.**

(IBC #189) A better vaccine against *Francisella tularensis* SchuS4 via FcR-targeting of antigens (BSL-3)...*Request for Continuation*: **Approved on 01/08/26.**

(IBC #121) Gene regulation and pathogenesis of Mycobacterium tuberculosis (BSL-3)...*Request*

*for Continuation: **Approved on 01/26/26.***

(IBC #140) Endothelial signaling pathways activated in ocular rosacea (BSL-2)...*Request for Continuation and to Amend Registration to include personnel: **Approved on 01/22/26.***

(IBC #153) Specialized pro-resolving mediators in atherosclerosis (BSL-2)...*Request for Continuation: **Approved on 01/26/26.***

(IBC #157) Yersinia spp.-based vaccines against plague and yersiniosis (BSL-2)...*Request for Continuation and to Amend Registration to include personnel: **Approved on 01/22/26.***

(IBC #158) Yersinia spp.-based vaccines against plague and yersiniosis (BSL-3)...*Request for Continuation and to Amend Registration to include personnel: **Approved on 01/22/26.***

Adjournment: The IBC Chair moved to adjourn the meeting at 2:58PM. The next meeting scheduled is for March 12, 2026 via Webex.