

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

June 12, 2025

Time: 2:00PM-4:00PM

Webex

IBC Members Present:

| Member Name | Type | Voting |
|--|--|--|
| Kevin Pumiglia, Ph.D., IBC Chair | <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 |
| Danielle Deloughery, MT (ASCP), CIC | <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 | <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 |
| Karsten R. O. Hazlett, Ph.D. | <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 | <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 | <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 |
| Julia Nalwalk, Instructor, Dept. of Neuroscience and Experimental Therapeutics | <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 |

Quorum:

The IBC has ten (10) voting members of whom 7 were present when the meeting convened at 2:05pm. When 1 left the meeting at 2:45pm, during the discussion of WCG Clinical Services, there were 6 members present. Quorum was maintained throughout the business of the meeting.

Other Individuals in Attendance:

AMC: Katy Blanchard, Asst. Director Research Administration; Kevin Root, IRB Coordinator; Paul Feustel, Ph.D., Director Research Administration; Toni Schaeffer, Research and Policy Coordinator
WGC Clinical Studies: Todd Lachiatto, Director of Business Development and Daniel Kavanagh, Ph.D., RAC

Call to Order: The IBC Chair called the meeting to order at 2:05pm

1. Review and approval of Meeting Minutes of February 13, 2025

Note: The March 13, April 10, and May 8 meetings were cancelled.

A motion was made and seconded to Approve the minutes.

Vote Total 7: Yes 6; No 0; Abstain 1

2. Conflicts of Interest - The Chair asked the members to disclose any potential or actual conflict of interest with any registration or discussion item to be reviewed at today's meeting.

☒ No conflicts were disclosed.

☐ One or more conflicts were disclosed.

3. New IBC Registrations and Amendments for Review: None

PI Name(s):

Registration Number/Title:

Project Overview:

NIH Guidelines Section:

Risk Assessment and Discussion:

Training:

Occupational Health Representative review (if applicable):

Biosafety Level Assignment:

IBC Vote: A motion was made and seconded to **Choose an item.**

Vote Total: Choose an item.; **Yes** Choose an item.; **No** Choose an item.; **Abstain** Choose an item.

Conflict(s) of Interest:

4. Review of Prior Business: Ms. Nil McManus, IBSO

A. The CDC has closed their November 2024 BSL-3 inspection with no further action required.

5. New Business/Additional Topics:

- A. NIH Office of Science Policy (OSP) Updated Transparency Measures - Dr. Kevin Pumiglia, IBC Chair
- i. The NIH OSP has posted the rosters of all active and registered IBCs via the [IBC-Registration Management System](#). Rosters include contact information for the IBC Chair, Biological Safety Officer, and IBC Contact.
 - ii. Approved meeting minutes from all IBC meetings occurring on, or after, June 1, 2025, must be posted publicly on an institutional website. It is NIH's expectation that minutes will be posted immediately after approval and once all appropriate and allowable redactions have been made. (To assist institutions, NIH revised its FAQs on [IBC Meetings and Minutes](#) and issued new guidance, [IBC Meeting Minutes Template and Points to Consider](#), to assist IBCs in producing meeting minutes that document fulfillment of its oversight responsibilities). The committee discussed the new requirements for the review process of applications, streamlining the minutes for clarity and conciseness, the importance of timely circulation and review of the minutes, and the possibility of approving the minutes via electronic communication.
- B. Update on the BSL-3 Annual Shutdown - Ms. Nil McManus, IBSO
- i. MS20 was deconned and passed BI testing. PM is beginning in MS20. The BSC motor broke and new installation or repair may delay reopening. A replacement motor has been ordered.
 - ii. MS24 was deconned, the first attempt failed, 2nd decon completed and passed BI testing.
 - iii. Recertification for both labs via 3rd party is scheduled for June 30-July 3. MS20 may be delayed due to the BSC motor replacement.
 - iv. Effluent Decontamination System (EDS) PM and validation testing to be completed during annual shutdown.
 - v. The training required for the reopening is in process.
- C. WCG Clinical Services Introduction – Ms. Katy Blanchard introduced the WCG Clinical Services team saying the AMC IRB has worked with WCG for several years on most of their industry sponsored studies and during an annual visit it was discussed that WCG also provides IBC services which we thought could be a good collaboration. Additionally, WCG shares with industry sponsors the institutions they do IRB and IBC work with, which could help grow our clinical research program.

Dr. Daniel Kavanaugh introduced himself and gave a brief overview of his background in research. He said WCG provides a centralized process for multicenter trials. When a sponsor has a trial, they contact WCG. We provide them with a list of sites that are utilizing our services, and the sponsor will ask us to contact those sites. WCG has a prefilled form we email to the Principal Investigator at the participating site. Once the PI signs and returns the form, the WCG analyst, who is an external biosafety officer, works with the site study coordinator to ensure that facilities, inspections, training, and procedures are fully documented. This process does not involve the local IBC, although some sites appoint a biosafety officer or faculty member to sit on the WCG IBC. WCG recruits two local

community members on behalf of the institution. Per NIH guidelines, WCG IBC meetings are open to the public. Regarding NIH requirements on the posting of minutes, WCG follows federal guidelines for redaction of the meeting minutes which are posted on behalf of the site to WCG's website.

6. Review of Incidents: None

7. Inspections/Ongoing Oversight: None

8. IBC Training: None

9. Public Comments: None

The Following Items are Informational Only:

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

(IBC #202) Targeted degradation of intracellular tau (BSL-1) ... **Approved on 04/03/25.**

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

(IBC # 145) Pathological Glutamate Release in Stroke and Hyponatremia (BSL-2) ... *Request to Amend Registration* to include personnel: **Approved on 02/25/25.**

(IBC #121) Gene regulation and pathogenesis of Mycobacterium tuberculosis (BSL-3)... *Request for Continuation and to Amend Registration* to include personnel: **Approved on 03/06/25.**

(IBC #166) Host-pathogen interactions in inflammation and immunity during Tuberculosis infection (BSL-2)... *Request for Continuation and to Amend Registration* to include personnel: **Approved on 03/06/25.**

(IBC #167) Host-pathogen interactions in inflammation and immunity during Tuberculosis infection (BSL-3)... *Request for Continuation and to Amend Registration* to include personnel: **Approved on 03/06/25.**

(IBC #176) Identification and characterization of host factors associated with SARS-CoV2 replication in vitro (BSL-3)... *Request for Continuation:* **Approved on 03/06/25.**

(IBC #21) Signal Transduction in Macrophages (BSL-2)... *Request for Continuation and to Amend Registration* to include personnel: **Approved on 03/18/25.**

(IBC #31) Role of Alpha3 Beta1 Integrin in EMT and Tumor Progression-in vivo studies (BSL-2)... *Request for Continuation* to include personnel: **Approved on 03/18/25.**

(IBC #71) Molecular Mechanisms of Smooth Muscle Function (BSL-1)... *Request for Continuation and to Amend Registration* to include personnel: **Approved on 03/18/25.**

(IBC #123) p53 in cancer and metabolism (BSL-2)... *Request for Continuation to Amend Registration* to include personnel: **Approved on 03/18/25.**

(IBC #145) Pathological Glutamate Release in Stroke and Hyponatremia (BSL-2)... *Request for Continuation:* **Approved on 03/18/25.**

(IBC #193) Elucidating the structure of heparan sulfate co-receptor in SARS-CoV-2 infection (BSL-2)... *Request for Continuation:* **Approved on 03/18/25.**

(IBC #194) Elucidating the structure of heparan sulfate co-receptor in SARS-CoV-2 infection (BSL-3)... *Request for Continuation:* **Approved on 03/18/25.**

(IBC #152) Hippo Pathway regulation of gene expression and its impact on human disease (BSL-2) ...*Request to Amend Registration* to include cell lines used: **Approved on 03/18/25.**

(IBC #19) Calcium/Calmodulin Activated Kinases in Smooth Muscle (BSL-2)... *Request for Continuation and to Amend Registration* to include personnel: **Approved on 04/14/25.**

(IBC #35) Mechanisms for Hypoxic Release in Pulmonary Artery Myocytes (BSL-2)... *Request for Continuation and to Amend Registration* to include personnel: **Approved on 04/14/25.**

(IBC #38) Role of Alpha3 Beta1 Integrin in EMT and Tumor Progression (BSL-2)... *Request for Continuation and to Amend* to include personnel: **Approved on 04/14/25.**

(IBC #61) BCR Modulation of MHC Class II Structure and Function (BSL-1)... *Request for Continuation*: **Approved on 04/14/25.**

(IBC #87) *Francisella* outer membrane proteins (BSL-2)... *Request for Continuation*: **Approved on 04/14/25.**

(IBC #140) Endothelial signaling pathways activated in ocular rosacea *aureus* (BSL-2)... *Request to Amend Registration* to include viral vector and personnel: **Approved on 04/14/25.**

(IBC #146) Grant #293017: Collagen-remodeling genes provide a niche for ovarian cancer stem cells (BSL-2)... *Request for Continuation*: **Approved on 04/14/25.**

(IBC #98) The mTOR pathway in epileptogenesis. The role of eIF5A hypusination in neurodegeneration (BSL-2)... *Request for Continuation and to Amend Registration* to include personnel: **Approved on 05/01/25.**

(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 for Continuation and to Amend Registration* to include personnel: **Approved on 05/01/25.**

(IBC #32) Regulation of endothelial cell function by adherens junctions (BSL-2)... *Request for Continuation*: **Approved on 05/12/25.**

(IBC #50) Regulation of endothelial barrier function by inflammatory mediators (BSL-2) *Request for Continuation*: **Approved on 05/13/25.**

(IBC #113) c-di-NMP responsive gene regulation and pathogenesis of *Mycobacterium tuberculosis* (BSL-2)... *Request for Continuation to Amend Registration* to include personnel: **Approved on 05/13/25.**

(IBC #124) Targeting the foam cell to prevent atherosclerosis (BSL-2)... *Request for Continuation and to Amend Registration* to include personnel: **Approved on 05/13/25.**

(IBC # 199) Transcription-driven epigenetics changes as a mechanism of severe inflammation sequelae (BSL-2) ... *Request for Continuation*: **Approved on 05/15/25.**

(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 to Amend Registration* to include personnel: **Approved on 05/15/2025.**

(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 to Amend Registration* to include personnel: **Approved on 05/15/2025.**

(IBC # 145) Pathological Glutamate Release in Stroke and Hyponatremia (BSL-2) ... *Request to Amend Registration* to include personnel: **Approved on 06/02/25.**

(IBC #182) Morphologic, Immunohistochemical and Molecular Evaluation of Gastrointestinal, Liver, and Pancreatobiliary Disease (BSL-2)... *Request for Continuation*: **Approved on 06/02/25.**

(IBC #196) Morphologic, Immunohistochemical and Molecular Evaluation of Breast Disease (BSL-2)... *Request for Continuation*: **Approved on 06/02/25.**

(IBC #197) Determining Risk Factors for *Aspergillus fumigatus* infection using animal models of aspergillosis (BSL-2)... *Request to Amend Registration* to include personnel: **Approved on 06/02/25.**

Adjournment: The IBC Chair moved to adjourn the meeting at 2:52pm. The next meeting scheduled is for July 10, 2025 via Webex.