

IBC MEETING SUMMARY

White Oak (WO) Institutional Biosafety Committee

Thursday, September 18, 2025

9:30AM – 12:30PM EST

Meeting Location: Teams

Facilitator: Derek Ireland

Recorder: Louis Schwartzman

VOTING MEMBERS

P	Allard, Marc HFP	P	Linden, Sara CDRH
A	Baer, Alan CBER	P	Miller, Mayumi CVM
P	Bramhall, Elizabeth Comm. Member	P	Pandey, Ruchi CDRH
P	Day, James HFP	P	Papafragkou, Efstathia (Efi) HFP
P	Debrabant, Alain CBER	P	Perlman, Amanda Comm. Member
P	Gannavaram, Sreenivas CBER	P	Richter, Taylor HFP
P	Inselman, Amy NCTR	P	Schwartzman, Louis OOSH
P	Ireland, Derek CDER	P	Singer, Daniel OHSS
P	Khan, Saeed A. NCTR	P	Stantchev, Tzanko CDER
P	Khanna, Marilyn OCS/OSLA	A	Tadesse, Daniel CVM
P	Krishna, Ashok CDER	P	Verma, Anita CBER
P	Laassri, Majid CBER	P	Waggener, Christopher T. HFP

EX-OFFICIO MEMBERS & OPTIONAL ATTENDEES

P	Aljazrawi, Aeveen OOSH	P	Lien, Christopher OC
A	Buttke, Thida OC	P	Lina, Taslima NCTR
A	Buckner, Anissa Comm. Member	A	Marth, Theresa HFP
A	Degrasse, Jeffrey OOSH	P	MacWilliams, Ziven OOSH
P	Deptola, Alexa CDRH	A	Nwoka, Adaobi* OC
P	Dixon, Jeremy OOSH	P	Pittas, Tanya OOSH
A	Fowler, Joe NCTR	P	Reid, Ericka CBER
P	Hadden, Phoebe OOSH	A	Sanad, Yasser Comm. Member
P	Howard, Michele OOSH	P	Snyder, Jessica CDER
P	Kemp, Margaret CBER	A	Tremonti, Annette OC

P = Present; A = Absent; CBER = Center for Biologics Evaluation and Research; CDER = Center for Drug Evaluation and Research; CDRH = Center for Devices and Radiological Health; CVM = Center for Veterinary Medicine; FDA = U.S. Food and Drug Administration; HFP = Human Foods Program; NCTR = National Center for Toxicological Research; OC = Office of the Commissioner; OCS = Office of the Chief Scientist; OOSH = Office of Occupational Safety and Health; OSLA = Office of Science and Laboratory Advancement

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ADMINISTRATIVE REVIEW APPROVALS

WO IBC Administrative Review Approvals Since 08/02/2025		
App. #	Title	Approval Date
13092	Using HEPG2 cells for RNA and protein extraction to facilitate optimization of total RNA-seq and automated Western analysis methods	09/15/2025
12699	(1) Modulation of Leukocyte Function by Alternative Signaling Pathways (Project Number: 1009) (2) Development of a spectral cytometry-based assay to assess the antibody-dependent cell-mediated cytotoxicity for characterization of biosimilar products (4077)	09/05/2025

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MEETING SUMMARY

I. Meeting Commencement:

- The WO IBC meeting commenced at 9:57am EST.

II. Attendance

- A total of 22 voting members were present, which fulfilled the quorum needed to conduct IBC business.
- T. Richter departed early due to meeting conflicts.

III. Update: Removal of OHS Surveillance Screening from the IBC review process

- L. Schwartzman gave an update on OHS surveillance process removal, including providing the IBC guidance documents to the IBC for review.
- D. Ireland mentioned that IBC Admin is working with OHSS to check for compliance as part of the annual survey inspection. D. Ireland recommends including survey clearance letters into the biosafety manuals to confirm compliance.

IV. Review of August 28, 2025, WO IBC Meeting Minutes:

- M. Laassri motioned for approval of the August 28, 2025 WO IBC meeting minutes, and A. Inselman seconded the motion.
- The August 28, 2025 meeting minutes were approved by 17 votes of approval and 5 abstentions due to absence.

V. Applications

App. #	Title	Reviewer	NIH Ref	Outcome
13102	Evaluating Internalization of Listeria monocytogenes in Fresh Produce through Blossoms	1. Primary Reviewer 2. Secondary Reviewer	N/A	Approved <input checked="" type="checkbox"/> Tabled <input type="checkbox"/>

*Approval is contingent upon full remediation of application, incorporating all reviewers' stipulations and requirements.

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Application #13102 Project Overview:

Section A: Synopsis

- This project is evaluating the internalization of Listeria monocytogenes in fruit following contamination of the blossoms. A erythromycin-resistant strain of Lm will be grown and inoculated via pipetting onto blossoms of strawberry, cantaloupe, apple, and peach plants grown in a BSL-2 plant facility. Following development of the fruit, the fruit will be harvested and used for Lm enrichment and enumeration.

Section G: Pathogen and/or Toxin

- Listeria monocytogenes.

General Comments from Primary Reviewer:

- Section A, please add the following details:
 - P.I. mentioned cantaloupes, apples, and peaches for the experiment, but only has methods for berries. Clarify that the methods are the same for other fruits
 - Recommend preparing the inoculum and plating in the BSC.
 - Please add details about waste disposal and decontamination of surfaces.
- Section G, please amend the following details:
 - P.I. answered “yes” to working with a toxin, but should be “no”, since they are working with the pathogen that produces the toxin, not a toxin on its own. Can also remove the text describing the toxin and the concentration.
 - P.I. said that the organism will be concentrated via autoclave, please correct.
 - P.I. can remove information concerning the permit, permit is needed for shipping across state lines, so doesn’t apply here.

General Comments from Secondary Reviewer:

- No additional comment from secondary reviewer.

IBC Committee Recommendations for Application #13102:

- Primary Reviewer motioned for approval of application 13102 with minor modifications. Secondary Reviewer supported the motion.
- Application was approved by 22 votes of approval, 0 votes of disapprovals, and 0 abstentions.

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App. #	Title	Reviewer	NIH Ref	Outcome
13096	Expanding the Genomic Landscape of Clostridium botulinum: Enhancing Surveillance, Outbreak Attribution, and Biodefense Preparedness.	1. Primary Reviewer 2. Secondary Reviewer	N/A	Approved* <input checked="" type="checkbox"/> Tabled <input type="checkbox"/>

*Approval is contingent upon full remediation of application, incorporating all reviewers' stipulations and requirements.

Application #13096 Project Overview:

Section A: Synopsis

- The goal of this research is to sequence ~100 Clostridium botulinum strains from previous US outbreaks to study genomic diversity. The research will involve conducting comparative genomic analysis to determine phylogenetic relationships and geospatial patterns, and developing an automated bioinformatics pipeline for genome assembly, annotation, and analysis.

Section G: Pathogen and/or Toxin

- Clostridium botulinum (neurotoxin producing) type A, B, E, and F

General Comments from Primary Reviewer:

- In Section A, the start date is indicated as 01/01/2025. Recommend changing to the current date.
- In Section G, please amend the following:
 - Recommend indicating whether centrifugation will take place within the BSC or if another method of concentration could be used to avoid the risk of aerosolization.
 - Centrifugation may generate aerosols. Recommend that researchers should explain how this will be mitigated
- Approval with minor modifications to ensure aerosolization risk is appropriately mitigated so that this work does not need to be elevated to a biosafety level 3 (BSL-3).

General Comments from Secondary Reviewer:

- As a secondary reviewer, I recommend approval of this application with following modifications:
 - Please describe any and/or all pre-extraction manipulations, list any risk mitigation measures during those manipulations to offset exposure risk.

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- PI needs to correct the start date of the project, please change to today's date.
- No researcher has been listed as a team member to perform the experiments in the laboratory. Please confirm. Otherwise, please add the name for researchers handling the pathogen.
- Please provide details for the procedure to be performed and measures to be taken to prevent the exposure to *C. botulinum*.
- Please mention the time of contact for 10% bleach for decontamination of *C. botulinum*.
- Centrifugation may generate aerosols. I recommend that researchers should explain how this will be mitigated, IBC recommends indicating whether centrifugation will take place within the BSC or if another method of concentration could be used to avoid the risk of aerosolization.

Discussions and Questions During the IBC Meeting

- Members recommend including another researcher to the application.
- Members recommend including contact time to bleach decontamination.

IBC Committee Recommendations for Application #13096:

- Primary Reviewer motioned for approval of application 13096 with minor modifications. Secondary Reviewer supported the motion.
- Application was approved by 20 votes of approval and 1 abstention from M. Allard due to possible conflict of interest.

App. #	Title	Reviewer	NIH Ref	Outcome
13099	Developing cell-based assay for testing the biological activities of menotropins	1. Primary Reviewer 2. Secondary Reviewer	III-D-2-a	Approved <input checked="" type="checkbox"/> Tabled <input type="checkbox"/>

*Approval is contingent upon full remediation of application, incorporating all reviewers' stipulations and requirements.

Application #13099 Project Overview:

Section A: Synopsis

- Menotropins (MENOPUR®) is an FDA-approved fertility medication composed of a mixture of follicle-stimulating hormone (FSH) and luteinizing hormone (LH).

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Menotropins is manufactured from the urine of postmenopausal women and the biological activity of FSH and LH are currently measured using assays in rats. Human chorionic gonadotropin (hCG) is also found within the drug product, but levels are not assessed. The goal of this research is to create reporter cell lines to develop cell based assays to test the bioactivities of follicle stimulating hormone (FSH), luteinizing hormone (LH), and human chorionic gonadotropin (hCG).

Section G: Pathogen and/or Toxin

- Not Applicable

General Comments from Primary Reviewer:

- In Section A, please amend the following:
 - Current application does not include PPE requirements nor list engineering controls (e.g., BSC) that is required for staff when working with the cell lines or pseudo lentiviral particles.
 - Include a brief description of disinfection and waste disposal procedures within this section.
- In Section B, please ensure the Principal Investigator has received OHS clearance prior application approval; PI is responsible for insuring clearance of remaining staff on the application.
- In Section C, please include the following:
 - rsNAMs will be obtained through commercial sources. A brief description of the specific recombinant vector/reporter gene complexes and experimental overview should be included here as well for clarity.
 - A brief description of the pseudo-lentiviral system and envelope protein within the application and any procedures that will be used in the manipulation or screening of the cell lines generated.
- In Section E, cell lines will be obtained from a commercial vendor; all lines are BSL-1 or BSL-2. Recommend including a statement regarding screening status of potential pathogens for the human lines.
- Section I was not completed; human cell lines will, however, be used. The details for the lines are included in Section E as they will be used in the generation of the reporter cell lines.
- Recommend approval at BSL-2 pending minor modifications to the application. PPE requirements for staff, engineering controls (i.e., BSC, containment centrifuge), disinfection and waste disposal protocols should be outlined in Section A.

Additionally, include a more detailed description of the experimental methods

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including the pseudo-lentiviral system in Section C along with an experimental overview of the methods for cell culture manipulations (e.g., centrifugation) and screening to ensure proper safety precautions are in place for protection of staff.

General Comments from Secondary Reviewer:

Secondary reviewer approves application pending the following modifications:

- In Section E, please amend the following:
 - Change the “yes” to question “In these experiments, will an infectious virus be generated (including replication incompetent viruses)?” to “no”. Unless I am reading this application incorrectly, no lentiviruses will be generated at the FDA for this project. Lentiviral particles generated at a commercial facility will be purchased and used at the FDA.
 - Cell lines will be obtained from a commercial vendor; all lines are BSL-1 or BSL-2. Recommend including a statement regarding screening status of potential pathogens for the human lines.
- In Section G, FSHR and LHR are potentially oncogenic and being expressed from a lentivirus that can integrate. I am assuming the PI is only going to use the promoters or TRE’s, but is this something we should get clarification on? Please clarify what portion of these proteins are being cloned and expressed.

Discussions and Questions During the IBC Meeting

- **Question:** After they transduce cell of interest, are they planning to sort or use other methods to obtain enrich or stable cell population expressing these receptors?
- **Response:** Researchers plan to use clonal expansion if they to get their stable salt line. They will dilute and do expansion under selection. Researchers did not mention flow.

IBC Committee Recommendations for Application #13099:

- Primary Reviewer motioned for approval of application 13099 with minor modifications. Secondary Reviewer supported the motion.
- Application was approved by 20 votes of approval and 1 abstention from D. Ireland due to possible conflict of interest.

VI. Meeting Adjournment: The IBC meeting was adjourned at 10:19am EST.

VII. Next IBC Meeting: The next meeting is scheduled for October 16, 2025.