IBC MEETING SUMMARY

White Oak (WO) Institutional Biosafety Committee

Thursday, August 28, 2025

9:30AM – 12:30PM EST

Meeting Location: Teams

Facilitator: Derek Ireland Recorder: Adaobi Nwoka			
VOTING MEMBERS			
P	Allard, Marc HFP	**P**	Linden, Sara CDRH
P	Baer, Alan CBER	**A**	Miller, Mayumi CVM
P	Bramhall, Elizabeth Comm. Member	**P**	Pandey, Ruchi CDRH
A	Day, James HFP	**P**	Papafragkou, Efstathia (Efi) HFP
A	Debrabant, Alain CBER	**P**	Perlman, Amanda Comm. Member
P	Gannavaram, Sreenivas CBER	**A**	Richter, Taylor HFP
A	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, Aveen	**A**	Lina, Taslima NCTR
A	Buckner, Anissa Comm. Member	**P**	Marth, Theresa HFP
P	Buttke, Thida OC	**A**	MacWilliams, Ziven OOSH
P	Degrasse, Jeffrey OOSH	**P**	Nayak, Rajesh
P	Deptola, Alexa CDRH	**P**	Nwoka, Adaobi* OC
P	Dixon, Jeremy OOSH	**P**	Pittas, Tanya OOSH
A	Fowler, Joe NCTR	**A**	Reid, Ericka CBER
P	Hadden, Phoebe OOSH	**A**	Sanad, Yasser Comm. Member
A	Howard, Michele OOSH	**P**	Snyder, Jessica CDER
A	Kemp, Margaret CBER	**P**	Tremonti, Annette OC
A	Lien, Christopher 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 07/15/2025		
App. #	**Title**	**Approval Date**
12979	Development of cell-based assay for interferon-λ drug potency and characterization of effects of receptor protein variants on potency assessment	08/01/2025
12947	Mumps virus vaccine, wild type strains and recombinant strains	07/16/2025
13012	Preparation of CBER Reference Standard Reagent	07/16/2025

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White Oak (WO) Institutional
Biosafety Committee

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9:30AM – 12:30PM EST
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MEETING SUMMARY

I. Meeting Commencement:

- The WO IBC meeting commenced at 9:32 AM EST.

II. Attendance

- A total of 18 voting members were present, which fulfilled the quorum needed to conduct IBC business.

III. Tracking Nonattendance/Vacation

- To ensure quorum will be met during future IBC meetings, L. Schwartzman encourages all voting members to send any upcoming leave to admin support.

IV. Introduction of (4) new IBC members

- Dr. Marc Allard – Human Foods Programs
- Dr. Efstathia Papafragkou – Human Foods Programs
- Dr. Daniel Singer – Office of the Commissioner
- Dr. Tzanko Stantchev – Center for Drug Evaluation and Research

V. Removal of OHS Surveillance Screening from the IBC review process

- **Background**:
  Currently, the IBC review and approval process requires all applications to have approval from Occupational Health Services (OHS) preceding the IBC committee review and approval process. Over the past couple years, the FDA has attempted to use the IBC as an enforcement mechanism to ensure compliance with OHS surveillance programs. This method has proven to delay the IBC review process.

  While the IBC can withhold IBC application approval process, granting incentives and punitive actions against employees who are not compliant with the OHS surveillance process (i.e. PMAPs/Awards), are restricted to supervisors and principal investigators (PI).

- **Revised OHS Surveillance Proposition**:

1. FDA IBC will segregate OHS surveillance verification from the IBC approval process.
2. Office of Occupational Safety and Health publishes a policy directive indicating that OHS Surveillance Compliance is the sole responsibility of supervisor or PI.
3. During annual surveys, inspection personnel may perform OHS compliance spot checks, ensuring that employees working on projects are enrolled in and are participating in relevant programs.
4. Approval letters for each application will indicate all approvals are contingent on the compliance of employee with any or all relevant surveillance programs. Approvals are null and void without requisite OHS compliance.

- L. Schwartzman motioned for the segregation of OHS surveillance screening from the IBC review process and D. Ireland seconded the motion.
- The OHS surveillance proposition was approved by 18 votes of approval, 0 votes of abstentions and 0 disapprovals.

VI. Review of July 17, 2025, WO IBC Meeting Minutes

- D. Ireland motioned for approval of the July 17, 2025, meeting minutes and A. Bear seconded the motion.
- The former meeting minutes were approved by 14 votes of approval and 4 votes of abstentions due to absence.

VII. Applications

App. #	Title	Reviewer	NIH Ref	Outcome
BSL-2 Facility and BSL-2 Work Practices				
12956	Development of Genomics-Driven Methods for Enhanced Identification and Typing of Cronobacter Species from Powdered Infant Formula and Manufacturing Environments	1. Primary Reviewer 2. Secondary Reviewer	N/A	Approved ☒ Tabled ☐

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

Application 12956 Project Overview:

White Oak (WO) Institutional Biosafety Committee

Thursday, August 28, 2025
9:30AM – 12:30PM EST
Meeting Location: Teams

Section A: Synopsis

- This project aims to develop, test and optimize the targeted amplicon re-sequencing panel developed in-house under Cronobacter project. Use the re-sequencing panel application for real-time molecular fingerprinting of Cronobacter and co-contaminating pathogens like Salmonella and E.coli.

Section G: Pathogen and/or Toxin

- PI will be working with a human pathogens and live bacteria for the experiments without any inactivation. PI listed *Salmonella typhimurium* LT2 and *Cronobacter sakazakii* the and the experiments will require the centrifugation for concentrating samples.

General Comments from Reviewers:

- The risk assessment for this application is moderate as the laboratory will be handling the human pathogen. However, the following changes should be made in the application:
    - In Section A, PI needs to change the start date of the project to today's date.
    - In Section A, it would be useful to identify the infant formula matrices and offer clarity on "some kind of enrichment broth".
    - The PI indicated the use of E. coli in section A but failed to list it in section G. Please include that in this section as well.
    - In Section G, please provide details for the procedure to be performed and measures to be taken to prevent the aerosol generation during enrichment of bacterial pathogen by centrifugation to be used for the execution of the project.

IBC Committee Recommendations for Application 12956:

- Primary Reviewer motioned for approval of application 12956 with minor modifications. Secondary reviewer supported the motion.
- Application 12956 was approved pending minor modification by 17 votes of approval, 1 abstention due to inability to review application.

IBC MEETING SUMMARY

White Oak (WO) Institutional
Biosafety Committee
Thursday, August 28, 2025
9:30AM – 12:30PM EST
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App. #	Title	Reviewer	NIH Ref	Outcome
BSL-2 Facility and BSL-2 Work Practices				
12795	Evaluation of the use of a gut-on-a-chip system for in vitro Propagation of Cyclospora cayetanensis	1. Primary Reviewer 2. Secondary Reviewer	N/A	Approved ☒ Tabled ☐

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

Application 12795 Project Overview:

Section A: Synopsis

- This project aims to use an organ on a chip technology where cells from human gut biopsies are used as host cells to cultivate Cylospora cayetanensis by seeding oocysts isolated from fecal samples. The goal is to generate a new method to grow the human intestinal parasite Cyclospora cayetanensis in vitro.

Section G: Pathogen and/or Toxin

- The two (2) pathogens handled in this project are listed as Cryptosporidium parvum and Cyclospora cayetanensis.

General Comments from Primary Reviewer:

- The following changes should be made to Section A:
  - A brief description of the feeder cells i.e., cells from human gut biopsy needs to be included to assess the safety characteristics.
  - Brief description of the culturing of the organoid including duration and method need to be provided.
  - In the synopsis section use of related organisms as a surrogate is proposed, however in the later sections no detail on how cultures of T. gondii, Eimeria maybe used is provided.
  - Handling and disposal of the feeder human gut cells needs to be described.
  - The proposed start date should be changed.
- In Section E, no description of Toxoplasma or Eimeria is provided.

- In Section G, if Toxoplasma gondii and Eimeria are going to be used, please provide the necessary description.
- In Section I, please describe what cell types are being used i.e., gut epithelial cells.

General Comments from Secondary Reviewer:

- The major safety risk about these studies is an accidental exposure to virulent Cryptosporidium oocysts. The decontamination procedures are not appropriate as described above. Cryptosporidium oocysts are very resistant and not effectively killed by exposure to 70% ethanol or 10% bleach. For disinfection of contaminated surfaces (e.g., benchtops and equipment), the BMBL manual recommends using commercial undiluted 3% hydrogen peroxide for 30 min. The remaining risks of potential pathogen exposure are properly mitigated by using standard BSL-2 work practices performed in a BSL-2 laboratory, as proposed by the PI.
- The following changes should be made to Section A:
    - Please clarify whether Toxoplasma and Eimeria organisms will be used in this project. If yes, they should be listed in Section G, if not, they should be deleted from this application.
    - Cryptosporidium oocysts are very resistant and not effectively killed by exposure to 70% ethanol or 10% bleach, commonly used as decontaminants (Weir et al., Applied and Environmental Microbiology May 2002, p. 2576–2579). For disinfection of contaminated surfaces (e.g., benchtops and equipment), the BMBL manual recommends using commercial undiluted 3% hydrogen peroxide for 30 min (Section VIII-C, page 229). Please modify Section A to reflect the BMBL recommendations. We recommend applying the same disinfection procedure when handling C. cayetanensis, to avoid discarding potentially infectious organisms in the environment.
    - Please describe briefly the organoid samples you plan to obtain from Baylor College of Medicine or provide a reference. Specifically, since they are derived from human material, they may contain infectious agents such as HIV or other viruses. Please comment on the safety risks associated with handling this material.
    - The proposed start date should be changed to today
- In Sections E and F, remove NIH classification since no rsNAMs are used.

IBC MEETING SUMMARY

White Oak (WO) Institutional
Biosafety Committee

Thursday, August 28, 2025
9:30AM – 12:30PM EST
Meeting Location: Teams

IBC Committee Recommendations for Application 12795:

- Primary reviewer motioned for approval of application 12795 with minor modifications. Secondary reviewer supported the motion.
- Application 12795 was approved pending minor modification by 16 votes of approval and 2 abstentions due to inability to review application.

App. #	Title	Reviewer	NIH Ref	Outcome
BSL-2 Facility and BSL-2 Work Practices				
13079	Development and Validation of Improved Cultural Detection and Characterization of L. monocytogenes and Listeria spp. in Food and Environmental Matrices	1. Primary Reviewer 2. Secondary Reviewer	N/A	Approved ☒ Tabled ☐

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

Application 13079 Project Overview:

Section A: Synopsis

- FDA's BAM Chapter 10 for Listeria detection relies on culture-based isolation and biochemical identification methods that are over a decade old and insufficient for current analytical demands and emerging pathogen variants.
- The goal of the study is to modernize decade old protocols to meet current analytical technology standards to accommodate emerging pathogen variants and enhance detection capabilities.

Section G: Pathogen and/or Toxin

- PI will be working with Listeria monocytogenes and Enterococcus faecalis various strains.

General Comments from Primary Reviewer:

- The PI needs to clarify the following:
  - Mixed containment practices- There appears to be mixed containment practices, for example, food inoculation occurs on an open bench.
  - Listeria is mixed with foods in sample bags by hand and evenly spread onto stainless surfaces using a spreader. Hand mixing is a concern. Manually mixing

White Oak (WO) Institutional Biosafety Committee

Thursday, August 28, 2025
9:30AM – 12:30PM EST
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Listeria with foods "by hand" in sample bags may increase exposure risk and reduce containment effectiveness compared to mechanical mixing methods.

General Comments from Secondary Reviewer:

- In Section A, would like to see inoculation of sample done in BSC rather than benchtop.

IBC Committee Recommendations for Application 13079:

- Primary reviewer motioned for approval of application 13079 with minor modifications. Secondary reviewer supported the motion.
- Application 13079 was approved pending minor modification by 17 votes of approval and 1 abstention due to inability to review application.

App. #	Title	Reviewer	NIH Ref	Outcome
BSL-2 Facility and BSL-2 Work Practices				
13080	Development and Validation of Improved Molecular Detection and Characterization of L. monocytogenes and Listeria spp. in Food and Environmental Matrices	1. Primary Reviewer 2. Secondary Reviewer	N/A	Approved ☒ Table ☐

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

Application 13080 Project Overview:

Section A: Synopsis

- The purpose of this application is to develop a new Listeria monocytogenes molecular screening tool for regulatory testing, using qPCR and to be able to molecularly identify different listeria spp. from Listeria monocytogenes.

Section G: Pathogen and/or Toxin

- PI will be working with Listeria monocytogenes and Enterococcus faecalis various strains.

General Comments from Reviewers:

- Similar to application #13079, reviewers had corresponding comments for the bench manipulations.

- In Section G, a permit for these organisms is not required by federal agencies. This section needs to be corrected.

IBC Committee Recommendations for Application 13080 :

- Primary reviewer motioned for approval of application 13080 with minor modifications. Secondary reviewer supported the motion.
- Application 13080 was approved pending minor modification by 17 votes of approval and 1 abstention due to inability to review application.

VIII. Meeting Adjournment: The IBC meeting was adjourned at 11:24 AM EST.

IX. Next IBC Meeting: The next meeting is scheduled for September 18, 2025.