

# IBC MEETING SUMMARY

## White Oak (WO) Institutional Biosafety Committee

Thursday, July 17, 2025

9:30AM – 12:30PM EST

Meeting Location: Teams

Facilitator: Derek Ireland

Recorder: Adaobi Nwoka

### VOTING MEMBERS

<b>P</b>	Baer, Alan CBER	<b>P</b>	Krishna, Ashok CDER
<b>A</b>	Berkower, Ira CBER	<b>P</b>	Laassri, Majid CBER
<b>P</b>	Bramhall, Elizabeth Comm. Member	<b>P</b>	Linden, Sara CDRH
<b>A</b>	Day, James HFP	<b>P</b>	Miller, Mayumi CVM
<b>P</b>	Debrabant, Alain CBER	<b>P</b>	Pandey, Ruchi CDRH
<b>A</b>	Gannavaram, Sreenivas CBER	<b>P</b>	Perlman, Amanda Comm. Member
<b>A</b>	Gutierrez, Sacha OOSH/OHSS	<b>P</b>	Richter, Taylor HFP
<b>P</b>	Inselman, Amy NCTR	<b>P</b>	Schwartzman, Louis OOSH
<b>P</b>	Ireland, Derek CDER	<b>P</b>	Tadesse, Daniel CVM
<b>P</b>	Khan, Saeed A. NCTR	<b>A</b>	Verma, Anita CBER
<b>P</b>	Khanna, Marilyn OCS/OSLA	<b>P</b>	Waggener, Christopher T. HFP

### EX-OFFICIO MEMBERS & OPTIONAL ATTENDEES

<b>P</b>	Buttke, Thida OC	<b>P</b>	Marth, Theresa HFP
<b>P</b>	Degrasse, Jeffrey OOSH	<b>P</b>	MacWilliams, Ziven OOSH
<b>A</b>	Fowler, Joe NCTR	<b>P</b>	Nwoka, Adaobi* OC
<b>P</b>	Hadden, Phoebe OOSH	<b>P</b>	Pittas, Tanya OOSH
<b>P</b>	Howard, Michele OOSH	<b>P</b>	Reid, Ericka CBER
<b>A</b>	Kemp, Margaret CBER	<b>P</b>	Snyder, Jessica CDER
<b>P</b>	Lien, Christopher OC	<b>P</b>	Tremonti, Annette OC
<b>P</b>	Lina, Taslima NCTR		

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; 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

App. #	Title	Approval Date
13063	Studies on Treponema pallidum in human blood and blood components	07/14/2025
13024	Evaluation and validation of the DEUF for the detection and quantification of Listeria monocytogenes in pre-harvest and post-harvest agricultural water	07/10/2025
12888	Efficacy of dry-heat treatment in reducing Salmonella and E. coli O157:H7 populations on sprout seeds	07/09/2025
12919	Development of a Rapid Targeted Amplicon Next Generation Sequence-Based Detection Method for Foodborne Pathogens in Leafy Green Produce	07/09/2025
13046	Integrating complementary in silico and in vitro data for identifying and prioritizing food chemical hazards	07/07/2025
13023	Identifying immune correlates of protection and viral clearance for human noroviruses	06/20/2025
13069	Utilizing Reverse Genetics to Study Rotavirus Biology and New Vaccine Design	06/20/2025

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### **I. Meeting Commencement:**

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

### **II. Attendance**

- A total of 16 voting members were present, which fulfilled the quorum needed to conduct IBC business.

### **III. Introduction of Adaobi Nwoka, New Administrative Staff**

- Adaobi Nwoka is the new administrative support for the IBC. She comes with a background in Human Food & Nutrition and Health Policy Management. She has assisted with managing several FSMA rules and initiatives including the Food Traceability, Laboratory Accreditation, Farm Definition and the New Era Smarter Food Safety.

### **IV. New Application Review Template**

- L. Schwartzman shared the new IBC application review template which outlines the application reviewers' expectations and requirements for approval. IBC application reviewers are encouraged to use this template moving forward.
- L. Schwartzman stated that the FDA IBC will be transparent about our research activities, while not sharing any trade secrets or proprietary information. Henceforth, the following items will be redacted from the public view:
  - Names of the researchers and research team,
  - Detailed methods of the research, and
  - The name of the application reviewers.

### **V. Tracking Upcoming Leave**

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

### **VI. Review of June 26, 2025, WO IBC Meeting Minutes**

- We received two comments on the June 26<sup>th</sup> IBC meeting minutes (see below):

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- **Application 12945:** Researcher noted Section III-D-1-a., which would indicate that they are modifying mumps or RSV. This does not accurately reflect what is being performed. The researcher is subcloning defective viral genomes into plasmids, which would be Section III-D-2-a. This change should be reflected in the application.
- **Application 13022:** General comments from the secondary reviewer was included in the primary reviewer section, which should be removed.
- D. Ireland motioned for approval of the June 26, 2025, meeting minutes and M. Laassri seconded the motion.
- The former meeting minutes were approved by 9 votes of approval, 7 votes of abstentions and 0 disapprovals.

## VII. Applications

### BSL-2 Facility and BSL-2 Work Practices

App. #	Title	Reviewer	NIH Ref	Outcome
12914	Development and Validation of Revised Protocols for the Detection of Cronobacter in Powdered Infant Formula, Environmental Samples and Other Infant Foods	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 12914 Project Overview:

#### Section A: Synopsis

- This FDA research project aims to improve how we detect Cronobacter bacteria in powdered infant formula and environmental samples. Cronobacter is a dangerous pathogen that can cause serious illness in infants, so having reliable detection methods is critical for food safety. The researchers are updating the official FDA testing procedures called the Bacteriological Analytical Manual (BAM) to make them more effective and current with modern technology. The study will test whether larger sample sizes and new laboratory techniques can better find Cronobacter when it's present in very small amounts.

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#### Section G: Pathogen and/or Toxin

- Researchers will be working with various strains of Cronobacter species. They also list other pathogens that they plan to test against, which includes various strains of Salmonella, Enterobacter, and Listeria monocytogenes.

#### General Comments from Primary Reviewer:

- In Section A, the start date is listed as 2022 and needs to be updated.
- In Section G, please clarify where the non-Cronobacter pathogens are being used.

#### General Comments from Secondary Reviewer:

- The following changes should be made to Section A,
  - Please specify the type of mask being used during powdered infant formula handling or use N95 mask and use enhanced PPE e.g., impermeable gowns, and shoe covers when processing large volumes outside of BSCs to provide comprehensive protection.
  - Processing 30 × 400g samples on open bench significantly increases aerosol generation and environmental contamination risk, especially with powdered materials. The missing elements include aerosol containment measures such as splash shields, partial enclosures, or portable fume extraction systems. Additionally, restricted access procedures during large-volume processing are needed to limit personnel exposure, along with enhanced PPE requirements for open bench work including N95/P100 respirators, full face shields, shoe cover, and impermeable gowns. Temporal isolation of open bench work from other laboratory activities should also be implemented to minimize cross-contamination and exposure risks.
- In Section J, please provide a spill cleanup plan (small spills and large-scale spill) because researchers are intending to work with large volumes of contaminated infant formulas

#### Discussions and Questions During the IBC Meeting

- **Question:** Is the Cronobacter species itself listed BSL 1 and transmitted by ingestion?
- **Response:** Yes, but they did not specify what strain they are using.

#### IBC Committee Recommendations for Application 12914:

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- Primary reviewer recommends approval of application pending minor modifications. Secondary reviewer seconded the recommendation.
- Application 12914 was approved pending minor modification by 16 votes of approval, 0 abstentions and 0 disapprovals.

**VIII. Meeting Adjournment:** The IBC meeting was adjourned at 10:05 AM EST.

**IX. Next IBC Meeting:** The next meeting is scheduled for August 21, 2025.