

IBC MEETING SUMMARY

National Center for Toxicological Research (NCTR) Institutional Biosafety Committee

Thursday, September 18, 2025

9:30AM – 12:30PM EST

Meeting Location: Teams

Facilitator: Amy Inselman

Recorder: Louis Schwartzman

VOTING MEMBERS

P	Allard, Marc HFP	P	Linden, Sara CDRH
A	Baer, Alan CBER	P	Miller, Mayumi CVM
A	Buckner, Anissa Comm. Member	P	Pandey, Ruchi CDRH
P	Day, James HFP	P	Papafragkou, Efstathia (Efi) HFP
P	Debrabant, Alain CBER	P	Richter, Taylor HFP
P	Gannavaram, Sreenivas CBER	P	Sanad, Yasser Comm. Member
P	Inselman, Amy NCTR	P	Schwartzman, Louis OOSH
P	Ireland, Derek CDER	A	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
P	Bramhall, Elizabeth Comm. Member	A	Marth, Theresa HFP
A	Degrasse, Jeffrey OOSH	P	MacWilliams, Ziven OOSH
P	Deptola, Alexa CDRH	A	Nwoka, Adaobi* OC
A	Dixon, Jeremy OOSH	P	Perlman, Amanda Comm. Member
A	Fowler, Joe NCTR	P	Pittas, Tanya OOSH
P	Hadden, Phoebe OOSH	P	Reid, Ericka CBER
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

NCTR IBC Administrative Review Approvals Since 04/02/2025

App. #	Title	Approval Date
13104	Determination of sex-based differences in inflammatory immune response to nanomaterials in individuals with inflammatory and auto-immune diseases (NCTR Protocol #C25015)	09/04/2025
13053	Development of In Vitro Vaginal Tract Models to Assess the Biotherapeutic Potential of Naturally-Occurring Lactobacillus Strains and the Lysostaphin-Producing <i>L. plantarum</i> WCFS1 Strain Toward Toxic Shock Syndrome Toxin-1 Producing Strains of <i>Staphylococcus aureus</i>	05/27/2025

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MEETING SUMMARY

I. Meeting Commencement:

- The NCTR IBC meeting commenced at 9:35am EST.

II. Attendance

- A total of 20 voting members were present, which fulfilled the quorum needed to conduct IBC business. Eighteen voting members were present during the attendance check and two members joined shortly after.

III. Review of May 15, 2025, NCTR IBC Meeting Minutes:

- On March 28, 2025, the NIH Office of Science Policy (OSP) Guide Notice instructed IBCs to publicly post approved minutes on or after June 1, 2025. As such, the FDA IBC decided to post the [May 15, 2025, NCTR IBC meeting minutes](#) as it was referenced in the September NCTR IBC meeting.
- Derek Ireland motioned for approval of the May 15, 2025 meeting minutes and Alain Debrabant seconded the motion.
- The May 15, 2025 NCTR IBC minutes were approved by 20 votes of approval, and 0 votes of disapproval.

IV. Applications

App. #	Title	Reviewer	NIH Ref	Outcome
13105	CBER Support Protocol: Comparison of Host Responses to Bordetella pertussis Infections in the Baboon Model with Different Pertussis Vaccines using Untargeted Metabolomics (NCTR Protocol #S00927)	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 #13105 Project Overview:

Section A: Synopsis

- This study investigates host responses to *Bordetella pertussis* infection in baboons with different immunization backgrounds (naïve, convalescent, acellular pertussis–vaccinated, whole-cell pertussis–vaccinated, and experimental vaccine–vaccinated).
- NPW samples are processed via ultrafiltration to remove viable cells before shipment to NCTR. Plasma and NPW filtrates (n=96) are then prepared for lipidomic and metabolomic profiling by LC/MS. Plasma undergoes pathogen-inactivating extraction steps using methanol and dichloromethane, while NPW filtrates require no further treatment.
- All work with nonhuman primate (NHP) materials is conducted under strict biosafety protocols, including use of a biosafety cabinet, PPE, and proper waste decontamination. The overarching goal is to differentiate immune and metabolic responses across vaccine backgrounds to inform development of improved next-generation pertussis vaccines.

Section G: Pathogen and/or Toxin

- *Bordetella pertussis* (Strain D420) was isolated in 2002 from a U.S. infant with severe pertussis (i.e., severe respiratory distress).

General Comments from Primary Reviewer:

- Please describe agreed shipping method – samples must be shipped using standardized biohazard shipping procedures and packaging (including absorbent material and secondary containers). Shipping must be performed by CBER staff who have completed training for the shipping of hazardous materials.
- Once samples are received, package handling and unpacking under containment should be described.
- Spill and decontamination procedures should be described, including appropriate disinfectant and contact time.
- Hepatitis B virus is a concern when handling baboon samples, therefore it should be described that staff are offered the HBV vaccine prior to beginning work on this project.

General Comments from Secondary Reviewer:

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- The Pall Omega 3 kDa centrifugal device would remove whole B. pertussis bacteria and whole B virus particles, since both are vastly larger than the cutoff.
- Only small molecules, peptides, lipids, and metabolites (the intended analytes) would pass through.
- While, the filtrates should not contain viable pathogens, conservative biosafety practices are still recommended and have been well described here.
- My only potential feedback is specifically spelling out plasma/NPW decontamination methods.

IBC Committee Recommendations for Application #13105:

- Secondary Reviewer motioned for approval of application 13105 with minor modifications. Primary Reviewer supported the motion.
- Application was approved by 20 votes of approval, 0 votes of disapproval, and 0 abstention.

V. Meeting Adjournment: The IBC meeting was adjourned at 9:56am EST.

VI. Next IBC Meeting: The next meeting is to be determined (TBD).