

MEETING SUMMARY

NCTR Institutional Biosafety Committee

Thursday, May 15th, 2025

9:30AM – 12:30PM EST

Meeting Location: Teams

Facilitator: Amy Inselman

Recorder: Natarsha Miller-Dunn

VOTING MEMBERS

P	Majid Laassri, CBER	P	Ashok Krishna, CDER
P	Alan Baer, CBER	P	Derek Ireland, CDER
P	Ira Berkower, CBER	P	Louis Schwartzman, OOSH
P	Anita Verma, CBER	P	Sacha Gutierrez, OOSH/OHSS
P	Alain Debrabant, CBER	P	Christopher T. Waggener, HFP
P	Mayumi Miller, CVM	A	James Day, HFP
P	Daniel Tadesse, CVM	P	Taylor Richter, HFP
P	Amy Inselman, NCTR	P	Sara Linden, CDRH
P	Saeed A. Khan, NCTR	P	Yasser Sanad, Comm. Member
P	Marilyn Khanna, OCS/OSLA	A	Anissa Buckner, Comm. Member

EX-OFFICIO MEMBERS & OPTIONAL ATTENDEES

A	Thida Buttke, ORA	A	Angela Ragan, CVM
P	David Harbourt, CVM	P	Christopher Lien, OC
P	Theresa Marth, HFP	P	Ericka Reid, CBER
P	Taslima Lina, NCTR	P	Keith Tate, OOSH
P	Natarsha Miller-Dunn, OOSH	P	Socrates Trujillo, HFP (Guest)
P	Adaobi Nwoka, OC	P	Tanya Pittas, OC
P	Annette Tremonti, OC	P	Margaret Kemp, CBER
P	Ruchi Pandey, CDRH	A	Joe Fowler, NCTR
P	Elizabeth Bramhall, Comm. Member	P	Amanda Perlman, Comm. Member

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

NCTR IBC Administrative Review Approvals Since 12/19/2024		
App. No	Title	Approval Date
13015	Identification and Characterization of microRNA Biomarkers to Predict “Best-In-Class” Drugs that Have the Lowest Risk for Drug-Induced Liver Injury: A Translational Study-Protocol Extension (NCTR Protocol #E0776901).	04/01/2025
12957	Mechanistic Investigation and Candidate Susceptibility Biomarker Identification for Montelukast-related CNS Effects (NCTR Protocol #C24043).	02/11/2025
12943	A new alternative human-based method to evaluate the safety of drugs/chemicals repurposed/proposed for COVID-19 treatment (NCTR Protocol #E0779901).	02/11/2025
12142	Placental–embryonic microphysiological system: a novel screening platform for predicting human embryotoxicity (NCTR Protocol #E07844).	01/28/2025
12938	Neurological Targets of Montelukast for Potential Adverse Neuropsychiatric Events (NCTR Protocol #E0775701).	01/21/2025

MEETING SUMMARY

I. Meeting Commencement:

- The NCTR IBC meeting commenced at 09:30am EST.

II. Attendance

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

III. Review of December 19th, 2024, NCTR IBC Meeting Minutes:

- The December 19th, 2024, meeting minutes have been approved by the committee. L. Schwartzman motioned for approval and D. Ireland seconded the motion.

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- The December 19, 2024 meeting minutes were approved by 14 votes of approval, 0 votes of disapproval, and 4 abstentions from D. Tadesse, A. Verma, A. Baer and Y. Sanad due to absence.

IV. Human Foods Program (HFP) Presenter: Dr. Socrates Trujillo, acting Deputy Office Director, Office of Applied Microbiology and Technology (OAMT), OLOAS, HFP

- In lieu of the IBC receiving several applications from HFP, Dr. Trujillo was invited to share information about HFPs' current research portfolio.

V. Applications

Application Number	Title	Reviewer(s)	NIH Ref	Outcome
BSL-2 Facility and BSL-2 Work Practices				
13018	Rapid Detection, Identification and Quantification of Foodborne Pathogens using Quantum Dot-Based Nanotechnology Platform (NCTR Protocol #C24003).	1. Primary Reviewer 2. Secondary Reviewer	N/A	Approved*

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

Application 13018 Project Overview:

Section A: Synopsis and Purpose of study

- The presence of pathogenic bacteria in the food products is an on-going concern for food safety and public health. There is an urgent unmet need to develop rapid and inexpensive methods for on-site analysis that are easy-to-use. The goal of this project is to develop a novel multiplexing nanomaterial-based platform for rapid detection of pathogenic bacteria in food using fluorescent quantum dots (QDs) to address this unmet need. The proposed study is a proof-of-concept method development study, where a nanomaterial-based platform, will be used to improve the detection sensitivity and specificity for *Salmonella* spp., *Escherichia coli* O157 and *Listeria monocytogenes* that are present in the food matrices.

Section G: Pathogen and/or Toxin

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- This section states that *Salmonella* spp., *Salmonella enterica* subsp. *enterica* serovar Gaminara Sal57 derived from FDA SAL5695, *Escherichia coli* (O157:H7) EC43 derived from FDA ESC1177(STEC), *Listeria monocytogenes* (1/2a) derived from FDA LS808, *Cyclospora cayetanensis* oocysts, NF1_C8 Nepal (accession PVNT01000000), and *Campylobacter jejuni* ATCC 33291, will be used in the study.

General comments from Primary Reviewer

- The following adjustments should be made in Section G:
 - The P.I. states "*The pathogens will be inactivated by heat prior to laboratory manipulation*". The sentence should be re-worded as "*pathogens will be inactivated by heat after experimental testing or use*".
 - Although, it is mentioned that the pathogens used in the study are not resistant to antibiotic(s), the primary reviewer doubts that the statement is true. Reviewer recommends testing the validity of that statement.

General comments from Secondary Reviewer

- The following adjustments should be made in Section A:
 - P.I. states, "*The antibody functionalized QDs will then enable a rapid and sensitive detection of pathogens, especially in the early stages of infection.*" Please clarify the meaning of "infection" in this sentence.
 - P.I. states, "*Template DNA will be isolated from the enriched cultures using Qiagen nucleic acid extraction kits.*" Please explain in which context the pathogen DNA will be used.
 - P.I. states, "*Parasites such as Cyclospora cayetanensis that are available for laboratory testing are oocysts, and these are usually harvested from clinical fecal samples.*" Please clarify if this IBC includes the purification of Cyclospora cayetanensis oocysts from stool samples. If yes, please provide a brief description of the method used for this purification and the safety precautions used for handling fecal material. If this is the case, the answer to Section H should be "yes". If no, please clarify the origin of the Cyclospora cayetanensis oocysts used under this protocol.
 - Additional experimental details are needed to better assess the risk of accidental exposure (i.e., volume of spiked material processed, and safety precaution used)
 - P.I. states, "*All potentially contaminated waste will be decontaminated with disinfectants including 70% ethanol or 3% bleach*". 1) You probably mean "surfaces" instead of "waste"; please clarify. 2) 3% bleach is not appropriate, freshly prepared 10% bleach should be used for decontamination or 3% commercial hydrogen peroxide. Please justify the use of 3% bleach or edit this

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paragraph. Please clarify the contact time used for the decontamination of Cyclospora cayetanensis exposed surfaces.

- The following adjustments should be made in Section G:
 - *Salmonella* spp, *Escherichia coli*, and *Listeria monocytogenes* appear to be obtained from other FDA projects. Please clarify the origin of these pathogens (collaborators etc.)
 - P.I. states the pathogens will be “heat inactivated”. This is not clear. The detection methods proposed are supposed to detect likely “live” infectious organisms in contaminated food. Please briefly describe the method used for heat inactivation.
 - Please describe when filtration will be used as it is not mentioned in Section A.

IBC Committee Recommendations for Application 13018:

- Primary reviewer motioned for approval of application 13018 with minor modifications. The secondary reviewer supported the motion. All the recommended changes were made with minor modifications.
- Application was approved by 18 votes of approval, 0 votes of disapproval, and 0 abstention.

VI. Meeting Adjournment: The IBC meeting was adjourned at 10:13am

VII. Next IBC Meeting: The next meeting TBA.