IBC MEETING SUMMARY

National Center for Toxicological Research (NCTR) Institutional Biosafety Committee

Thursday, December 11, 2025

9:30AM – 12:30PM EST

Meeting Location: Teams

Facilitator: Louis Schwartzman Recorder: Adaobi Nwoka			
VOTING MEMBERS			
P	Allard, Marc HFP	**P**	Lina, Taslima NCTR
P	Baer, Alan CBER	**P**	Linden, Sara CDRH
A	Day, James HFP	**P**	Miller, Mayumi CVM
P	Debrabant, Alain CBER	**P**	Pandey, Ruchi CDRH
P	Evans, Anissa Comm. Member	**P**	Papafragkou, Efstathia (Efi) HFP
P	Gannavaram, Sreenivas CBER	**P**	Richter, Taylor HFP
P	Inselman, Amy NCTR	**A**	Sanad, Yasser Comm. Member
P	Ireland, Derek CDER	**P**	Schwartzman, Louis OOSH
P	Khan, Saeed A. NCTR	**P**	Stantchev, Tzanko CDER
P	Khanna, Marilyn OCS/OSLA	**A**	Tadesse, Daniel CVM
P	Kochan, Travis CBER	**P**	Venkataraman, Thiagarajan (Raja) CBER
A	Krishna, Ashok CDER	**P**	Verma, Anita CBER
A	Laassri, Majid CBER	**P**	Waggener, Christopher T. HFP

EX-OFFICIO MEMBERS & OPTIONAL ATTENDEES			
P	Aljazrawi, Aveen OOSH	**P**	Lien, Christopher OC
P	Buttke, Thida OC	**P**	Marth, Theresa HFP
P	Bramhall, Elizabeth Comm. Member for WO	**P**	MacWilliams, Ziven OOSH
A	Degrasse, Jeffrey OOSH	**P**	Nwoka, Adaobi* OC
A	Fowler, Joe NCTR	**P**	Perlman, Amanda Comm. Member for WO
P	Hadden, Phoebe OOSH	**A**	Reid, Ericka CBER
P	Howard, Michele OOSH	**P**	Snyder, Jessica CDER
A	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 09/05/2025		
App. #	**Title**	**Approval Date**
13127	Relative Genotoxicity Evaluation of HPHCs Using the Ames Assay: Hazard Identification to Risk Characterization	11/18/2025

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MEETING SUMMARY

I. Meeting Commencement:

- The NCTR IBC meeting commenced at 9:31am EST.

II. Attendance

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

III. Review of September 18, 2025, NCTR IBC Meeting Minutes:

- D. Ireland motioned for approval of the September 18, 2025 and A. Debrabant seconded the motion.
- The September 18, 2025 meeting minutes were approved by 18 votes of approval, 0 votes of abstentions and 0 votes of disapproval.

IV. Applications

App. #	Title	Reviewer	NIH Ref	Outcome
13106	Neurological Targets of Montelukast for Potential Adverse Neuropsychiatric Events	1. Primary Reviewer 2. Secondary Reviewer	Section III-D	Approve ☒ Table ☐

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

Application #13106 Project Overview:

Section A: Synopsis

- The research objective of this study is to identify novel binding targets of montelukast in the central nervous system to better understand the potential mechanisms underlying adverse neuropsychiatric effects associated with this medication.

Section G: Pathogen and/or Toxin

- Not Applicable

General Comments from Primary Reviewer:

Primary Reviewer requests the PI answer the following questions/update the application:

- Section A: Please update - to clean the BSC, you should use at least a 1:10 dilution of bleach followed by 70% EtOH. You wrote a 1:100 dilution in your application.
- Section D: How will you propagate the transfer vector containing the HTR5A sequence? This is normally performed using bacterial cells and you stated you will not use prokaryotic cells.
- Section E: You state infectious virus, including replication incompetent virus, will not be generated. This application appears to generate lentivirus. Please update your response to "yes" or explain if you are not generating replication incompetent virus.
- Section H: Please explain where the rat brains used in the proposed experiments will be sourced.

General Comments from Secondary Reviewer:

Secondary Reviewer recommendations are as follows:

- Section A:
  - The description of the handling and decontamination of the biohazard waste in Section A needs to be more precise:
  - One paragraph implies that the biohazard waste will be collected in biohazard bags, placed in cardboard boxes and autoclaved, which is not feasible.
  - It should be specified which biohazard waste will be chemically inactivated and which will be autoclaved.
  - Per NIH recommendations the proposed 1/100 bleach dilution may be too high for BSL-2 decontamination (recommended 1/10 dilution)
- Section B:
  - The investigators are current on their General Biosafety and Blood Born Pathogens trainings. However, the lab safety inspection survey is outdated (02/14/23)
- Section C:
  - It should be clarified if rDNA expression constructs will be used to generate the protein panels described in Specific aim #1.
- Section D:

  - The application describes cloning procedures for the generation of 5-HT5A gene encoding plasmids and this will likely include work with E. coli competent cells. Therefore, the answer in Section D should be changed from "no" to "yes".
- Section E:
  - Specific aim #3 describes work with primary human cells. The cells will be obtained from commercial sources, but the proposed work may still require an Exemption Letter from the Human Subject Protection (HSP) Executive Officer, Office of the Chief Scientist (OCS).
  - The PI also describes the generation of 5-HT5A receptor expressing cell line SH-SY5Y. The description of this process implies the use of both transfection and transduction. If transduction is used information regarding the production and handling of the 5-HT5A encoding VLP should be provided.
  - Specific aim #3 also describes the use of human CNS-3D organoids. Information regarding these human organoids should be provided, along with information for the contractor lab which will generate and use the organoids.
- Section G:
  - No work with potential pathogens, infectious agents or toxins. However, for safety reasons primary human cells should be treated as potentially infectious.
- Section H:
  - No live vertebrate animals will be exposed to a pathogen and/or rsNAM. However, information should be provided how the animal tissue lysates described in Specific aim #2 will be generated and a reference should be made to an approved animal protocol.

IBC Committee Recommendations for Application 13106:

- Primary Reviewer motioned for approval of application 13106 with minor modifications. Secondary Reviewer supported the motion.
- Application 13106 was approved by 18 votes of approval, 0 votes of disapproval, and 0 abstentions.

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App. #	Title	Reviewer	NIH Ref	Outcome
13134	Synergistic Interactions Between Nanoparticles, Antibiotics, and Essential Oils in Combating Multidrug-resistant Bacterial Pathogens and Biofilms	1. Primary Reviewer 2. Secondary Reviewer	N/A	Approve ☒ Table ☐

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

Application #13134 Project Overview:

Section A: Synopsis

- This project will evaluate the antimicrobial and anti-biofilm effects of silver and copper nanoparticles, essential oils, and antibiotics against several multidrug-resistant bacterial pathogens. They will use standardized antimicrobial and biofilm efficacy tests of individual and combinations of treatments against the pathogens, followed by imaging and proteomic analysis.

Section G: Pathogen and/or Toxin

- Staphylococcus epidermidis, Enterococcus faecium, Pseudomonas spp. Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli, Enterococcus faecalis, Proteus mirabilis and Klebsiella pneumoniae

General Comments from Primary Reviewer:

Primary Reviewer recommendations are as follows:

- Section A: Change BSL-2 containment "will" be used for all bacterial.
- Section D: This section is for prokaryotes used in recombinant work. The methods written here can be moved to section A.

General Comments from Secondary Reviewer:

Secondary Reviewer recommendations are as follows:

- Section A: Change BSL-2 containment "will" be used for all bacterial strains. Also please describe the types of essential oils or antibiotics that will be tested be added to the application for full transparency
- Section B: Researcher will need to update their lab safety training; current training expired on 12/10/2024.

- Section D: This section is for prokaryotes used in recombinant work. The methods written here can be moved to section A and/or section G.
- Section G: PI answered "yes" to whether the resultant organism will be antibiotic resistant; however, no recombinant work is planned within the current application to confirm additional resistance to the strains.

IBC Committee Recommendations for Application 13134:

- Primary Reviewer motioned for approval of application 13134 with minor modifications. Secondary Reviewer supported the motion.
- Application 13134 was approved by 18 votes of approval, 0 votes of disapproval, and 0 abstentions.

V. Meeting Adjournment: The IBC meeting was adjourned at 10:15am EST.

VI. Next IBC Meeting: The next meeting is TBD.