

IBC MEETING SUMMARY

National Center for Toxicological Research (NCTR) Institutional Biosafety Committee

Thursday, April 16, 2026
9:30 a.m. – 12:30 p.m. EDT
Meeting Location: Teams

Facilitator: Amy Inselman

Recorder: Adaobi Nwoka

VOTING MEMBERS

A	Allard, Marc HFP	P	Lina, Taslima NCTR
A	Baer, Alan CBER	P	Linden, Sara CDRH
P	Debrabant, Alain CBER	A	Miller, Mayumi CVM
A	Evans, Anissa, Comm. Member	P	Pandey, Ruchi CDRH
A	Gannavaram, Sreenivas CBER	P	Papafragkou, Efstathia (Efi) HFP
P	Ge, Beilei CVM	P	Richter, Taylor HFP
P	Inselman, Amy NCTR	P	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	P	Venkataraman, Thiagarajan (Raja) CBER
P	Kochan, Travis CBER	A	Verma, Anita CBER
P	Krishna, Ashok CDER	P	Waggener, Christopher T. HFP
P	Laassri, Majid CBER		

EX-OFFICIO MEMBERS & OPTIONAL ATTENDEES

A	Aljazrawi, Aven	P	Marth, Theresa HFP
A	Bramhall, Elizabeth Comm. Member for WO	A	MacWilliams, Ziven OOSH
P	Brown, Tracey OOSH	P	McNeil, Ronald OOSH
A	Buttke, Thida OC	P	Nwoka, Adaobi* OOSH
A	Degrasse, Jeffrey OOSH	P	Perlman, Amanda, Comm. Member for WO
P	Dixon, Jeremy OOSH	P	Perrine, Albert
P	Fowler, Joe NCTR	A	Ragan, Angela OOSH
A	Hadden, Phoebe OOSH	P	Reid, Ericka CBER
P	Howard, Michele OOSH	A	Snyder, Jessica CDER
A	Kemp, Margaret CBER	A	Tremonti, Annette OC
P	Lien, Christopher OOSH	P	Marth, Theresa HFP

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 =

ADMINISTRATIVE REVIEW APPROVALS

NCTR IBC Administrative Review Approvals Since 3/11/2026

App. #	Title	Approval Date
13226	An International Inter-Laboratory Ring Trial to Evaluate the Feasibility and Reproducibility of Multiorgan-On-A-Chip Technology in Aiding Safety Assessment of Food Mixtures (A Proposal funded by the Chief Scientist's Cross Agency Regulatory Science (CARS) Program in 2026) (NCTR Protocol #C24029)	04/13/2026
13152	Integrated Multi-Technology Approach to Evaluate Breast Cancer Subtype Responses to Vorinostat (Zolanza®) Using 3D Human Spheroids (NCTR Protocol #C25023)	1/30/2026
13139	Relative Genotoxicity Evaluation of HPHCs Using the Ames Assay: Hazard Identification to Risk Characterization (NCTR Protocol #C25020)	12/11/2025

MEETING SUMMARY

I. Meeting Commencement:

- The NCTR IBC meeting commenced at 9:33 a.m. EDT.

II. Attendance

- A total of 18 voting members were present, which fulfilled the quorum needed to conduct IBC business. (2 voting members arrived after roll call.)

III. Review of December 11, 2025, NCTR IBC Meeting Minutes:

- Derek Ireland motioned for approval of the December 11, 2025, meeting minutes and Louis Schwartzman seconded the motion.
- The December 11, 2025, meeting minutes were approved by 15 votes of approval, 3 abstentions and 0 votes of disapproval.

IV. Applications

App. #	Title	Reviewer	NIH Ref	Outcome
13211	Safety assessment of excipients incorporated in formulation of drugs by nanotechnology: A NAMs-Based Regulatory Science Approach	1. Primary Reviewer 2. Secondary Reviewer	N/A	Approve ☒ Table ☐
13216	Assessment of impact of sex on CAR-T cell therapy outcomes	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 #13211 Project Overview:

Section A: Synopsis

- This study aims to develop a human-relevant, mechanistic framework using New Approach Methodologies (NAMs) to evaluate the gastrointestinal safety of pharmaceutical excipients and associated nitrosamine impurities. The research focuses on identifying early biological effects on intestinal barrier function, host defense, microbiome interactions, and carcinogenic risk that may not be detected by traditional toxicology methods. Ultimately, the goal is to improve regulatory assessment and support the design of safer drug formulations.

Section G: Pathogen and/or Toxin

- *Salmonella enterica serovar Typhimurium Heidelberg*

General Comments from Primary Reviewer:

Primary reviewer recommends approval pending revisions and clarification. The primary reviewers' recommendations are as follows:

- **Section A:** Please revise the application to provide a more detailed description of the proposed *Salmonella enterica* serovar Heidelberg procedures, including culture/manipulation methods, infection assay workflow, anticipated bacterial inoculum concentrations, and inoculation volumes used during experimentation (specifically, please provide volumes and concentrations in Tier 3).
- **Section E:** The PI uses the general term "enteric pathogens" and "bacteria" without explicitly naming *Salmonella Typhimurium (Heidelberg)*. Section G specifies a single agent: *Salmonella Typhimurium (Heidelberg)*. Please clarify that all infection assays will be conducted exclusively with the listed *Salmonella* strain, or update the application to include any additional organisms if applicable.
- **Section G:** Please confirm use of sealed centrifuge rotors or safety cups when concentrating organisms.
- Confirm handling and disposal considerations for materials involving both biological agents and potentially hazardous chemical compounds (e.g., nitrosamines), if applicable.
- Clarify how human-derived tissues are managed from a biosafety perspective (e.g., screening status or use of universal precautions).

General Comments from Secondary Reviewer:

Secondary reviewer recommends approval pending revisions and clarification. The secondary reviewer concurs with the recommendations of the primary reviewer.

Discussions and Questions During the IBC Meeting

- None.

IBC Committee Recommendations for Application #13211:

- Primary reviewer motioned for approval of application #13211. Secondary reviewer supported the motion.
- Application #13211 was approved by 18 votes of approval, 0 votes of disapproval, and 0 abstentions.

Application #13216 Project Overview:

Section A: Synopsis

- This study examines whether the biological sex of T cell donors influences the safety and effectiveness of CAR-T therapy. Researchers will use two mouse models—SCID-beige mice with functional immune cells and huNOG-EXL mice with human immune cells—to investigate these sex-based differences. The findings could enable physicians to better predict patient risk profiles, develop safer CAR-T therapies, and create personalized treatment strategies, particularly for cancers that predominantly affect women.
- Based on the protocol C24022 attached to this IBC application, this study has three main objectives or hypothesis.
 - Evaluate anti-tumor potency and safety profile of human CAR-T cells derived from male and female donors against ovarian cancer cells in ex vivo models.
 - Identify and characterize the biological and molecular factors that influence efficacy and safety profiles of male-derived versus female derived CAR-T cells and develop evidence-based strategies for optimizing their therapeutic performance.
 - Determine whether the biological sex of CAR-T cell donors influences therapeutic efficacy and safety profiles in two complementary pre-clinical models: SCID-beige immunodeficient mice and huNOG-EXL humanized immune system mice.

Section G: Pathogen and/or Toxin

- N/A

General Comments from Primary Reviewer:

Primary reviewer recommends approval pending revisions and clarification. The primary reviewers' recommendations are as follows:

Section A:

1. PI indicates that the source of engineered CD19+ SKOV3 ovarian cancer cells, human CAR-T cells and untransduced human T cells are from CBER under the IBC# 11462. But this IBC application doesn't contain any information about this cell line and engineering details of CD19+ SKOV3 ovarian cancer cells as well as CAR-T cells. The IBC# 11462 needs to be modified to reflect the engineering details of the human derived SKOV3 cancer cell line and T cells from human donors obtained from NIH.
2. Liquid waste from NALM6, SKOV3, and CAR-T cell cultures is decontaminated with bleach (1:10 dilution, 20-minute incubation). The decontamination time for liquid waste from NALM6, SKOV3, and CAR-T cell cultures using a 1:10 bleach dilution is generally recommended to be at least 30 minutes to ensure complete inactivation of human cells and potential viral vectors.
3. Include freshly prepared 10% of bleach solutions and 70% ethanol will be utilized for disinfection of surfaces and equipment in the laboratory.
4. Include use of secondary containers for transportation of material from BSL2 enhanced lab for storage and transfer.

Section C:

1. Information provided in the “What are your sources of DNA for this research” section is not conducted with this IBC application, so the details of the rsNAM engineering is not required in this application.
2. In this section, it is mentioned that CD19+ SKOV3 ovarian cancer cells will be administered to mice by tail vein injection, but in other places it is mentioned as intra-peritoneal injection.

Section E: It mentioned here that “modified CD19+ SKOV3 ovarian cancer cells (BSL-1, generated by CBER)” handled in BSL-1. Genetically modified cells often require BSL-2 containment.

Section H: Once approved, the details of the animal study protocol should be included in this section.

Section I: This section needs to be completed as this study uses human untransduced T cells and anti-CD19 CAR-T cells in animal studies.

General Comments from Secondary Reviewer:

Secondary reviewer recommends approval pending revisions and clarification. The secondary reviewer concurs with the recommendations of the primary reviewer and recommends:

- Section C: Recommend that the PI may remove the description of recombination because it is in the IBC application 11462 and not in this application. This group is not seeking approval for the generation of CAR-T cells.

Discussions and Questions During the IBC Meeting

- None.

IBC Committee Recommendations for Application #13216:

- Primary reviewer motioned for approval of application #13216 with modifications. Secondary reviewer supported the motion.
- Application #13216 was approved by 19 votes of approval, 0 votes of disapproval, and 0 abstentions.

V. Meeting Adjournment: The IBC meeting was adjourned at 10:51 a.m. EDT.

VI. Next IBC Meeting: The next meeting is scheduled for May 22, 2026, at 9:30 a.m. EDT.