IBC MEETING SUMMARY

White Oak (WO) Institutional Biosafety Committee

Thursday, June 18, 2026
9:30 a.m. – 12:30 p.m. EDT
Meeting Location: Teams

Facilitator: Derek Ireland
Recorder: Tracey Brown*

VOTING MEMBERS

P	Allard, Marc HFP	**P**	Lina, Taslima NCTR
P	Baer, Alan CBER	**P**	Linden, Sara CDRH
P	Bramhall, Elizabeth Comm. Member	**P**	Miller, Mayumi CVM
P	Debrabant, Alain CBER	**P**	Pandey, Ruchi CDRH
P	Gannavaram, Sreenivas CBER	**P**	Papafragkou, Efstathia (Efi) HFP
P	Ge, Beilei CVM	**P**	Perlman, Amanda Comm. Member
P	Inselman, Amy NCTR	**P**	Richter, Taylor HFP
P	Ireland, Derek CDER	**P**	Schwartzman, Louis OOSH
P	Khan, Saeed A. NCTR	**A**	Stantchev, Tzanko CDER
P	Khanna, Marilyn OCS/OSLA	**P**	Venkataraman, Thiagarajan (Raja) CBER
A	Kochan, Travis CBER	**A**	Verma, Anita CBER
P	Krishna, Ashok CDER	**A**	Waggener, Christopher T. HFP
P	Laassri, Majid CBER		

EX-OFFICIO MEMBERS & OPTIONAL ATTENDEES

A	Aljazrawi, Aveen	**A**	Marth, Theresa HFP
P	Brown, Tracey* OOSH	**A**	MacWilliams, Ziven OOSH
A	Buttke, Thida OC	**P**	McNeil, Ronald OOSH
A	Degrasse, Jeffrey OOSH	**A**	Nayak, Rajesh NCTR
P	Deptola, Alexa CDRH	**P**	Nwoka, Adaobi* OOSH
A	Dixon, Jeremy OOSH	**P**	Perrine, Albert OOSH
A	Evans, Anissa Comm. Member for NCTR	**A**	Ragan, Angela OOSH
A	Fowler, Joe NCTR	**P**	Reid, Ericka CBER
P	Hadden, Phoebe OOSH	**A**	Sanad, Yasser Comm. Member for NCTR
P	Howard, Michele OOSH	**P**	Snyder, Jessica CDER
A	Kemp, Margaret CBER	**A**	Tremonti, Annette OC
P	Lien, Christopher OOSH		

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

ADMINISTRATIVE REVIEW APPROVALS

WO IBC Administrative Review Approvals Since 5/07/2026		
App. #	**Title**	**Approval Date**
13230	Identifying molecular and morphological features important for stem cell function	06/02/2026
13243	(1) Modulation of Leukocyte Function by Alternative Signaling Pathways (Project Number: 1009) (2) Development of a spectral cytometry-based assay to assess the antibody-dependent cell-mediated cytotoxicity for characterization of biosimilar products (4077) (3) Development and validation of an antibody-dependent cellular phagocytosis bioassay for potency and characterization of therapeutic antibodies against Alzheimer's disease (4078)	06/02/2026
13201	Evaluation of nonclinical NAMs and microphysiological systems as useful tools in the prediction of clinically relevant pharmacokinetic and toxicological properties of drugs.	05/19/2026

MEETING SUMMARY

I. Meeting Commencement:

- The WO IBC meeting commenced at 9:31 A.M. EDT.

II. Attendance

- A total of 21 voting members were present, which fulfilled the quorum needed to conduct IBC business.

III. Review of May 21, 2026, WO IBC Meeting Minutes:

- Derek Ireland motioned for approval of the May 21, 2026, minutes and Marc Allard seconded the motion.
- The May 21, 2026, meeting minutes were approved by 19 votes of approval, 0 votes of disapproval, and 2 abstentions.

IV. Applications

App. #	Title	Reviewer	NIH Ref	Outcome
13265	Immunogenicity of Protein-based Therapeutics	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 #13265 Project Overview:

Section A: Project Description

- An important part of determining the clinical safety and efficacy of protein-based therapeutic products is measuring their tendency to trigger antibody formation, this work seeks to understand why some individuals or ethnicities develop anti-drug antibodies while others do not. This group plans to develop computational methods and bio-assays, specifically in silico immunogenicity prediction, human ex vivo cellular assays, and immunopeptidomics to predict the potential immunogenicity of new products early in development against Cas proteins. Specific Aims are:

  Aim 1. Validate fit for purpose NAM workflows for immunogenicity risk assessment across Cas proteins and delivery modalities.
  Aim 2. Develop and qualify tetramer based assays to quantify Cas specific $CD8^+$ and $CD4^+$ T cell risk.
  Aim 3. Establish computational pipelines to predict immunogenic risk arising from off target gene editing events.

Section G: Pathogen and/or Toxin

- **Yes:** Staphylococcal enterotoxin B (SEB) will be used in very low amounts (10 ng/ml) as an assay control.

General Comments from Primary Reviewer:

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

- Section D: Applicant should clarify if prokaryote cells will be used in generation of plasmids or constructs as they have currently selected No to prokaryote use.
- Section E: Applicant has classified Section E work under Section III-A-1 of NIH Guidelines, this appears incorrect as there is no infectious/defective virus and no helper system. A classification of III-D-2 should be applied as this covers experiments where DNA is cloned into a nonpathogenic host-vector system.
- Section F: Applicant has classified Section F work under Section III-A-1 of NIH Guidelines, this appears incorrect and a classification of III-D is appropriate as there is no drug resistance transfer, no virulence enhancement, and no toxin encoding.

General Comments from Secondary Reviewer:

Secondary reviewer recommends approval pending minor clarifications from the PI. The secondary reviewers' recommendations are as follows:

- Section E: The question regarding expression of a foreign gene is answered "N/A," yet Cas9 is listed as the expressed protein in the follow-up field — this is internally inconsistent and must be corrected by the PI.
- Section F: The PI classifies the work under Section III-A-1 of the NIH Guidelines, which pertains to prohibited experiments. This is more likely to fall under Section III-D or III-E. This needs to be verified by PI.

Discussions and Questions During the IBC Meeting

- None.

IBC Committee Recommendations for Application #13265:

- Primary reviewer motioned for approval of application #13265 with minor modifications. Secondary reviewer supported the motion.
- Application #13265 was approved by 21 votes of approval, 0 votes of disapproval, and 0 abstentions.

App. #	Title	Reviewer	NIH Ref	Outcome

13237	Efficacy of antimicrobial 405 nm light-based pathogen inactivation of HTLV-1 and HTLV-2	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 #13237 Project Overview:

Section A: Synopsis

- This study aims to evaluate the efficacy of 405 nm blue light as a pathogen reduction technology for inactivating both cell-associated and cell-free Human T-cell Lymphotropic Virus (HTLV-1 and HTLV-2). The virus will be spiked into standard human platelet and plasma units, and the level of viral inactivation will be quantified to assess the technology's potential for improving blood product safety.

Section G: Pathogen and/or Toxin

- Human T-cell Lymphotropic retroviruses HTLV-1 and HTLV-2, which are pathogenic to humans. It specifies that a Class II Biosafety Cabinet will be used for containment and that the agent is not classified as a 'Select Agent'.

General Comments from Primary Reviewer:

The primary reviewer recommends approval with minor modifications. The primary reviewers' recommendations are as follows:

- Section A: The estimated start date is listed as 06/01/2026, which is in the past. Please update this to the current date.
- Section G:
  - This section indicates that the organism will not be concentrated. However, the synopsis on Page 2 explicitly describes creating a "concentrated stock of infected cells" and using a "concentrated virus stock" for spiking. Please amend this section to accurately reflect the concentration methods used.
  - The application answers "No" to performing "significant aerosol generating procedures." This contradicts the synopsis on Page 3, which correctly identifies that "harvesting MT-2 cells, centrifugation, 0.45 µm filtration...and aliquoting...are all procedures with the potential to generate aerosols or droplets." The PI must change this response to "Yes" and ensure the mitigation strategies detailed in the synopsis are referenced.
  - The application states "No" to having a sample repository, but then notes that the pathogen will be stored in "Br. McGivern's lab freezer." Please clarify if this constitutes a repository and update the section for consistency.
- The description of sample manipulation techniques is incomplete, listing only "exposure to 405 nm light." Please expand this section to include all relevant manipulation techniques mentioned in the synopsis, such as centrifugation, filtration, spiking, and mixing.
- The application is well-written and provides a detailed description of the experimental workflow and safety considerations in the synopsis. The risk mitigation strategies for handling human blood products and potential aerosols, such as the use of a Class II Biosafety Cabinet and sealed centrifuge rotors, are well-described.
- However, there are several significant inconsistencies between the detailed information provided in the synopsis and the answers provided in the formal sections of the application, particularly in Sections G and I. This application can be approved once the minor modifications are made to resolve these contradictions and ensure all sections accurately reflect the described procedures.

General Comments from Secondary Reviewer:

The secondary reviewer recommended approval with minor clarifications/modifications. The secondary reviewers' recommendations are as follows:

- Section A: Virus and Cell Line: A well-characterized, high-titer strain of HTLV-1 and HTLV-2 will be propagated in the MT-2 human T-cell line: please provide the origin of cells and viruses. Please use acronyms after having first introduced cells/viruses
    - Though it is mentioned that all personnel are trained in BSL-2 practices, it would be useful to include the use of gloves, gowns, or other personal protective equipment utilized
    - It would be useful to include a statement on how to carry tubes from the BSC to the centrifuges.
    - Surface decontamination with bleach for how long? Followed by ethanol use?
    - For liquid biological waste, please include the appropriate contact time prior to disposal
    - Please include approach in case of spills
    - Please clarify whether the ELISA testing will be performed outside the BSC? Which practices (spiking, mixing etc.) will be performed inside or outside the BSC?
- Section G: Specify location, building room number of freezer where viruses and any samples generated are stored

Discussions and Questions During the IBC Meeting

- None.

IBC Committee Recommendations for Application #13237:

- Primary reviewer motioned for approval of application #13237. Secondary reviewer supported the motion.
- Application #13237 was approved by 20 votes of approval, 0 votes of disapproval, and 0 abstentions.

App. #	Title	Reviewer	NIH Ref	Outcome
13246	Development of Immunomodulatory Therapeutics	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 #13246 Project Overview:

Section A: Synopsis

- Viral proteins will be expressed in several different human cell lines and primary PBMC. In this iteration of the application, the PI is adding the use of lentiviral vector systems to express viral proteins in these eukaryotic cell models. Because of the use of lentiviral vectors, the PI correctly describes the use of BSL-2 enhanced techniques, working in a BSL-2 laboratory.

Section G: Pathogen and/or Toxin

- AAV strain 2, 6, 8 and 9 and HIV based lentiviral vectors. The viruses are not inactivated and are concentrated in containment centrifuge.

General Comments from Primary Reviewer:

The primary reviewer recommends approval of this application with minor modifications. The primary reviewers' recommendations are as follows:

- Section A: rewrite the following sentence for clarity "Soak paper towels in straight bleach and place them on top of the spill. Place a diaper on top of the paper towels, with the plastic side away from the spill".
- Section E: Provide expanded forms of all viruses mentioned.
- Section F: Provide expanded forms for the cellular proteins mentioned.

General Comments from Secondary Reviewer:

The secondary reviewer recommends approval of this application with minor modifications. The secondary reviewers' recommendations:

- Section A:
  - In this section, the PI describes the use of straight bleach in spill procedures. This should be replaced with 10 % bleach.
  - For spill procedures, add description of placing contaminated materials in small biohazard bag before removal from BSC to biohazard box.
- Section B: Sources of the vectors used are appropriately described. However, a few more details about the plasmids being used should be provided, including the plasmids being sourced and the generation of the lentiviral vectors used being obtained.
- Section E: A very brief description of how the T cells are isolated from PBMC (e.g., negative selection using magnetic beads) would help complete information needed for a risk assessment of handling human samples. It should be stated that the primary human cells are de-identified and an exemption from IRB review has been obtained.
- Section G: HCV, Yellow Fever and HGV pathogens have been removed from section G, but are still described in Section E. Please provide clarity and make sure that these two sections are in parity.

Discussions and Questions During the IBC Meeting

- None.

IBC Committee Recommendations for Application #13246:

- Primary reviewer motioned for approval of application #13246. Secondary reviewer supported the motion.
- Application #13246 was approved by 20 votes of approval, 0 votes of disapproval, and 0 abstentions.

App. #	Title	Reviewer	NIH Ref	Outcome
13257	Impact of drying stress on Cronobacter recovery during rehydration in low-moisture food systems	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 #13257 Project Overview:

Section A: Synopsis

- The study is to be conducted under BSL2 conditions. It seeks to better understand how different drying conditions (i.e., liquid, freeze-dried, and air-dried) influence the recovery of Cronobacter strains (an opportunist human pathogen and causes severe infections in infants) using three representative species (Cronobacter malonaticus, Cronobacter sakazakii, and Cronobacter turincensis) in powdered infant formula. The strain recovery behavior and gene expression will be characterized by RNA-seq. Section G: Pathogen and/or Toxin Opportunistic human pathogen - Cronobacter spp.Not inactivated, < 10 liters.Concentrated by centrifugation, filtration, and precipitation.Handled in BSC Class II hoods and stored in walk-in refrigerator and freezer.

Section G: Pathogen and/or Toxin

- Opportunistic human pathogen – *Cronobacter* spp.
- Not inactivated, < 10 liters.
- Concentrated by centrifugation, filtration, and precipitation.

- Handled in BSC Class II hoods and stored in walk-in refrigerator and freezer.

General Comments from Primary Reviewer:

The primary review concurs with the secondary reviewer's comments and recommends approval of this application with minor modifications, with review of spelling and syntax.

General Comments from Secondary Reviewer:

The secondary reviewer recommends approval of this application with minor modifications. The secondary reviewers' recommendations:

- Section A:
  - In the experimental section of the Synopsis, it is mentioned that air- and freeze-dried samples will be rehydrated but the information about how long after the drying, samples will be rehydrated, is missing.
  - Recovery details of Cronobacter samples after spiking of powdered milk formula are missing. Also, it is not mentioned whether Ziplock bags that were used to store spiked PIF samples were sterilized or not.
  - The start date is indicated as 06/01/2026. This needs to be changed to reflect current date.
- Section D: Under this section, the question to be answered is, "I plan to create rsNAMs or otherwise use prokaryotic cells." The secondary reviewer believes that that the answer to this should be "Yes" because the PI is using prokaryotic cells for the study.

Discussions and Questions During the IBC Meeting

- None.

IBC Committee Recommendations for Application #13257:

- Primary reviewer motioned for approval of application #13257. Secondary reviewer supported the motion.
- Application #13257 was approved by 20 votes of approval, 0 votes of disapproval, and 0 abstentions.

V. Meeting Adjournment: The IBC meeting was adjourned at 10:28 A.M. EDT.

VI. Next IBC Meeting: The next meeting is scheduled for July 16, 2026.