IBC MEETING SUMMARY

White Oak (WO) Institutional Biosafety Committee

Thursday, March 19, 2026

9:30AM – 12:30PM EST

Meeting Location: Teams

Facilitator: Derek Ireland Recorder: Adaobi Nwoka			
VOTING MEMBERS			
A	Allard, Marc HFP	**A**	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
A	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	**P**	Stantchev, Tzanko CDER
A	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			
P	Aljazrawi, Aveen	**P**	Lien, Christopher OOSH
P	Brown, Tracey OOSH	**A**	Marth, Theresa HFP
P	Buttke, Thida OC	**A**	MacWilliams, Ziven OOSH
A	Degrasse, Jeffrey OOSH	**P**	McNeil, Ronald OOSH
P	Dixon, Jeremy OOSH	**P**	Nwoka, Adaobi* OOSH
A	Evans, Anissa Comm. Member for NCTR	**P**	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	**P**	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

WO IBC Administrative Review Approvals Since 2/12/2026		
App. #	**Title**	**Approval Date**
13172	Characterization of the immunomodulatory effect of impurities that activate the innate immune response in human cells or tissues	03/10/2026
13173	In vivo assessment of IIRMI activity to correlate with in vitro assays	03/10/2026
13180	Fluorescence-based neutralization assay for influenza virus	03/10/2026
13188	Replication and pathogenesis of hepatitis C virus	03/10/2026
13190	Cell culture models of Hepatitis E virus (HEV) infection and development of reference reagents	03/10/2026
13191	Animal models of HEV transfusion transmission and pathogenesis	03/05/2026
12014	Immunogenicity of Protein-based Therapeutics	03/03/2026
13171	Production of EBV-immortalized cell lines to generate materials for blood group molecular genotyping reference panels	03/03/2026
13165	Development of novel Human Lymphoid Follicle microphysiology system (MPS) for evaluation of immunogenicity risk.	02/18/2026

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MEETING SUMMARY

I. Meeting Commencement:

- The WO IBC meeting commenced at 9:32am EST.

II. Attendance

- A total of 20 voting members were present, which fulfilled the quorum needed to conduct IBC business.
- T. Venkataraman joined at 9:37am and B. Ge joined at 9:42am.

III. Review of February 19, 2026, WO IBC Meeting Minutes:

- D. Ireland motioned for approval of the February 19, 2026, and A. Inselman seconded the motion.
- The February 19, 2026, meeting minutes were approved by 17 votes of approval and 1 vote of abstention from A. Baer due to absence in the meeting.

IV. Applications

App. #	Title	Reviewer	NIH Ref	Outcome
13175	Biotechnology, biomanufacturing, and characterization of recombinant proteins	1. Primary Reviewer 2. Secondary Reviewer	Sections III-D-2-a & III-D-3	Approve ☒ Table ☐

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

Application 13175 Project Overview:

Section A: Synopsis

- The current application describes how manufacturing processes affect the quality and performance of protein-based therapeutics through four related projects/goals:
  - **Project 1**: Creates proteins in bacterial and mammalian cells at different production scales, then tests how changes in manufacturing conditions alter the protein's structure, function, and potential to trigger immune reactions.

- **Project 2**: Uses advanced genetic and protein analysis tools to identify differences in the cells and materials used to make these medicines, comparing traditional manufacturing methods with newer cell-free systems.
- **Project 3**: Focuses specifically on antibody drugs (like rituximab and trastuzumab), examining how oxidation damages these proteins and affects their therapeutic activity under different stress conditions.
- **Project 4**: Provides technical support to centers for cell line creation, small-scale protein production, and quality analysis of laboratory and commercial drug products

- These goals will provide an understanding of how manufacturing choices impact protein drug quality to ensure these drugs are safe and effective.

Section G: Pathogen and/or Toxin

- Lentivirus Clontech

General Comments from Primary Reviewer:

The primary reviewer recommends the PI clarifies several sections in the application. Reviewers' recommendations are as follows:

- This project includes experiments involving recombinant DNA and lentiviral vector work. According to NIH Guidelines all lentiviral vector work requires BSL-Level 2 containment with BSL-2 enhanced practices. This practice is important because many lentiviral vectors are pseudotyped with VSV-G that allow these to infect a wide variety of mammalian cells including human cells. Although risk is low, however the ability to infect human cells and integrate into DNA requires this practice.
- Work procedures include double gloving, eye and face protection when splash risk exists, sharps use should be minimized.
- Lentiviral stocks must be stored in sealed labeled containers in designated freezers.
- All lab personnel must complete lentiviral-specific training.
- Please ensure the two staff members mentioned for this project have completed all relevant training for OHS clearance.

General Comments from Secondary Reviewer:

The secondary reviewer recommendations are as follows:

- In Section A, the research scope clearly describes four projects. However, there is no description of the historical rat plasma samples from IBC 11752 that will be used in Project 3. Please provide a brief description of the historical rat plasma samples in Section A.

- Regarding the decontamination protocol, in this application you mentioned two different concentrations and contact times: 20% bleach for 10 minutes and 10% bleach for 30 minutes. Please specify which protocol you are using and confirm its effectiveness.
- In Section I, you responded "No" but Project 3 mentions using "historical oxidized plasma proteins previously harvested from rat serum under IBC 11752." This appears contradictory and needs clarification.
- This project includes lentiviral vectors that are pseudo typed with VSV-G, allowing these to infect a wide variety of mammalian cells including human cells. Although risk is low, however the ability to infect human cells and integrate into DNA requires this practice. Because of this, please change “what is the proposed work practices biosafety level”: to BSL-2 enhanced and include the language below:
- Work procedures should include double gloving, eye and face protection when splash risk exists, sharps use should be minimized.
- Lentiviral stocks must be stored in sealed labeled containers in designated freezers.
- All lab personnel must complete lentiviral-specific training.
- Please ensure the two staff members mentioned for this project have completed all relevant training for OHS clearance.

Discussions and Questions During the IBC Meeting

- The IBC Chair recommends the PI includes additional information to the following:
  - Change from 100% bleach to 10% bleach for decontamination followed by ethanol to prevent damage to the hoods.
  - Although spill kits were mentioned, PI should include additional detail on large scale spill cleanup and containment.
- **Comment**: There might be a spill containment device used for large barrels in hazardous waste environments. May need to follow up with waste contractors for recommendations.

IBC Committee Recommendations for Application 13175:

- Primary reviewer motioned for approval of application 13175 with minor modifications. Secondary reviewer supported the motion.
- Application 13175 was approved by 20 votes of approvals.

V. Meeting Adjournment: The IBC meeting was adjourned at 10:12am EST.

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