IBC MEETING SUMMARY

White Oak (WO) Institutional Biosafety Committee

Thursday, February 19, 2026

9:30AM – 12:30PM EST

Meeting Location: Teams

Facilitator: Derek Ireland Recorder: Adaobi Nwoka			
VOTING MEMBERS			
P	Allard, Marc HFP	**P**	Lina, Taslima NCTR
A	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
A	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
P	Khanna, Marilyn OCS/OSLA	**P**	Venkataraman, Thiagarajan (Raja) CBER
P	Kochan, Travis CBER	**P**	Verma, Anita CBER
P	Krishna, Ashok CDER	**P**	Waggener, Christopher T. HFP
P	Laassri, Majid CBER		

EX-OFFICIO MEMBERS & OPTIONAL ATTENDEES			
P	Aljazrawi, Aveen OOSH	**P**	Lien, Christopher OC
P	Brown, Tracey OOSH	**P**	Marth, Theresa HFP
A	Buttke, Thida OC	**A**	MacWilliams, Ziven OOSH
A	Degrasse, Jeffrey OOSH	**P**	Nwoka, Adaobi* OC
A	Evans, Anissa Comm. Member for NCTR	**P**	Ragan, Angela* OOSH
A	Fowler, Joe NCTR	**A**	Reid, Ericka CBER
A	Hadden, Phoebe OOSH	**A**	Sanad, Yasser Comm. Member for NCTR
A	Howard, Michele OOSH	**A**	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

WO IBC Administrative Review Approvals Since 12/02/2025		
App. #	**Title**	**Approval Date**
13160	In vitro permeation test (IVPT) to support bioequivalence (BE) approach development for a test product referencing Aklief® (trifarotene) topical cream, 0.005%, new drug application (NDA) # 211527	02/11/2026
12489	Evaluation of blood product potency and thrombogenicity in vitro	02/06/2026
13072	Development of a Discriminatory IVPT Method for Ivermectin Topical Cream, 1%	02/05/2026
13007	Study the mechanism of action and critical quality attributes of HER family receptor-targeted monoclonal antibodies, antibody-drug conjugates and bi- and tri-specific antibodies and develop/quality the bioassays to support OPQ mission	01/30/2026
13144	Characterizing the impact of mycoplasma contamination of analytical cell line on HER family antibody bioassay development	01/22/2026

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MEETING SUMMARY

I. Meeting Commencement:

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

II. Attendance

- A total of 23 voting members were present, which fulfilled the quorum needed to conduct IBC business.
- A. Verma departed at 10:46am

III. Review of January 15,2026, WO IBC Meeting Minutes:

- D. Ireland motioned for approval of the January 15,2026 and L. Schwartzman seconded the motion.
- The January 15,2026 meeting minutes were approved by 21 votes of approval and 2 votes of abstentions due to absence in the meeting.

IV. Applications

App. #	Title	Reviewer	NIH Ref	Outcome
13161	Detection and pathogenesis of transfusion transmissible tick-borne pathogens	1. Primary Reviewer 2. Secondary Reviewer	Section III-D-1-a	Approve ☒ Table ☐

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

Application #13161 Project Overview:

Section A: Synopsis

- The aim of the studies is to develop molecular diagnostics for certain tick-borne agents that are transfusion transmissible. There are no licensed donor screening assays for the Tick-borne agents such as Anaplasma and Ehrlichia. The investigators also plan to undertake studies of pathogenesis of Babesia, Anaplasma and Ehrlichia using CRISPR, transposon and inducible gene knockdown methods. Plasmids used in this study will be obtained from commercial vendors.

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Section G: Pathogen and/or Toxin

- Anaplasma phagocytophilum, Ehrlichia chaffeensis and Babesia divergens

General Comments from Primary Reviewer:

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

- Section A: We recommend BSL-2 enhanced due to the lentivirus use and the random nature of the insertions. Please add the following enhanced practices when dealing with live LV: double gloves, closed front gowns, MPW, and avoid sharps whenever possible.
- Section C: Please revise the section to reflect which genome is being modified in each of the paragraphs i.e., host or pathogen. Adding a sentence on the purpose of the genetic manipulation at the beginning of each section will be helpful. Please also remove references to "in my previous laboratory' in this section.
- Section D: In the description of the experiment, the PI only mentions the transposon plasmid. Both the transposon and transposase plasmids should be named.
- Section E: Having the list of genes that will be modified would increase safety assurances. Also, please include a description of the molecular diagnostic assays using human blood and blood products here.
- Section E: While rare, there is a risk of transmission through aerosolization. Is the FACS contained and have HEPA filtration or in a BSC? Are you using the flow core?
- Section I: This should be yes since they are using blood from the NIH blood bank.

General Comments from Secondary Reviewer:

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

- Section A: Please revised the sentence "The first goal of this project is to develop new molecular diagnostics for all transfusion transmissible tick-borne pathogens". Since the program is focusing on Babesia, Anaplasma and Ehrlichia, and not all tick-borne agents are BSL-2, it is appropriate to be selective.
- Section C: Revise the section to reflect which genome is being modified in each of the paragraphs i.e., host or pathogen. Adding a sentence on the purpose of the genetic manipulation at the beginning of each section will be helpful. Proofreading of this section to remove references to "in my previous laboratory' is desirable.
- Section E: Some description of the molecular diagnostic assays using human blood and blood products hers is appropriate.

- Section I: This should be 'yes' since spiking experiments are proposed to be conducted using blood and blood products.

IBC Committee Recommendations for Application #13161:

- Primary reviewer motioned for approval of application 13161 with minor modifications. Secondary reviewer supported the motion.
- Application 13161 was approved by 23 votes of approval, 0 votes of disapproval, and 0 abstentions.

App. #	Title	Reviewer	NIH Ref	Outcome
13156	Whole-Genome Sequencing Approaches for Hepatitis A Virus to Enhance Foodborne Outbreak Detection and Source Attribution	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 #13156 Project Overview:

Section A: Synopsis

- The goal of this project is to conduct a coordinated, inter-laboratory evaluation of targeted and non-targeted HAV sequencing approaches to identify optimal methods for detecting, genotyping, and discriminating against HAV strains from low-titer food and clinical samples. The proposed evaluation will be performed on frozen raspberries, the most reported carrier of HAV associated with outbreaks in the US. This work will support method development and optimization, improve the capacity to confirm HAV in presumptive samples, and enable the integration of high-quality HAV genome data into ViroTrakr, therefore facilitating source tracking during outbreaks.

Section G: Pathogen and/or Toxin

- Hepatitis A virus

General Comments from Primary Reviewer:

Primary reviewer recommends the PI clarifies the following sections in the application:

- Section A:

- Provide more detail about how serum samples will be processed
- Raspberries mentioned in first paragraph. Please describe how they will be used in the study. Will any spiking experiments with HAV be performed.
- Transport should be completed in sealed secondary containers with coolers inside the containers.
- Please specify that exterior of containers will be decontaminated inside BSC prior to transport outside the BSC and samples will be place in secondary containers inside BSC.
- Provide lysis method for RNA isolation to allow for full assessment of its ability to inactivate HAV.
- 10 % Bleach in BSC should be followed by 70 % ethanol to prevent metal corrosion. 70 % ethanol also an effective disinfectant on its own. Include contact time with chosen disinfectant. HAV has a dwell time of at least 15 minutes due to its environmental stability (stable for months on surfaces)
- Replace "capped rotor" with "biocontainment rotor"
- Remove sentence "Spills are unlikely…." and replace will spill clean-up and decontamination procedures.
- Indicate lab workers will decontaminate and remove gloves inside BSC prior to removing hands from BSC. Then hands will be immediately washed before working outside the BSC.
- Include vaccination in sentence regarding OHS.

- Section B:
  - Is PI only person working this project? If additional staff, please add. Please also use updated office and division information.
- Section G:
  - Can remove HAV from Toxin description and LD50
  - The PI has answered "10% bleach solution" to the question "If the agent will be inactivated prior to other laboratory manipulation" which is incorrect as this disinfection applies to biosafety cabinets and lab benches. Describe the RNA extraction agent/lysis agent here.
  - The PI should doublecheck whether a permit is required from the CDC, USDA or FDA for acquiring or working with this agent.

General Comments from Secondary Reviewer:

Secondary reviewer recommends the PI clarifies the following sections in the application:

- Section A:
  - The PI should describe how and where the work with the seeded foods will be conducted as well as the sequencing
  - The disinfection of biosafety cabinet should be more detailed including contact times (freshly prepared 20% bleach solution for 20 min followed by 70% ethanol and a UV sterilization for 10 min)
- Section B: If possible, use the new office, division information
- Section G:
  - The PI in the question of "Will you be working with a toxin" has answered "yes" which is not applicable
  - The PI has answered "10% bleach solution" to the question "If the agent will be inactivated prior to other laboratory manipulation" which is incorrect as this disinfection applies to biosafety cabinets and lab benches
  - The PI should doublecheck whether a permit is required from the CDC, USDA or FDA for acquiring or working with this agent

IBC Committee Recommendations for Application #13156:

- Primary reviewer motioned for approval of application 13156 with minor modifications. Secondary reviewer supported the motion.
- Application 13156 was approved by 23 votes of approval, 0 votes of disapproval, and 0 abstentions.

App. #	Title	Reviewer	NIH Ref	Outcome
13158	Bacteriophage therapy for Vancomycin resistant Enterococcus (VRE)	1. Primary Reviewer 2. Secondary Reviewer	Section III-D-1-a	Approve ☒ Table ☐

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

Application #13158 Project Overview:

Section A: Synopsis

- The purpose of this study is to examine the feasibility of developing bacteriophage-based therapy against vancomycin-resistant Enterococcus (VRE) and to investigate potential regulatory issues, including how mutations in both the phage and bacterial strains over time might affect therapeutic effectiveness. The research also aims to

evaluate phage/host effectiveness in animal models using bioluminescent VRE strains to enable real-time quantification of bacterial load.

Section G: Pathogen and/or Toxin

- Enterococcus spp.

General Comments from Primary Reviewer:

Primary reviewer recommends the PI clarifies the following sections in the application:

- Section A:
  - PI did not specify the list of bacteriophages or VRE strains in this section.
  - The PI described that they will use a range of VRE hosts and a range of phages to study bacterial resistance to phages and the change of host range specificity in phages, next generation sequencing etc., but experimental details were missing. Some degree of specificity and details about experimental strategy would be useful.
  - The start date of the project is mentioned as 10/15/2015. This need to be updated.
  - Please mention the ID of bacterial strains and phages used and the status of any of ASPs (2018-60, and 2016-03?)
  - Describe how aerosol generation will be mitigated and details of decontamination procedure.
- Section D:
  - The PI has mentioned the use of Enterococcus faecium and E. faecalis but no mention of specific phages to be used. No details of experimental procedures are given. The PI should mention, any ASPs currently under development or in active status, in this section.

General Comments from Secondary Reviewer:

Secondary reviewer recommends the PI clarifies the following sections in the application:

- Section A:
  - Please provide details on the list of VRE and phage strains that will be used in this project.
  - Please verify the start date of the project.
- Section D:
  - Please clarify whether the bioluminescent VRE strains will be shared outside the laboratory or used in collaborative studies, and if so, what containment measures will be in place.

- Section G:
  - Please specify the BEI Resources catalog numbers or strain identifiers for the VRE isolates to be used.
  - Please clarify the storage and inventory procedures for the bacteriophage isolates in addition to the bacterial strains, including their location and containment.
  - Please elaborate on how the bacterial preparations will be concentrated by centrifugation and what the final concentration will be.
  - Please clarify the decontamination procedures for bacteriophage work. While you mention using 10% bleach for consistency with C. difficile work, please confirm this is appropriate for inactivating the bacteriophages being studied.

IBC Committee Recommendations for Application #13158:

- Primary reviewer motioned for approval of application 13158 with minor modifications. Secondary reviewer supported the motion.
- Application 13158 was approved by 23 votes of approval, 0 votes of disapproval, and 0 abstentions.

App. #	Title	Reviewer	NIH Ref	Outcome
13170	Novel ATP bioluminescence methods for microbial detection in product quality assessments (Rapid Sterility Testing WG)	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 #13170 Project Overview:

Section A: Synopsis

- This project aims to compare the performance of commercial Rapid Microbiological Methods (RMM) to conventional compendial methods for sterility testing of biologic products. They list three pieces of RMM equipment and one additional commercial kit with ten bacterial species.

Section G: Pathogen and/or Toxin

- Several pathogens were listed including, Shigella flexneri, Staphylococcus aureus, Serratia marcescens, Enterobacter cloacae, Acinetobacter baumannii, Klebsiella oxytoca, Enterococcus faecalis, Proteus spp., Klebsiella aerogenes and Micrococcus Species.

General Comments from Primary Reviewer:

Primary Reviewer recommends the PI clarifies the following sections in the application:

- Section A:
  - What are the methods associated with the recombinant factor C? It is mentioned as one of the commercial kits that will be tested, but there are not further descriptions of it in the methods.
  - Should add the clarifying information about the sample preparation from the email to the application.
- Section B: Please update all organization names to accurately reflect current structure.
- Section G: Should specify the species for the Proteus and Micrococcus

The secondary reviewer agrees that the application lacks key experimental details.

IBC Committee Recommendations for Application #13170:

- Primary reviewer motioned for approval of application 13170 with minor modifications. Secondary reviewer supported the motion.
- Application 13170 was approved by 21 votes of approval, 0 votes of disapproval, and 0 abstentions.

V. Meeting Adjournment: The IBC meeting was adjourned at 10:55 am EST.

VI. Next IBC Meeting: The next meeting is scheduled for March 19, 2026.