

IBC MEETING SUMMARY

White Oak (WO) Institutional Biosafety Committee

Thursday, May 21, 2026
9:30 a.m. – 12:30 p.m. EDT
Meeting Location: Teams

Facilitator: Derek Ireland

Recorder: Tracey Brown

VOTING MEMBERS

A	Allard, Marc HFP	P	Lina, Taslima NCTR
A	Baer, Alan CBER	P	Linden, Sara CDRH
A	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
A	Khan, Saeed A. NCTR	P	Stantchev, Tzanko CDER
P	Khanna, Marilyn OCS/OSLA	A	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

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

ADMINISTRATIVE REVIEW APPROVALS

WO IBC Administrative Review Approvals Since 4/10/2026

App. #	Title	Approval Date
13235	Recombinant Vaccinia Virus (WR) constructs expressing hepatitis C virus proteins	05/06/2026
12627	Assessment of passage of Zika Virus in a laboratory model of the placental barrier	05/04/2026
13181	Calibration of US Reference Standards for Tetanus and Diphtheria Antitoxins.	05/04/2026
13185	Development and validation of in vitro and in vivo assays to predict immunogenicity risk factors associated with product quality attributes of small drugs, generic peptides and therapeutic proteins	05/04/2026
13248	Human blood and body fluids	05/04/2026
13213	NAT Reference Panels for Tick-Borne Bacterial Infections - Anaplasma phagocytophilum	04/28/2026

MEETING SUMMARY

I. Meeting Commencement:

- The WO IBC meeting commenced at 9:01 a.m. EDT.

II. Attendance

- A total of 19 voting members were present, which fulfilled the quorum needed to conduct IBC business.

III. Review of April 16, 2026, WO IBC Meeting Minutes:

- T. Richter motioned for approval of the April 16, 2026, minutes and A. Inselman seconded the motion.
- The April 16, 2026, meeting minutes were approved by 17 votes of approval, 2 votes of abstentions and 0 votes of disapproval.

IV. Applications

App. #	Title	Reviewer	NIH Ref	Outcome
13215	Evaluation of dPCR and ddPCR systems for STEC detection and risk assessment	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 #13215 Project Overview:

To develop a digital PCR (dPCR) for STECs in the Qiagen QIAcuity and Bio-Rad ddPCR platforms to detect STEC in mixed enrichment cultures and directly analyze the co-occurrence of major virulence genes (stx1, stx2, and eae), offering a faster method to assess the risk of severe disease.

Section A: Synopsis

- They cover all biosafety steps well in the safety and Decontamination section of the synopsis.

Section G: Pathogen and/or Toxin

- E. coli STEC Strains O157:H7 and O26:H11 along with two Salmonella strains, Centrifugation and BSC Class II.
- Has a repository of samples stored on site in -80C.

General Comments from Primary Reviewer:

- Application is straight forward. The safety practices are described in detail. Recommend for approval.

General Comments from Secondary Reviewer:

- The PI provides a thoroughly detailed description of planned experiments.
- Recommend one member of laboratory staff to complete laboratory safety training.

Discussions and Questions During the IBC Meeting

- None.

IBC Committee Recommendations for Application #13215:

- Primary reviewer motioned for approval of application #13215. Secondary reviewer supported the motion.
- Application #13215 was approved by 19 votes of approval, 0 votes of disapproval, and 0 abstentions.

App. #	Title	Reviewer	NIH Ref	Outcome
13222	Evaluation and Optimization of the Dead-End Ultrafiltration (DEUF) Collection Technique and Subsequent Culture for the Detection and Isolation of Salmonella from Water	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 #13222 Project Overview:

PI wants to optimize the use of Dead-end ultrafiltration (DEUF) method to analyze surface water samples during outbreak investigations and inspections for *Salmonella* detection. This project will examine the feasibility of DEUF device for collecting and shipping the water samples for analysis from field to the laboratory. Additionally, they want to establish cultural and molecular methods for detection of *Salmonella* in including metagenomics in water samples.

Section A: Synopsis

- PI provided a clear concept and the objectives for the proposed project.
- PI described all the biosafety measures to be taken and mitigation strategies to execute the project.
- PI could handle the contaminated DEUF in biosafety cabinet.

Section G: Pathogen and/or Toxin

- Human and animal Pathogen: Salmonella

General Comments from Primary Reviewer:

The primary reviewers' recommendations are as follows:

- Correct the start date of the project to today's date.
- Handle the contaminated DEUF in biosafety cabinet.
- List Salmonella species that will be handled in the laboratory to execute this project in section G.
- A spill response protocol for volumes larger than 100mL to be provided.
- Strain identifiers or catalog numbers for the GFP-labeled strains should be provided.

General Comments from Secondary Reviewer:

The secondary reviewers' recommendations:

- Concur with the Primary Reviewer.

Discussions and Questions During the IBC Meeting

- Include a spill response protocol for larger spills that are up to 500 mL.

IBC Committee Recommendations for Application #13222:

- Primary reviewer motioned for approval of application #13222 with minor modifications. Secondary reviewer supported the motion.
- Application #13222 was approved by 19 votes of approval, 0 votes of disapproval, and 0 abstentions.

App. #	Title	Reviewer	NIH Ref	Outcome
13224	Studies on <i>Treponema pallidum</i> in human blood and blood components	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 #13224 Project Overview:

Office of Blood Research and Review, Division of Emerging Transfusion-Transmitted Diseases regulates blood screening tests for syphilis and thus they are interested in investigating the effect of storage on survival of *Treponema pallidum* in human blood and blood components.

Section A: Synopsis

- The framework of this application is to reassess whether routine cold storage of blood or blood components reliably eliminate infectivity with *Treponema. Pallidum*. Other goals in the applications include:
- Pathogen inactivation (405 nm light) reduces Tp infectivity in plasma platelets and evaluates efficacy via rabbit infection studies.
- Cell interaction studies to measure effects on viability, apoptosis and immune signaling
- Propagation of Tp in vitro to reduce reliance on rabbit propagation models.

Section G: Pathogen and/or Toxin

- *Treponema pallidum*/Nichol's strain.

General Comments from Primary Reviewer:

The primary reviewers' recommendations are as follows:

- Provide detailed information about the tri-gas chamber, information on physical containment, for example the size, state of the tri-gas chamber, safety procedures for opening the sealed chamber.
- Include an SOP on safe procedures for opening the sealed chamber after 7 days (there should be some sort of qualification procedure for its use in the BSL-2 use).
- Include any details on physical containment of the gases in the chamber or any malfunction outside the BSC. Include information on ventilation in the absence of an oxygen-deficient atmosphere.
- Reference an IRB exemption of using human blood samples in an FDA research lab.
- Revise and replace the Medical Officer in the application.

General Comments from Secondary Reviewer:

The secondary reviewer's recommendations are as follows:

- Provide details of how many more samples and volumes will be included in the proposed work.

Discussions and Questions During the IBC Meeting

None.

IBC Committee Recommendations for Application #13224:

- Primary reviewer motioned for approval of application #13224 with minor modifications. An alternate IBC voting member supported the motion.
- Application #13224 was approved by 19 votes of approval, 0 votes of disapproval, and 0 abstentions.

App. #	Title	Reviewer	NIH Ref	Outcome
13234	Studies on immunity and pathogenesis of Plasmodium parasites that infect humans and mice and tick-borne infections caused by Babesia microti, B. divergens, Borrelia burgdorferi, B. miyamotoi and Anaplasma phagocytophilum in animals and humans.	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 #13234 Project Overview:

The goal of this research is to study the mechanism of immunity and pathogenesis induced by infection with the blood parasites *Plasmodium* and *Babesia microti* that cause human malaria and Babesiosis, respectively. This research also includes the development of reference panels for tick-borne infections *Babesia microti*, *borrelia miyamotoi* and *Anaplasma phagocytophilum* to support development of donor screening assays against these pathogens.

Section A: Synopsis

- Provide a brief description of the manipulations of live pathogens and infected tissues.
- Address the following:
 - Decontamination methods (type and concentration of disinfectant; procedures before and after work).
 - Personal protective equipment (PPE) requirements (e.g., lab coat, gloves, double-gloving, eye/face protection, respirators, shoe covers, hearing protection).
 - Engineering controls (e.g., BSCs, centrifuge safety cups or sealed rotors, PCR workstations).
 - Waste handling and disposal procedures

Section G: Pathogen and/or Toxin

- Provide the catalog number or origin of the Plasmodium knowlesi.
- Add Plasmodium chabaudi to the list.
- Add the tick-borne pathogens Borrelia miyamotoi and Borrelia burgdorferi to the list of pathogens, unless only bacteria DNA (obtained from outside source) will be used. Please clarify.

General Comments from Primary Reviewer:

The primary reviewers' recommendations are as follows:

- The proposed work in a BSL2 Lab and using BSL2 work practices as proposed is acceptable.
- Clarify if PI intends to perform flow cytometry with specimens containing live pathogens. If so, please describe the safety and decontamination procedures used for this experiment.
- Identify refrigerators and freezers that will be used to store these pathogens and indicate their locations (Building, room number, freezer ID#).

General Comments from Secondary Reviewer:

The secondary reviewers' recommendations are as follows:

- Clearly identify the human Babesia strains.

Discussions and Questions During the IBC Meeting

- None.

IBC Committee Recommendations for Application #13234:

- Primary reviewer motioned for approval of application #13234 with minor modifications. Secondary reviewer supported the motion.
- Application #13234 was approved by 18 votes of approval, 0 votes of disapproval, and 0 abstentions.

App. #	Title	Reviewer	NIH Ref	Outcome
13240	Integrated Phenotypic and Multi-Omics Characterization of the Survival and Adaptation of Salmonella and E. coli O157:H7 on Fresh Onions.	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 #13240 Project Overview:

This project plans to explore the survival of two foodborne pathogens, Salmonella enterica and E. coli O157:H7 on onions.

Section A: Synopsis

- Recommend inoculating the onions in a BSC.
- Update the methods to include the details about the cell recovery methods.
- The summary is clear and provides appropriate context regarding foodborne illness risks associated with fresh produce.

Section G: Pathogen and/or Toxin

- Resulting antibiotic resistant organisms should be "no".
- The study involves Risk Group 2 pathogens handled under BSL-2 conditions with appropriate containment.
- Minor clarifications: clarify and confirm antibiotic resistance status of the microorganisms used.

General Comments from Primary Reviewer:

The primary reviewers' recommendations are as follows:

- A few edits to the document will be necessary for clarity, but I recommend approval of the application.

General Comments from Secondary Reviewer:

The secondary reviewers' recommendations are as follows:

- The proposed work is within the scope of IBC review and appropriate for BSL-2 containment. No concerns.
- Minor clarifications:
 - Recommend inoculating the onions in a BSC
 - Ensure clear handling and disposal procedures are documented for inoculated onion samples.
 - Update the methods to include the details about the cell recovery methods.
 - Confirm antibiotic resistance status in section G.

Discussions and Questions During the IBC Meeting

- They will not be generating any antibiotic-resistant organisms. Some of their organisms already have some antibiotic resistance, so they should clarify.

IBC Committee Recommendations for Application #13240:

- Primary reviewer motioned for approval of application #13240 with minor modifications. Secondary reviewer supported the motion.
- Application #13240 was approved by 17 votes of approval, 0 votes of disapproval, and 0 abstentions.

V. Meeting Adjournment: The IBC meeting was adjourned at 11:21 a.m. EDT.

VI. Next IBC Meeting: The next meeting is scheduled for June 18, 2026, at 9:30 a.m. EDT.