IBC MEETING SUMMARY

White Oak (WO) Institutional Biosafety Committee

Thursday, December 11, 2025

9:30AM – 12:30PM EST

Meeting Location: Teams

Facilitator: Amy Inselman Recorder: Adaobi Nwoka			
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
A	Day, James HFP	**P**	Pandey, Ruchi CDRH
P	Debrabant, Alain CBER	**P**	Papafragkou, Efstathia (Efi) HFP
P	Gannavaram, Sreenivas CBER	**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	**A**	Tadesse, Daniel CVM
P	Kochan, Travis CBER	**P**	Venkataraman, Thiagarajan "Raja" CBER
A	Krishna, Ashok CDER	**P**	Verma, Anita CBER
A	Laassri, Majid CBER	**P**	Waggener, Christopher T. HFP

EX-OFFICIO MEMBERS & OPTIONAL ATTENDEES			
A	Aljazrawi, Aveen OOSH	**P**	Lien, Christopher OC
P	Buttke, Thida OC	**P**	Marth, Theresa HFP
A	Degrasse, Jeffrey OOSH	**A**	MacWilliams, Ziven OOSH
A	Fowler, Joe NCTR	**P**	Nwoka, Adaobi* OC
P	Hadden, Phoebe OOSH	**A**	Reid, Ericka CBER
P	Howard, Michele OOSH	**P**	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 09/16/2025		
App. #	**Title**	**Approval Date**
13130	Influence of Hormone Exposure on Drug Metabolism and Transport in Human Hepatocytes from Female Donors in Different Age Groups	12/01/2025
13119	Analysis of Antibody responses in post Filovirus infection and vaccination plasma/sera samples	11/19/2025
13049	Assessment of protein yield and attenuation phenotype of genetically modified influenza vaccine candidates	11/14/2025
13040	Identifying molecular and morphological features important for stem cell function	11/05/2025
13121	In Vitro and In Vivo Modeling of the Novel Human Coronaviruses (2019-nCoV or SARS-CoV-2)	10/10/2025
12976	Hematopoietic stem cell generation through endothelial-to-hematopoietic transition	10/03/2025
13031	To advance the development of effective immune globulin products for hepatitis C	10/01/2025
13111	Cell-Based Uptake Assays to Determine Substrates and Inhibitors of SLC Drug Transporters	09/29/2025
13070	Evaluating extractables of blood-contacting medical devices.	09/16/2025

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MEETING SUMMARY

I. Meeting Commencement:

- The WO IBC meeting commenced at 10:15am EST.

II. Attendance

- A total of 19 voting members were present, which fulfilled the quorum needed to conduct IBC business.
- D. Ireland, E. Papafragkou, M. Miller, and T. Stantchev departed early due to meeting conflicts.
- A. Debrabant departed after the review his application due to conflict of interest.

III. Review of September 18, 2025, WO IBC Meeting Minutes:

- D. Ireland motioned for approval of the September 18, 2025 and T. Richter seconded the motion.
- The September 18, 2025 meeting minutes were approved by 19 votes of approval, 0 abstentions and 0 disapprovals.

IV. Applications

App. #	Title	Reviewer	NIH Ref	Outcome
BSL-2 Facility and BSL-2 Work Practices				
13078	Investigating the impact of food-borne Listeria monocytogenes on the functioning of gut barrier 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 #13078 Project Overview:

Section A: Synopsis

- This six-month pilot study aims to investigate the potential internalization of Listeria monocytogenes strains utilizing Caco2 cells as an in vitro screening system. For this goal, Caco2 cells will be grown and differentiated in trans well plates and infected with

Listeria monocytogenes strains and probiotic bacteria (Lactobacillus spp.) strains and the pathogen internalization will be assessed by evaluating the integrity of the tight junctions in the cell monolayers by measuring the trans-epithelial electrical resistance (TEER).

Section G: Pathogen and/or Toxin

- Listeria monocytogenes

General Comments from Primary Reviewer:

Primary Reviewer states there are no potentially hazardous procedures in this study; however, the application should be reviewed/edited to reflect testing procedures and use of cell lines along with posting of decontamination procedures. Reviewers' recommendations are as follows:

- In Section A, please add the following details:
  - There is no mention of how and how biosafety cabinets will be used in the study and no discussion about disinfection disinfected
  - There is no discussion about waste disposal
  - There is no mention of if test will be conducted in a BSC.
    - Assessment of cell epithelial barrier integrity by measuring trans-epithelial electrical resistance (TEER) and lucifer yellow flux after treatments with certain Lm strains or purified cell wall proteins of Lm Assessment of cell epithelial barrier integrity by measuring trans-epithelial electrical resistance (TEER) and lucifer yellow flux after treatments with certain Lm strains or purified cell wall proteins of Lm
- In Section E, this section says "No" on the application; however, PI clearly states working with human intestinal epithelial adenocarcinoma Caco-2 cells. Should revise this section.
- In Section G., what is being used along with Class II BSCs?
- In Section I, PI stated "No," but clearly is working with human intestinal epithelial adenocarcinoma Caco-2 cells. This section will need to be revised.
- In Section J, please add the following details:
  - PI stated "No" to most of the questions which seems appropriate but there was a "No" to questions regarding plan for decontamination of spill posted. This is probably one that should be a "Yes" since dealing with a pathogen.
  - Form does state that all staff have been trained in disposal of waste.

General Comments from Secondary Reviewer:

Secondary Reviewer states the application is lacking key experimental details. Reviewers' recommendations are as follows:

- Please revise Section A to address the following points:
    - **Listeria growth conditions:**
      The application does not describe how *Listeria monocytogenes* will be cultured. Although PI provided this information in IBC application #12844, these details must also be included here. Please add the full description of how *L. monocytogenes* strains will be grown (e.g., overnight growth in BHI broth at 37°C with agitation, followed by centrifugation and resuspension in MRS broth).
    - **Use of LM cell wall proteins:**
      No information is provided on how experiments involving the *Listeria* cell wall proteins will be performed. Please include a description of these experimental procedures.
    - **Host commensal microbiota experiments:**
      The application does not clarify whether any work will be conducted with *Lactobacillus* or *Bifidobacterium*. Please specify if experiments involving these commensal organisms will occur, and if so, outline the procedures.
    - **Disinfection and discard procedures:**
      Please provide details on how culture plates will be discarded and how biosafety cabinets (BSCs) will be disinfected before and after use.
    - **Biosafety cabinet usage:**
      There is no description of how BSCs will be utilized in the study or how surfaces/equipment will be disinfected. Please address both points.
    - **Waste disposal procedures:**
      The application currently does not include any discussion of waste handling or disposal. Please provide the required information.
    - **Work conducted in a BSC:**
      Please clarify whether the proposed experimental procedures will be performed in a BSC and describe which steps require BSC use.
- In Section E, this section is marked "No," but the application states that human intestinal epithelial adenocarcinoma Caco-2 cells will be used. Please revise Section E to accurately reflect the use of these cells.
- In Section I, this section is also marked "No," yet the study will use human-derived Caco-2 epithelial cells. Please update this section to correctly indicate the use of human cell lines.

- In Section G, several outbreak-related *Listeria* strains are listed; however, no sequencing or strain-identification details are provided. Please add any available characterization data or specify whether sequencing or other identification methods will be performed.
- In Section J, the response to the question regarding the presence of a spill decontamination plan is marked "No." Given that this work involves a pathogen, this response should be updated to "Yes" with an accompanying description of the spill response procedures.

IBC Committee Recommendations for Application #13078:

- Primary Reviewer motioned for approval of application 13078 with minor modifications. Secondary Reviewer supported the motion.
- Application 13078 was approved by 18 votes of approval, 0 votes of disapproval, and 0 abstentions.

App. #	Title	Reviewer	NIH Ref	Outcome
BSL-2 Facility and BSL-2 Work Practices				
13124	Evaluation of coagulation factor potency and thrombogenicity in rodent models	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 #13124 Project Overview:

Section A: Synopsis

- This research aims to develop tests that can predict whether certain blood clotting enzymes in medical products might cause dangerous blood clots in patients. Since these enzymes can contaminate plasma-based medicines like immune globulins, researchers are using mice to study how these contaminants cause clots and to validate laboratory tests that could detect this risk before the products reach patients.

  The study will also examine how these enzymes affect pregnant mice to help establish safety limits for vulnerable populations and investigate whether impurities in these products might trigger unwanted immune responses that could make the medicines less effective or cause adverse reactions.

Section G: Pathogen and/or Toxin

- Not applicable

General Comments from Primary Reviewer:

Primary Reviewer recommends the following:

- All members should be counselled on B virus exposure and the B virus response kits should be provided from OHS to the lab.
- Lab should include description of containment (BSC and centrifuges) for blood handling and disposal.
- In Section A, please update project start date.

General Comments from Secondary Reviewer:

Secondary Reviewer recommends incorporating the following statements regarding the handling of NHP tissues into Section A of the IBC application:

- This project will utilize rhesus macaques as the non-human primate species. The study involves the collection of blood samples and skin biopsies. Blood samples will be processed to obtain plasma and serum, while RNA will be extracted from skin biopsy specimens for downstream molecular analyses. Planned assays include the Bethesda Assay, ELISA, and RNA transcription to DNA for subsequent DNA sequencing.
- All tissue preparation must be conducted at BSL-2, within a certified biological safety cabinet (BSC), using biosafety rotors on all centrifuges and following universal precautions for blood and bodily fluids. Standard personal protective equipment (PPE)—including gloves, a lab coat, and eye protection—will be worn throughout all procedures. Whenever possible, the use of sharps will be avoided when handling NHP materials to minimize exposure risk.
- Non-human primate samples may potentially harbor Herpes B virus. In the event of any exposure to NHP-derived biological materials, personnel must immediately report to the Occupational Health Unit (OHU) for assessment and treatment.
- If a blood sample spill occurs, personnel will don appropriate PPE before approaching the area. Access to the spill site will be restricted, and absorbent materials will be placed around the perimeter to prevent spread. The spill will then be treated with a 10% bleach solution and allowed to sit for 10–20 minutes before cleanup using disposable tools.
- All contaminated absorbent materials, PPE, and cleanup supplies will be disposed of in red biohazard bags as regulated medical waste. Any sharps or broken glass will be discarded in approved puncture-resistant sharps containers. All single-use protective equipment will be disposed of according to regulated medical waste requirements.

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IBC Committee Recommendations for Application #13124:

- Secondary Reviewer motioned for approval of application 13124 with minor modifications. An alternate IBC voting member supported the motion.
- Application 13124 was approved by 15 votes of approval, 0 votes of disapproval, and 0 abstentions.

App. #	Title	Reviewer	NIH Ref	Outcome
BSL-2 Facility and BSL-2 Work Practices				
13083	Detection and measurement of specific cell surface virulence proteins to identify hypervirulent strains of Listeria monocytogenes	1. Primary Reviewer 2. Secondary Reviewer	Section III-D-2-a	Approve ☒ Table ☐

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

Application #13083 Project Overview:

Section A: Synopsis

- The goal of this study is to develop a method to accurately predict the potential virulence of L. monocytogenes strains encountered in the food industry. These studies will be used to develop a system based on Luminex xMAP technology to predict the pathogenic potential of Lm strains isolated in the food industry during outbreaks. Antibodies will be used to analyze the secretion and cell surface association of specific virulence proteins from Lm strains grown in culture media and compared to the invasive capabilities of these strains which will be analyzed using a Caco-2 cell line invasion assay.

Section G: Pathogen and/or Toxin

- Listeria monocytogenes

General Comments from Secondary Reviewer:

Secondary Reviewer recommends the PI clarify the following items in Section A:

- The PI should describe the type of "chemical work" that will be done in the fume hood.
- The estimated start date of this project should be changed to a date after the review and approval of the application
- In Section G, Lm is not a "select agent. Please make this correction.

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IBC Committee Recommendations for Application #13083:

- Primary Reviewer motioned for approval of application 13083 with minor modifications. Secondary Reviewer supported the motion.
- Application 13083 was approved by 15 votes of approval, 0 votes of disapproval, and 0 abstentions.

App. #	Title	Reviewer	NIH Ref	Outcome
BSL-2 Facility and BSL-2 Work Practices				
13097	Evaluation of transfusion transmissibility of an emerging tick-borne disease caused by Borrelia miyamotoi	1. Primary Reviewer 2. Secondary Reviewer	Section III-D-1-a; III-D-2-a	Approve ☒ Table ☐

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

Application #13097 Project Overview:

Section A: Synopsis

- This research protocol aims to study the transfusion transmissibility of Borrelia miyamotoi, an emerging tick-borne pathogen, transmitted by hard-bodied Ixodes ticks that spreads Lyme disease. Experimental research shows that these viable spirochetes can survive in both fresh and stored blood and can potentially be transmitted by transfusion in mouse models. Such studies highlight the risk of transmissibility through transfusions. Thus, the need to develop highly sensitive and specific detection assays to assess the safety of the US blood supply. The protocol appropriately designates this work as BSL-2, which is correct for B. miyamotoi and B. burgdorferi research. These organisms are classified as Risk Group 2 pathogens.

Section G: Pathogen and/or Toxin

- Borrelia ssp. (pathogenic), Borrelia miyamotoi, and Borrelia burgdorferi Strain B31

General Comments from Primary Reviewer:

Primary Reviewer recommendations are as follows:

- In Section A, please revise the following items:
  - The estimated start date of the project needs to be updated.

- Please add more details concerning the blood transfusion transmissibility assays in mouse and the animal study protocol (ASP) as well as any relevant experiment safety details related to Aim 2.
- Consider using sealed chamber slides or implementing additional containment during microscopy.
- Conduct electroporation within BSC or implement additional containment measures (sealed chamber, immediate transfer protocols).

- In Section I, please provide more experimental details here concerning these manipulations.

General Comments from Secondary Reviewer:

Secondary Reviewer recommendations for Section A are as follows:

- Consider using sealed chamber slides or implementing additional containment during microscopy.
- Conduct electroporation within BSC or implement additional containment measures (sealed chamber, immediate transfer protocols).

IBC Committee Recommendations for Application #13097:

- Primary Reviewer motioned for approval of application 13097 with minor modifications. Secondary Reviewer supported the motion.
- Application 13097 was approved by 14 votes of approval, 0 votes of disapproval, and 0 abstentions.

App. #	Title	Reviewer	NIH Ref	Outcome
BSL-2 Facility and BSL-2 Work Practices				
13114	Phenotypic and Genotypic Characterization of Heavy Metal Resistance in Salmonella Isolates from Food Animal Environment and Humans	1. Primary Reviewer 2. Secondary Reviewer	Section III-D-2-a	Approve ☒ Table ☐

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

Application #13114 Project Overview:

Section A: Synopsis

- The consumption of heavy metals (HMs) by humans and animals through ingestion of contaminated food or animal feed may lead to the selection of HM resistant bacteria, which may impact food safety and public health through modification of the gut bacteria and/or alternating the food animal environment. The objective of the current application is to identify plasmid carrying HM resistance (HMR) genes in Salmonella and investigate mechanisms of horizontal transfer of plasmid HMR to E. coli.

Section G: Pathogen and/or Toxin

- Salmonella spp.

General Comments from Primary Reviewer:

Primary Reviewer states the risk assessment for this application is moderate as the laboratory will be handling the human pathogen. Reviewer's recommendations are as follows:

- Section A: PI should describe decon methods including the use of the 10% bleach followed by the 75% ethanol for decontamination of work surfaces.
- Section D: Prokaryotic Hosts: Complete Section D for prokaryote hosts with information for the E. coli J53 strain(s) to be used in the conjugation experiments. Experiments should also be classified under the appropriate NIH Guideline (i.e., Section III-D-2-a). Also, PI needs to correct section D and mark it as "YES" as PI is proposing to use E. coli host to mobilize the HMR plasmids.
- Section E: Eukaryote Cells: Experiments involving Salmonella infection of Caco-2 cells do not fall under the current NIH Guidelines for recombinant work. Recommend removing this information from Section E and instead complete Section I for the Caco-2 line of cells.
- Section F: Research Product: Complete Section F describing the transconjugants expected from the conjugation experiments and classify under the appropriate NIH Guideline
- Section I: Human or Nonhuman Primate Blood, Body Fluid, or Tissue Use: Please add the Caco-2 cells as described in section C.

General Comments from Secondary Reviewer:

Secondary Reviewer recommendations are as follows:

- Section D: Complete Section D for prokaryote hosts with information for the E. coli J53 strain(s) to be used in the conjugation experiments. Experiments should also be classified under the appropriate NIH Guideline (i.e., Section III-D-2-a).
- Section E: Experiments involving Salmonella infection of Caco-2 cells do not fall under the current NIH Guidelines for recombinant work. Recommend removing this information from Section E and instead complete Section I for the Caco-2 line of cells.

- Section F: Complete Section F describing the transconjugants expected from the conjugation experiments and classify under the appropriate NIH Guideline.
- Section I: Complete Section I for the Caco-2 line of cells.

IBC Committee Recommendations for Application #13114:

- Primary Reviewer motioned for approval of application 13114 with minor modifications. Secondary Reviewer supported the motion.
- Application 13114 was approved by 15 votes of approval, 0 votes of disapproval, and 0 abstentions.

App. #	Title	Reviewer	NIH Ref	Outcome
BSL-2 Facility and BSL-2 Work Practices				
13122	Development of potency assays for gonadotropin hormones	1. Primary Reviewer 2. Secondary Reviewer	Section III-E-1	Approve ☒ Table ☐

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

Application #13122 Project Overview:

Section A: Synopsis

- The goal of this project is to develop bioassays and characterize the correlation of functional attributes to molecular structure to facilitate the regulation of biosimilars for gonadotropin hormones.

Section G: Pathogen and/or Toxin

- Not Applicable

General Comments from Secondary Reviewer:

- In Section C, provide a brief description of how the leftover material and are going to be safely discarded, although no replication capable lentiviral particles are expected to be generated.

IBC Committee Recommendations for Application #13122:

- The primary reviewer motioned for approval of application 13122 with minor modifications. An alternate IBC voting member supported the motion.

- Application 13122 was approved by 15 votes of approval, 0 votes of disapproval, and 0 abstentions.

V. Meeting Adjournment: The IBC meeting was adjourned at 11:25am EST.

VI. Next IBC Meeting: The next meeting is scheduled for January 15, 2026.