IBC MEETING SUMMARY

White Oak (WO) Institutional Biosafety Committee

Thursday, June 26th, 2025

9:30AM – 12:30PM EST

Meeting Location: Teams

Facilitator: Derek Ireland Recorder: Adaobi Nwoka			
VOTING MEMBERS			
P	Baer, Alan CBER	**P**	Laassri, Majid CBER
P	Berkower, Ira CBER	**P**	Linden, Sara CDRH
P	Bramhall, Elizabeth Comm. Member	**P**	Miller, Mayumi CVM
A	Day, James HFP	**P**	Pandey, Ruchi CDRH
A	Debrabant, Alain CBER	**A**	Perlman, Amanda Comm. Member
P	Gannavaram, Sreenivas CBER	**P**	Pittas, Tanya OC (*Voting on behalf of L. Schwartzman.)*
A	Gutierrez, Sacha OOSH/OHSS	**A**	Richter, Taylor HFP
A	Inselman, Amy NCTR	**A**	Schwartzman, Louis OOSH
P	Ireland, Derek CDER	**A**	Tadesse, Daniel CVM
P	Khan, Saeed A. NCTR	**A**	Verma, Anita CBER
P	Khanna, Marilyn OCS/OSLA	**A**	Waggener, Christopher T. HFP
P	Krishna, Ashok CDER		

EX-OFFICIO MEMBERS & OPTIONAL ATTENDEES			
P	Buttke, Thida OC	**P**	Marth, Theresa HFP
A	Fowler, Joe NCTR	**P**	Miller-Dunn, Natarsha*, OC
P	Harbourt, David CVM	**P**	Nwoka, Adaobi* OC
P	Hadden, Phoebe OOSH	**A**	Ragan, Angela CVM
A	Kemp, Margaret CBER	**P**	Reid, Ericka CBER
P	Lien, Christopher OC	**P**	Snyder, Jessica CDER
A	Lina, Taslima NCTR	**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; 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

App. No	Title	Approval Date
13068	Norovirus: understanding disease by exploring viral diversity	06/17/2025
12633	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.	06/10/2025
12934	The mechanism of action, efficacy and safety of therapeutic secretory IgA.	06/10/2025
13060	Ion channel pharmacology using overexpression cell lines.	06/10/2025
13064	Development of cell based STAT3 reporter assays to improve potency assessment of therapeutics targeting STAT3 signaling pathway.	06/10/2025
12946	Luciferase Immunoprecipitation System (LIPS) Assay to Detect and Characterize Antibody Responses to Paramyxovirus Proteins.	06/04/2025
12944	Measles Neutralization Assays.	05/29/2025
13003	Processing of human blood and body fluids for the propagation and study of diverse strains of HIV.	05/29/2025
13033	Transmission of Plasmodium Parasites in Mosquito Vector and Efficacy of Transmission Blocking Vaccines and Drugs.	05/29/2025
13061	Development of neutralization assays for viruses using the VSV platform.	05/29/2025
11288	Human Blood and Body Fluids.	05/15/2025

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MEETING SUMMARY

I. Meeting Commencement:

- The WO IBC meeting commenced at 9:38am EST.

II. Attendance

- A total of 13 voting members were present, which fulfilled the quorum needed to conduct IBC business.

III. Introduction of Dr. Ruchi Pandey, CDRH New Member

IV. Review of May 15th, 2025, WO IBC Meeting Minutes:

- The May 15th, 2025, meeting minutes were approved by the IBC. D. Ireland motioned for approval and M. Laassri seconded the motion.
- Past meeting minutes were approved by 11 votes of approval and, and 2 abstentions from T. Pittas and R. Pandey due to absence in the meeting and/or inability to review the minutes.

V. Applications

Application Number	Title	Reviewer	NIH Ref	Outcome
BSL-2 Facility and BSL-2 Work Practices				
12916	Development of Protocols for Detection and Characterization of Enteric Viruses in Products Implicated in Outbreaks.	1. Primary Reviewer 2. Secondary Reviewer	N/A	Approved*

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

Application 12916 Project Overview:

Section A: Synopsis

- This project aim is to develop molecular methods for detection and characterization of enteric viruses to expand the breath of virus targets and increase sensitivity to detect multiple strains in food samples.
- The goal of this study is to develop molecular methods for the detection of enteric viruses from shellfish and soft fruit food matrices. The food matrices will be spiked with norovirus and hepatitis A virus in a volume </= 100 uL.
- The proposed facility biosafety level is BSL 2, and work practices biosafety level is BSL 2. The facility and work practices biosafety level are appropriate for this work.
- Serum and feces will be used for this study. Samples will be manipulated by pipetting for RNA extraction.

Section G: Pathogen and/or Toxin

- PI is using Norovirus strains GI, GII and GIV and for Hepatitis A virus genotype I, II and III for this study. These agents are pathogenic to humans. The viruses will not be inactivated or concentrated and the work will be conducted in class II biosafety cabinet. PI identified the refrigerators and freezers where the samples will be stored.

General Comments from Primary Reviewer:

Based on the review, this work involves handling of norovirus and hepatitis A virus which is biosafety level 2 viral pathogens. This study incorporates standard microbiological techniques, BSL 2 work practices, appropriate PPEs and disinfectants which are sufficient to perform the work safely. I recommend approval of this IBC application after addressing the following comments as well as secondary reviewer comments.

- In section A, PI mentioned that the food matrices will be spiked with norovirus and hepatitis A virus in a volume </= 100 uL. Please provide the infectious dose range of these viruses.
- In section G, the source of hepatitis A virus and norovirus is not given. Also, it is not known whether the PI will grow and titrate the virus in the lab. Provide this information in the application. Please include contact time for bleach.
- In section I, it is mentioned that serum and feces will be used in this study. But no information is given in the application how this will be used in the study. Please clarify and include necessary information.
- PI should provide information on waste disposal method.

General Comments from Secondary Reviewer:

- Norovirus can be very stable in the environment and is highly infectious with relatively low exposure concentrations. As such appropriate PPE, decontamination and containment is necessary to prevent spread. No vaccine for norovirus infection is

available. There is a vaccine available for hepatitis A, which should be made available to staff.

- The following changes should be made to Section A,
  - A brief overview of methods should be provided in the text. Details can be referenced in the Bacteriological Analytical Manual (BAM).
  - The source of norovirus and hepatitis should be provided, and procedures described if cultured in the lab.
  - Decontamination procedures, including contact times, should be given here. Waste disposal and spill clean-up procedures should also be included.
  - Change "BSC2" to BSC Class II.
- In Section I, please describe the handling procedures for human fecal samples.

Discussions and Questions During the IBC Meeting:

- **Question:** Did they provide the spill cleaning plan because they're dealing with a virus?
- **Response:** Correct. This would be part of the decontamination description and will be added later.

IBC Committee Recommendations for Application 12916:

- Primary reviewer motioned for approval of application 12916 pending minor modifications. Secondary reviewer supported the motion.
- Application 12916 was approved pending minor modification by 13 votes of approval and 0 abstentions.

Application Number	Title	Reviewer	NIH Ref	Outcome
BSL-2 Facility and BSL-2 Work Practices				
12985	Risk characterization of microbial hazard exposures during Nutrient Film Technique (NFT) hydroponic system leafy green production.	1. Primary Reviewer 2. Secondary Reviewer	N/A	Tabled

Application 12985 Project Overview:

Section A: Synopsis

- Leafy greens grown in controlled environment agriculture (CEA) systems have previously been associated with outbreaks of foodborne illness. The potential risks for microbial growth and contamination between different CEA systems is not known.
- The current proposal investigates the Nutrient Film Technique (NFT) hydroponic system and examines how the pathogens behave in the test system when introduced, evaluating over time where and if pathogens can persist in the system. Salmonella spp., Listeria monocytogenes, or pathogenic E. coli will be the microorganisms evaluated.
- Proposed biosafety level 2; proposed work practices biosafety level 2.
- PI indicates an approved plan for decontamination of spills is posted. Laboratory staff have been trained on the disposal of waste and been provided with laboratory & equipment-specific safety information/SOPs according to the application.

Section G: Pathogen and/or Toxin

- *Salmonella enterica* (SAL1985), Listeria monocytogenes (LISO4534), and Escherichia coli (ESCO3796) are being proposed for use. It is assumed these organisms are part of an in-house collection; however, the source should be specified within the application.

General Comments from Primary Reviewer:

Concerning the contamination with pathogenic, organisms including E colli, Salmonella and listeria, please make the following changes to Section A:

- Please describe the Leafy Green culture system in better detail. For Leafy green and nutrient film, describe the source of nutrients and consumption of growth media over time.
- For contaminated cultures: describe the source of pathogens and their sensitivity to antibiotics. For bacterial contamination, please include the source of pathogens, and their sensitivity to antibiotics.
- Please describe the source and methods for measuring antibiotic sensitivity.
- Describe the un- inoculated control plugs vs the experimental inoculated control plugs.

General Comments from Secondary Reviewer:

Reviewer recommends tabling the application until the following additional details are provided:

- The following changes should be made to Section A,
    - Please provide a more through description of the NFT system within the application is recommended. Details provided in this review are based on a web-search and may not be relevant to the system planned for use.
    - PPE requirements for staff are not included and should be outlined for each stage of the experiment, as some steps may present increased risk.

- Appropriate PPE for the staff will need be identified. Additionally, references or other supporting data to document the decontamination of the hydroponic system is warranted along with the presentation of a sampling plan.
- Are spill plans developed and in place for handling potential leaks and spills of large volumes?
- Are the decontamination plans described sufficient to disinfect areas with spills or to clean the NFT system after pathogen exposure? References or history of disinfection procedures should be added to support the proposed methods. Additional specific questions regarding disinfection are included below:
    i. For disinfection wipes – what type of wipe (i.e., chemical) is being used and is the contact time enough to kill any pathogen present on the surface?
    ii. Is an overnight contact time with bleach needed for the inoculum trays? How was the contact time determined? Where will the trays be kept during disinfection? Will the trays be covered, will signage be in place indicating disinfection is in-progress, and are their engineering controls to help with fumes from the bleach? Will the entire amount of liquid following decontamination of the inoculum trays be placed into disposable bags or is there an alternative method that could be used to prevent exposure of staff from potential spills and leaks?
    iii. For sanitization of the NFT system, is 0.02% - 0.04% (200 - 400 ppm) bleach, along with 70% ethanol, enough to clean the system? How long will this be circulated through the system? Will only water samples be collected or will the pumps, etc. also be screened for potential bacteria?
- Include a description of how the samples will be screened for pathogens after sample (i.e., lettuce) collection. Experimental details following removal from the NFT should also be included for any planned experiments. How long is the experiment expected to run?
- Start date of the project should be updated.

- In Section B, the laboratory where the work will be conducted should also be added to the IBC application system.
- In Section G, please correct to indicate the volume of the liquid within the NFT system if there is the potential for contamination throughout the system. The PI indicated that they anticipate working with an unconcentrated volume >10 liters, but then answered only 1-2 liters would be used when indicating the amount. Please correct to indicate the

volume of the liquid within the NFT system if there is the potential for contamination throughout the system.

Discussions and Questions During the IBC Meeting:

- **Question**: In section A, it says the wastewater will be disposed of according to OAMT's safety rules. We need more clarification on what this means. Also is it 40 liters or 1-2 liters for the samples?
- **Response:** We will inform the PI to clarify both questions.

IBC Committee Recommendations for Application 12985:

- Primary reviewer recommended tabling the application 12985 until additional information is provided. Secondary reviewer supported the motion.

Application Number	Title	Reviewer	NIH Ref	Outcome
BSL-2 Facility and BSL-2 Work Practices				
12945	Studies to evaluate and measure protective immunity against respiratory syncytial virus (RSV).	1. Primary Reviewer 2. Secondary Reviewer	Section III-D-2-a	Approved*

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

Application 12945 Project Overview:

Section A: Synopsis

- The purpose of this project is to develop tests that can detect protective antibody responses against RSV, such as those directed against the F and G proteins of RSV, which are the dominant targets of the immune response. These tests can be used to identify new RSV vaccine candidates and to produce an RSV reference standard antibody that can be used to accurately measure neutralizing antibody responses as well as antibodies against specific protective epitopes.
- Project team has an approved animal protocol (Protocol# 2024-16, ABSL1).

Section G: Pathogen and/or Toxin

- Respiratory syncytial virus (RSV): A2, B1, 18537 and clinical isolates.

General Comments from Primary Reviewer:

- Overall application needs procedure, PPE and description of decontamination or removing gloves before RSV included in the application. Additional information is needed in Sections C, D, E.
- In Section A, please update the estimated start date. Also please provide some details of the plasmids used for rsNAM work and an overview of the methods/use of the rsNAMs.
- In Section C, please provide some details of the plasmids used for rsNAM work and an overview of the methods/use of the rsNAMs.
- In Section D, is mumps virus being used as a backbone for RSV expression? Unclear why this section is describing mumps. Please update accordingly.
- In Section E, please provide a brief overview of handling procedures and virus propagation, including estimates of concentrations used/generated. Include PPE description, methods of decontamination (including exposure times) and containment.
- In Section G, if mumps is being used, the pathogen should be listed here.
- In Section H, the 2024-16 listed here as ABSL-1. Should it be ABSL-2?
- In Section I, human blood is not mentioned anywhere else in this application. If being used, please include overview of handling, source of blood products and specify that products are de-identified and exempt from IRB approvals.

General Comments from Secondary Reviewer:

- In section D, you mentioned the use of mumps genes it looks not clear how you will use them in this RSV research project, maybe you will use only DVG from mumps. Please clarify.
- In section D, please check your response the question "W*hat percent of the source genome will be cloned into your rsNAMs*"?
- In section G, please provide the source of the pathogens will be used in this project.
- In section I, please provide source of the blood that will be used.

IBC Committee Recommendations for Application 12945:

- Primary reviewer motioned for approval of application 12945 pending minor modifications. Secondary reviewer supported the motion.
- Application 12945 was approved pending minor modification by 13 votes of approval and 0 abstentions.

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Application Number	Title	Reviewer	NIH Ref	Outcome
BSL-2 Facility and BSL-2 Work Practices				
13062	Development of enhanced methodologies for purification, sporulation and excystation of Cyclospora cayetanensis oocysts.	1. Primary Reviewer 2. Secondary Reviewer	N/A	Approved*

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

Application 13062 Project Overview:

Section A: Synopsis

- This is proposal is a request to use Cyclospora cayetanensis oocysts isolated from human fecal samples and to develop improved methods of sporulation and excystation towards better detection and control strategies. Feces will be used and manipulated by centrifugation and pipetting.

Section G: Pathogen and/or Toxin

- Cyclospora cayetanensis

General Comments from Primary Reviewer

- The following changes should be made to Section A,
  - The summary section of the proposal states that the intent is to develop enhanced methods towards improving characterization of Cyclospora cayetanensis. The investigators plan to purify oocysts from clinal stool samples (5-10ml) by discontinuous sucrose and cesium chloride gradient centrifugation. The investigators state that the unused stool sample will be placed in sharps container. The investigators need to describe how the unused samples are decontaminated prior to disposal into a sharp container.
  - Please refine the statement 'The handling of human stool samples will be done in a certified biosafety cabinet (BSC) whenever possible' in the Synopsis section.
  - No information is provided about the source of the Oocysts except that it is from a state partner.
  - The Cyclospora oocyst spiked basil leaves are incubated under different conditions to allow sporulation and excystation processes. Basil leaves are washed in plastic bags to isolate the oocysts. No containment procedures for handling the leaves are described.

- In Section E, since Cyclospora is a eukaryotic organism, it should be marked a 'Yes'

General Comments from Secondary Reviewer

- The following changes should be made to Section A,
  - Per protocol BAM, on collecting samples using wash bags. Please describe how/where washing/sample mixing and collection will occur. Recommend usage of a 'BagClip/Closing clip' (see Interscience Cat. # 231 040 400 mL or similar) to prevent spillage of the bag while washing/handling.
  - Materials exposed to potentially infectious samples should be disinfected prior to disposal, e.g., hemocytometers should be autoclaved with the biological waste bags, or disinfected, prior to putting them in burn boxes.
  - Counting of infectious samples should either be performed in a BSC or disinfection procedure for external microscope usage outlined after each use.
  - Clinical stool samples and any infectious oocysts that will be stored in a refrigerator should be placed in a labeled secondary container.
  - Handling of infectious samples has not been adequately described, please provide: 1) how the BSC and equipment/materials, prior to removal from the BSC, will be cleaned (including disinfectant used, note this should be appropriate for both human stool and C. cayetanensis oocysts) and 2) general infectious material handling and transportation e.g., use of secondary containers, a description of primary containers and how plant growth chambers will be disinfected after usage.
  - The summary section of the proposal states that the intent is to develop enhanced methods towards improving characterization of Cyclospora cayetanensis. The investigators plan to purify oocysts from clinal stool samples (5-10ml) by discontinuous sucrose and cesium chloride gradient centrifugation. The investigators state that the unused stool sample will be placed in sharps container. The investigators need to describe how the unused samples are decontaminated prior to disposal into a sharp container.
  - Please refine the statement 'The handling of human stool samples will be done in a certified biosafety cabinet (BSC) whenever possible' in the Synopsis section.
  - No information is provided about the source of the Oocysts except that it is from a state partner.
  - The Cyclospora oocyst spiked basil leaves are incubated under different conditions to allow sporulation and excystation processes. Basil leaves are washed in plastic bags to isolate the oocysts. No containment procedures for handling the leaves are described.

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Discussions and Questions During the IBC Meeting:

- **Question:** Where were the comments about the sharp container located?
- **Response:** In the Synopsis section.

IBC Committee Recommendations for Application 13062:

- Primary reviewer motioned for approval of application 13062 pending minor modifications. Secondary reviewer supported the motion.
- Application 13062 was approved pending minor modification by 13 votes of approval and 0 abstentions.

Application Number	Title	Reviewer	NIH Ref	Outcome
BSL-2 Facility and BSL-2 Work Practices				
13022	Development of Identification and Detection Methods for Grimontia hollisae.	1. Primary Reviewer 2. Secondary Reviewer	N/A	Approved*

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

Application 13022 Project Overview:

Section A: Synopsis

- This project aims to develop a laboratory method that can detect and quantify human pathogenic L-threonine dehydrogenase (TDH) + Grimontia hollisae, formerly Vibrio Hollisae, to support seafood safety.
- PPE including lab coat, eye protection, and gloves will be worn throughout all lab experiments and biohazard waste disposal. Small spills will be decontaminated with 70% isopropyl alcohol solution. Larger spills will be cleaned using spill kits located outside of the lab.

Section G: Pathogen and/or Toxin

- This project does include work with a pathogen in the Vibrio species, Grimontia hollisae.

General Comments from Primary Reviewer:

Approval with minor modifications to include responses to the below within the application:

- In section G, the box for aerosol generation is checked. Please list in what steps in your method will generate aerosols, and how the aerosols will be mitigated in section A.
- The following changes should be made to Section A,

- The application specifically states that a BSC hood will not be used. However, in section G, a BSC Class II hood is listed under containment equipment. Please clarify if BSC is used. The IBC recommends using a BSC whenever possible for RG-2 pathogens and above (at least the part where the bacterial culture streaking from a frozen stock to agar plates, from agar plates to broth media or from broth culture to a microfuge tube is described.)
- Please include the length of contact time with the 70% isopropyl alcohol for small spills with G. hollisae.

General Comments from Secondary Reviewer:

- Overall, the work for this project involves the routine handling of a risk group 2 bacterial pathogen, using standard microbiology techniques. The following changes should be made to Section A,
  - For better clarity, the abbreviations such as CARTS, MPN and tdh+ should be elaborated a little bit. The PI has not provided the details as to what gene or DNA region will be targeted for the PCR detection of G. hollisae. I am just guessing that it is going to be the detection of thermostable direct hemolysin (tdh) gene but if it is any other gene and how specific that gene is to detect tdh+ G. hollisae, it needs to be mentioned.
  - The tdh gene is present in majority of G. hollisae but not in all Vibrio species. However, a variety of Vibrio species, including V. cholera non-O1, V. parahaemolyticus, V. mimicus, and V. alginolyticus have been reported to possess thermostable direct hemolysin (tdh) or a tdh-related hemolysins (trh) gene. So, if the tdh and/or trh genes are present in other vibrio species, how would the PCR method, if used for the detection of tdh/trh gene(s), be useful in specifically detecting only G. hollisae? If any other specific region of tdh+ G. hollisae is going to be used for the detection/verification by PCR, that needs to be mentioned.
  - The PI says that the proposed facility is of a BSL2 level but also indicates that no work for this project will be performed in a biological safety cabinet. I think that it is probably a mistake and should be corrected for at least the part where the bacterial culture streaking from a frozen stock to agar plates, from agar plates to broth media or from broth culture to a microfuge tube is described.
  - The spill kit should be available inside the laboratory so that the person handling the spill doesn't need to get outside the laboratory while dawning the PPE and fetching the spill kit from a storage in the hallway.

- In Section G, the PI has answered yes for aerosol generation in section G but in section A, it is mentioned that no aerosol generation is anticipated. That part in section A needs to be modified.

Discussions and Questions During the IBC Meeting:

- **Question:** Does this bug travel by aerosol? Will somebody get infected with it if it's not by aerosol? Looks like the main routes is a water exposure into open wounds or seafood consumption.
- **Response:** It could be harmful if ingested**.**

IBC Committee Recommendations for Application 13022:

- Primary reviewer motioned for approval of application 13022 pending minor modifications. Secondary reviewer supported the motion.
- Application 13022 was approved pending minor modification by 13 votes of approval and 0 abstentions

Application Number	Title	Reviewer	NIH Ref	Outcome
BSL-2 Facility and BSL-2 Work Practices				
13041	Differential Expression Analysis of Agricultural Pathogen Salmonella Newport (REPJJ03) in ex vivo gut model v. tomato Model.	1. Primary Reviewer 2. Secondary Reviewer	N/A	Approved*

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

Application 13041 Project Overview:

Section A: Synopsis

- This study aims to investigate the gene expression profiles of different sequence types (STs) of S. Newport in both tomato environments and during human cell infection.
- The study emphasizes the importance of identifying gene expression overlaps between plant colonization and human infection to improve food safety risk assessment, enhance detection methods, and inform better agricultural practices to reduce Salmonella contamination in fresh produce.
- Proposed biosafety level 2; prosed work practices biosafety level 2.

Section G: Pathogen and/or Toxin

- Salmonella species: Salmonella enterica serovar Newport

General Comments from Primary Reviewer:

- Recommend approve with minor modifications.
- In Section A, proposed start date is this past March. Might need to be changed.
- In Section E, please update to encompass use of eukaryotic cells/cell lines. Application addresses any safety issues and decontamination strategies. Environmental controls are well described. No safety concerns are noted.

General Comments from Secondary Reviewer:

- Overall, there are no biosafety concerns with this application and recommend approval.
- In Section A, several details are provided on the tomato portion of the project, but not on the human cell portion. I would suggest that they add a few sentences about those methods.

IBC Committee Recommendations for Application 13041:

- Primary reviewer motioned for approval of application 13041 pending minor modifications. Secondary reviewer supported the motion.
- Application 13041 was approved pending minor modification by 13 votes of approval and 0 abstentions.

Application Number	Title	Reviewer	NIH Ref	Outcome
BSL-2 Facility and BSL-2 Work Practices				
12919	Development of a Rapid Targeted Amplicon Next Generation Sequence-Based Detection Method for Foodborne Pathogens in Leafy Green Produce.	1. Primary Reviewer 2. Secondary Reviewer	N/A	Approved*

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

Application 12919 Project Overview:

Section A: Synopsis

- The PI describes the development of next gen sequence-based methods to detect low abundance microbial species present in food related metagenomic samples. From a safety risk assessment standpoint, this is a low-risk project.

- The goal is to evaluate the effectiveness of a new approach in detecting low-level foodborne pathogens, potentially improving food safety testing procedures.
- The PI provides appropriate safety conditions when conducting these experiments.

Section G: Pathogen and/or Toxin

- PI will be working with two different human pathogens i.e., E. coli O157:H7 or Salmonella typhimurium.

General Comments from Primary Reviewer:

- In Section A, the estimated start date of the project: 08/01/2022. I was unable to determine if this application has been reviewed by the IBC previously since the estimated start date of this project is 08/01/2022. I suggest changing this date to the current application submission date.
- In Section B, the PI mentions the Center as CFSAN, which needs to change to the current organization which is HFP. Also, there is no mention of OHS Clearance. Include information on OHS clearance.

General Comments from Secondary Reviewer:

- In Section A, PI needs to correct the start date of the project.
- The risk assessment for this application is moderate as the laboratory will be handling the human pathogens. However, PI has detailed out all the necessary measures to be taken for safe handling and working with these pathogens in the laboratory.

IBC Committee Recommendations for Application 12919:

- Primary reviewer motioned for approval of application 12919 pending minor modifications. Secondary reviewer supported the motion.
- Application 12919 was approved pending minor modification by 13 votes of approval and 0 abstentions.

Application Number	Title	Reviewer	NIH Ref	Outcome
BSL-2 Facility and BSL-2 Work Practices				
13024	Evaluation and validation of the DEUF for the detection and quantification of Listeria monocytogenes in pre-harvest and post-harvest agricultural water.	1. Primary Reviewer 2. Secondary Reviewer	N/A	Approved*

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Application 13024 Project Overview:

Section A: Synopsis

- Listeria, which is commonly found in irrigation and natural surface waters, can lead to contamination of produce such as stone fruits, apples, leafy green salad, cantaloupes, frozen vegetables and sprouts, and thus has resulted in outbreaks of listeriosis. However, there is no currently validated method for detecting Listeria monocytogenes in agricultural water samples, so the goal of this research is to develop a standardized analytical method for detection and quantification.
- In the methods, PI mentions that the filters will be backflushed on the benchtop with 600ml Buffered Listeria Enrichment Broth (BLEB) and aliquoted into MPN tubes. I recommend considering conducting this step within the biosafety cabinet to reduce the risk of exposure.
- The proposed biosafety level is BSL2, which is appropriate for this research.

Section G: Pathogen and/or Toxin

- Researchers will be working with potential pathogens or infectious agents.
- Researchers list Listeria monocytogenes

General Comments from Primary Reviewer:

- In Section B, the Laboratory Safety Training is completed for all researchers. However, PI latest Lab Safety Training Date is 01/29/22. General Lab Safety should be completed annually.
- The following changes should be made to Section G,
    - Researchers indicate unconcentrated volumes >10L will used. However, researchers indicate up to 600ml will be used, so this should be answered as "No".
    - Researchers indicate that the organism will not be concentrated. However, researchers indicate that the method includes concentration by DEUF, so I recommend that this is notated.
    - Containment equipment available includes BSC Class II. Researchers indicate that the DNA extraction procedures include the use of a centrifuge, so I recommend additionally including centrifuge here.
- In Section J, the plan for decontamination of spills is not posted and researchers are not trained in disposal of waste. I recommend that these issues are resolved since the

researchers will need to be aware of decontamination and disposal procedures and plans need to be in an accessible location.

General Comments from the Secondary Reviewer:

- The following changes should be made to Section A:
  - P.I.'s latest Lab Safety Training Date is 01/29/22. General Lab Safety should be completed annually.
  - Nanopore MinION sequencing is used for genotyping, with 1 mL of enriched sample collected for DNA extraction. I recommend conducting this step (collecting 1mL enriched sample) in BSC to decrease the risk of exposure to the pathogen. Reviewer recommends limiting containment.
- In Section G, Unconcentrated volumes >10L will be used. However, researchers indicate up to 600ml will be used, so this should be answered as "No". I recommend correcting this.
- In Section J, the plan for decontamination of spills is not posted and researchers are not trained in disposal of waste. However, the researchers mentioned the spill cleanup procedures in detailed information regarding project methodology, potential risks and strategies for mitigating them (bullet 16). I recommend correcting this.

Discussions and Questions During the IBC Meeting:

- **Question:** The water collection that they're concentrating is 600 mils. Is the water they're collecting starting at a volume greater than 10 liters?
- **Response:** PI mentioned no more than 600mL

IBC Committee Recommendations for Application 13024:

- Primary reviewer motioned for approval of application 13024 pending minor modifications. Secondary reviewer supported the motion.
- Application 13024 was approved pending minor modification by 13 votes of approval and 0 abstentions.

VI. Meeting Adjournment: The IBC meeting was adjourned at 11:33am

VII. Next IBC Meeting: The next meeting is scheduled for July 17th, 2025.