

# Minutes of Regular IBC Meeting

**Date:** *August 14, 2025*

**Location:** **Microsoft Teams Meeting**

**Call to Order:** **C. Bailey called the meeting to order at 11:02h (CDT)**

**Members Present:** M. Russell, S. Altmann, C. Bailey, M. Anderson, A. Patel, R. White, H. Wood

**Advisors:** None

**Others:** C. Weiss, A. Fitzpatrick, C. Mammen

**Conflict of Interest Declarations:** None declared

**Review of Minutes from 5/8/2025 Meeting:** Minutes approved as written.

**VOTES:** **YES:**  **NO:**  **ABSTAIN:**

## 1. Old Business:

### 1.1. **Tabled NF registrations:**

None

### 1.2. **NFs with Contingencies Met:**

None

## 2. New Business:

### 2.1. **NF registrations:**

None

### 2.2. **NF Amendments:**

<b>NF Number:</b>	<b>KCNF24-07(R-25)</b>	<b>Storage Only?:</b> <input type="checkbox"/>
<b>Initial Approval Date:</b>	<b>26Jul2024</b>	
<b>TITLE:</b>	<b>Persimmon GMP Manufacturing</b>	
<b>PI:</b>	<b>C. Weiss</b>	
<b>REVIEWED BY:</b>	<b>Full IBC Committee</b>	



**Project Biosafety Level:** BSL-2

**NIH Guidelines reference:** III-E

**IBC MOTION:** Approve contingent on items discussed being addressed by the PI and revisions to the NF being made and reviewed by an IBC member.

<b>IBC ACTION:</b>	<b>Approve</b>	<input type="checkbox"/>	<b>VOTES:</b>	<b>YES</b>	<input type="checkbox"/> 6
	<b>Approve Contingent</b>	<input checked="" type="checkbox"/> X		<b>NO</b>	<input type="checkbox"/> 0
	<b>Table</b>	<input type="checkbox"/>		<b>ABSTAIN</b>	<input type="checkbox"/> 1
	<b>Deny</b>	<input type="checkbox"/>			

**RESEARCH REVIEW:**

**Objective of Study:** Persimmon is a cross-business unit program spanning Integrated Health Surveillance and Diagnostics and Integrated Pharmaceutical Solutions. Persimmon includes a pre-clinical safety study of a recombinant biological test article consisting of modified *Staphylococcus epidermidis* (RG-1 organism), biological sequencing from the safety study, and cGMP manufacturing of the biological material for human studies. Human testing is outside of the scope of this program. Preclinical safety studies have concluded at MRIGlobal, but sequencing and cGMP manufacturing remain within the scope of this renewal.

**Changes to the Protocol:** *Removed tasks completed in year 1 including all references to animal work. Added 6 additional microbes for testing with the test article per USP requirements.*

The PI provided an overview of the project details including the changes and safety procedures. The committee reviewed the facilities, personnel training, medical surveillance and occupational health requirements.

**IBC Discussion:** The committee asked for clarification on certain aspects of the study related to handling of the recombinant organisms and the safety procedures implemented during the production aspects for the study compound. The PI was able to answer and address most concerns. Edits to the document were requested by the committee to address unresolved questions.

<b>NF Number:</b>	KCNF25-05(R-25-2)	<b>Storage Only?:</b> <input type="checkbox"/>
<b>Initial Approval Date:</b>	19May2023	
<b>TITLE:</b>	RADx	
<b>PI:</b>	C. Mammen, B. Knight, A. Fitzpatrick	
<b>REVIEWED BY:</b>	Full IBC Committee	



**Project Biosafety Level:** BSL-3  
**NIH Guidelines reference:** III-D-1-b

**IBC MOTION:** Approve as written.

<b>IBC ACTION:</b>	<b>Approve</b>	X	<b>VOTES:</b>	<b>YES</b>	7
	<b>Approve Contingent</b>			<b>NO</b>	0
	<b>Table</b>			<b>ABSTAIN</b>	0
	<b>Deny</b>				

**RESEARCH REVIEW:**

**Objective of Study:** The purpose of this study is to perform an evaluation of the RADx Analytical Tests to detect SARS-CoV-2, Influenza A, and Influenza B. Studies performed in the BSL-3 include microbial interference/microbial cross reactivity (SARS-CoV, MERS) and inclusivity (various Influenza A strains and virulent SARS-CoV-2). Inactivated SARS-CoV-2 and live BSL-2 Influenza A and B strains may be used in a co-spike during the microbial interference study, in addition to SARS-CoV and MERS. Only one BSL-3 strain will be handled at a time. This work only describes use of material. Propagation of viruses is covered by a different NF.

**Changes to the Protocol:** *Indicate that SARS-CoV-1 strain being used is recombinant (NR-18925) Update section A, C, D, & G accordingly. Remove staff that have left MRIGlobal. Removed culture volume in Table D-1 as virus is not cultured for this study.*

The BSO provided an overview of the project details including the changes, safety procedures, facilities, personnel training, medical surveillance and occupational health requirements.

**IBC Discussion:** There were no discussion or questions beyond those raised during the pre-meeting document review period. All questions from the pre-meeting review were addressed.

**2.3. BSO/IBC Chair approved NF Amendments:**

**NF Number:** KCNF24-09(R-25) **Storage Only?:**

**Initial Approval Date:** 26 Jul 2024

**TITLE:** DBPAO Bacillus anthracis Recombineering

**PI:** C. Weiss, Z. DeMars

**Project Biosafety Level:** BSL-2

**NIH Guidelines reference:** III-F-8, Appx, C-II, III-D-1-a, III-D-2-a

**RESEARCH REVIEW:**



**Summary of Changes:**

Addition of fixation protocol for sample send-out to image with electron microscopy. Three new chemicals included in this, glutaraldehyde, paraformaldehyde, and sodium cacodylate buffer. Procedure will involve the following:

Standard plaque assay protocol that is outlined in the previous NF version, adding the resuspension of samples in 4% paraformaldehyde/1% glutaraldehyde in 0.1M sodium cacodylate buffer. Minimal amounts of 16% paraformaldehyde (2.5mL), 10% glutaraldehyde (1mL) and sodium cacodylate buffer at 0.2M (5mL) will be used and manipulated for sample preparation. (Section A.1)

J. Stone removed as Project Lead and Z. DeMars added to cover project leads. (Section A, project summary)

<b>NF Number:</b>	<b>KCNF25-01 (R-25-2)</b>	<b>Storage Only?:</b> <input type="checkbox"/>
<b>Initial Approval Date:</b>	<b>26 Jul 2024</b>	
<b>TITLE:</b>	<b>First Ripple</b>	
<b>PI:</b>	<b>H. Wood, B. Vohra</b>	
<b>Project Biosafety Level:</b>	<b>BSL-2</b>	
<b>NIH Guidelines reference:</b>	<b>III-F-1, III-F-2</b>	

**RESEARCH REVIEW:****Summary of Changes:**

2/6/25 - Addition of sterility verified nucleic acids to section G-1 (R. prowazekii and various C. botulinum strains). Addition of Rickettsia canadensis to sections D and G-1. Minor edits to correct typographical errors in sections D and G-1. Added Variola synthetic positive control to Section G1. Added Oxivir-1 as an optional disinfectant.

4/30/25 – Added 4 staff, removed 2 staff. Replaced J. Lucas with H. Wood as PI. Added synthetic positive controls to Section G1 for EEEV and for C. botulinum toxin A and B (sterility verified extracts are limited in volume for these targets and cannot be acquired externally). Added in vitro transcripts for the same targets since RNA is unavailable for these targets.

**2.4. NIH Exempt NF Approvals:**

None



**2.5. NF Terminations:**

None

**2.6. NF Renewals with No Changes:**

<b>NF Number:</b>	KCNF24-23(RM-25)	<b>Storage Only?:</b> <input type="checkbox"/>
<b>TITLE:</b>	<b>NCI Prevent MVA Plasmid Potency</b>	
<b>PI:</b>	<b>Rachel Ginther, Carolyn Mammen</b>	
<b>Project Biosafety Level:</b>	BSL-2	
<b>NIH Guidelines reference:</b>	III-F-8, Appx. C-I	

**RESEARCH REVIEW:**

**Changes to Personnel:** Yes, added 2 staff, removed 1 and changed role of Carolyn Mammen from staff to PI.

**Changes to Facilities:** None

**Changes to Disinfectants:** None

**Comments:** None

**3. Other Business:**

- Report regarding KCNF25-05
  - BSO presented the report and answered questions about the circumstances and actions implemented.

**4. Next Meeting:**

Next scheduled IBC meeting is September 11, 2025 @ 11:00h (CDT), if a study is received for review.

**5. Adjourn:**

**Action:** Chair adjourned the meeting at 11:44h (CDT)

