Minutes of Regular IBC Meeting

Date: ***October 2, 2025***

Location: **Microsoft Teams Meeting**

Call to Order: **C. Bailey called the meeting to order at 13:01h (CDT)**

Members Present: M. Russell, S. Altmann, C. Bailey, M. Anderson, A. Patel,

Members Absent: R. White, H. Wood

Advisors: None

Others: B. Knight

Conflict of Interest Declarations: None declared

Review of Minutes from 8/14/2025 Meeting: Minutes approved with correction to a committee member's name spelling.

VOTES: **YES:** 5 **NO:** 0 **ABSTAIN:** 0

1. Old Business:

1.1. Tabled NF registrations:

None

1.2. NFs with Contingencies Met:

NF Number:	**KCNF24-07(R-25)**
TITLE:	**Persimmon GMP Manufacturing**
PI:	**C. Weiss**
Project Biosafety Level:	**BSL-2**
NIH Guidelines reference:	III-E
Date of IBC Review:	**8/14/2025**
Previous 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.
Previous IBC ACTION:	***Approved Contingent***
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.
Date of PI Response:	**8/15/2025**
Summary of Revisions/Edits:	All requested revisions were made and reviewed by the IBC Vice-Chair with no additional changes. Contingencies met, NF is approved.

2. New Business:

2.1. NF registrations:

NF Number:	**KCNF25-13**	**Storage Only?:**	
TITLE:	**DBPAO PCR Conformance Testing**		
PI:	**B. Knight**		
REVIEWED BY:	**M. Russell, S. Altmann, C. Bailey, M. Anderson, A. Patel**		
Project Biosafety Level:	**BSL-2**		
NIH *Guidelines* reference:	**III-D-2-a**		

IBC MOTION: The motion to approve was given by A. Patel, second by C. Bailey.

IBC ACTION:			**VOTES:**	
	Approve	X	**YES**	4
	Approve Contingent		**NO**	0
	Table		**ABSTAIN**	1
	Deny			

RESEARCH REVIEW:

Objective of Study:	The objective of this work is to provide 3rd party conformance testing on real-time PCR reagents manufactured by the Naval Medical Research Command (NMRC) to support JPEO-CBRND's mission of managing a resource called OSCAR (Ordering System for Critical Assays and Reagents), which provides critical assays and reagents to DoD and Other Government Agency (OGA) customers. Testing will be performed on each new lot of master mix produced by NMRC, as well as positive controls and dirty filter extracts (matrix testing).
IBC Discussion	S. Altmann asked if the various dusts in Section E was dirt. B. Knight verified that it is dirt because they are for the matrix testing.

2.2. NF Amendments:

NONE

2.3. BSO/IBC Chair approved NF Amendments:

NF Number:	**KCNF25-05(R-25-3)**	**Storage Only?:** ☐
Initial Approval Date:	**14Sep2025**	
TITLE:	**RADx Testing SARS, MERS, FluA (BSL-3)**	
PI:	**C. Mammen, B. Knight, A. Fitzpatrick**	
Project Biosafety Level:	**BSL-3**	
NIH Guidelines reference:	III-D-1-b	
Approval Date:	26Sep2025	
RESEARCH REVIEW:		
Summary of Changes:	Added new strain of SARS-CoV-2 (JN.1). This is a non-recombinant strain and is used for cross-reactivity testing on these projects. No change to NIH Guidelines assessment.	

NF Number:	**KCNF24-06(R-2025)**	**Storage Only?:** ☐
Initial Approval Date:	**03Oct2024**	
TITLE:	**MRIGlobal Clinical Laboratories Infectious Diseases Clinical and Research Testing**	
PI:	**S. Guilford**	
Project Biosafety Level:	**BSL-2**	
NIH Guidelines reference:	III-F-1, III-F-2	
Approval Date:	26Sep2025	
RESEARCH REVIEW:		
Summary of Changes:	Addition and removal of personnel. Removal of specifics to PANDA project. Removal of some agents that will not be worked with in the future. Addition of clinical microbiology techniques for BSL-2. Updates to Section D, E and G related to details required for new NF form.	

NF Number:	**KCNF24-23**	**Storage Only?:** ☐
Initial Approval Date:	**08Oct2024**	
TITLE:	**NCI MVA pDNA Potency**	
PI:	**C. Mammen, R. Ginther**	

REVIEWED BY:	Full IBC Committee
Project Biosafety Level:	**BSL-2**
NIH *Guidelines* reference:	III-F-8, Appx. C-II
Approval Date:	01Oct2025
RESEARCH REVIEW:	
Objective of Study:	This NF is meant to cover the transfection of HEK293T cells with plasmid DNA containing six tumor associated antigens (TAA). The antigens are HER2, Mucin1, Survivin, hTERT, Mammaglobin A, and MAGEA3. mRNA expression of each TAA will be quantified using qPCR. These proteins have been implicated in various cancers, but the constructs used in this study have modified sequences to force excretion of the proteins or to split the proteins to reduce the chance of producing intact protein. Protein expression of each TAA will be quantified using six C.O.T.S. (Commercially Off The Shelf) ELISA kits. Western blot analysis will be performed to identify the expression of the specific proteins during the transfection. Method validation and verification will be performed, and the qPCR, western blot, and ELISA assays will be used to evaluate the effect of different plasmid DNA formulations on the transfection efficiency and stability.
Changes to the Protocol:	Added additional info related to transition to new NF form, added research personnel. Added information and hazard analysis for western blot analysis.

2.4. NIH Exempt NF Approvals:

NF Number:	KCNF25-11
TITLE:	NCR Operational Program R&D – Multiplex qPCR
PI:	**E. Merritt**
Project Biosafety Level:	BSL-2
NIH *Guidelines* reference:	III-F-1
Approval Date:	05Sep2025
RESEARCH REVIEW:	
Objective of Study:	The purpose of this project is to develop a multiplex qPCR assay using existing, singleplex operational assays and test for feasibility and limited range-finding and limit of detection. Future work (via an amended or new Notification of Research submission, not contained in this document) will seek to evaluate the resulting multiplex assay in complex

	matrices, different challenge material (inclusivity and exclusivity), by different operators at different sites. The ultimate goal is operational implementation of the new multiplex assay. The work proposed in this study is limited to in silico compatibility and initial feasibility/detection testing using synthetic oligo positive controls of partial gene targets that are currently in-use by the Gaithersburg operational program.
BSO comments:	• **Low risk project involving PCR of nucleic acid fragments from 3 select agents and one RG-2 organism. The fragments do not encode intact genes and do not contain an ORI or ability to interact with DNA or RNA polymerase.**

2.5. NF Terminations:

None

2.6. NF Renewals with No Changes:

None

3. Other Business:

- The Report, regarding KCNF25-05, to NIH discussed at the last IBC meeting was submitted on 9/4/2025. No response from NIH OSP has been received yet.

4. Next Meeting:

Next scheduled IBC meeting is November 13, 2025 @ 11:00h (CDT), if a study is received for review.

5. Adjourn:

Action: Chair adjourned the meeting at 13:37h (CDT)