

IBC Meeting
February 24, 2026 11AM, Zoom Virtual Meeting
Minutes

1. CALL TO ORDER:

1. The meeting was called to order at: 11:03 am
2. In Attendance:
 - a. Ken Malcolm (Chair)
 - b. Cristina Penaranda (Co-Chair)
 - c. Doria Cladis (Non-Affiliated community member)
 - d. Tom Merry (Non-Affiliated community member)
 - e. Vanessa Rodriguez (Member/administrator)
 - f. Katie Kopf (Animal Expert/Veterinarian) joined the meeting at 11:10 am
 - g. Peter Farina (Safety Officer)
 - h. Matthew D. Rosenbaum (Animal Expert/Veterinarian)
3. Non Attendance: Joanne E. Streib (Technical Member)
4. Reviewed and approved the 12/16/2025 minutes

2. PROTOCOLS AND ADDENDA:

1. **BH-Taylor-Cousar (VX21-522)-02-23 PI: Jennifer Taylor-Cousar. Triennial Review. Reviewer: Ken Malcolm**
Discussion: The reviewer presented the renewal submission to the committee noting the study will involve rDNA and human samples. The PI has submitted the appropriate appendices for this research and has appropriately identified the risk groups and biosafety levels.

Modifications and/or Clarification Requested:

1. Section I.3 Appendix G should not be checked
2. Section I.4 A training plan is needed
3. Section I.5 A list of off-site locations should be added if applicable
4. Section IV.10.C should be checked Yes with a list of CF pathogens
5. Section IV.10.D should be NO
6. Section IV.10.E Human tissues should be checked with a list biopsies and brushings as applicable

Lab signs

1. Remove infectious agents

Determination and vote: The committee voted to approved with modifications as indicated above.

Total: 8 For: 7 Against: 0 Abstentions: 1

Katie abstained from the vote as she joined the meeting after the discussion.

2. **BH-Janssen-03-20 PI: William Janssen, MD Triennial Review. Reviewer: Ken Malcolm**

Discussion: The reviewer presented the renewal submission to the committee noting some aspects of the study will need to be removed given each PI will need to submit a separate application to the IBC for review. The study will involve rDNA,

infectious agents, human samples, live animals, flow cytometry, toxins, and SARS-CoV. The PI has submitted the appropriate appendices for this research and has appropriately identified the risk groups and biosafety levels.

Revisions:

1. Section I.4 should only list personnel conducting the protocol activities Dr. Janssen will supervise, identifying who will use toxins. Clarification regarding the training plan is also required.
2. Section II.7.4 Clarify is AAV production is in mouse cells or human cells.
3. Section III.8 Categories and personnel no longer under this protocol need to be removed.
4. III.9.C should be no, only listing agents for the Janssen lab. In the others section it should be noted that clinical strains are not known to be multidrug resistant.
5. Section IV.10.C, confirm the use of CF sputum.
6. Section IV.10.E, confirm the use of Heat Moisture Exchange (HME) filter fluid, tracheal aspirate fluid.
7. Section 11.E, Pre for Flexivent should not be checked as this is a terminal procedure. Post for microCT should not be checked, as infectious agents are not allowed on the microCT at this time.

Lab Signs

1. Pseudomonas, NTM and Sputum, and Recombinant DNA information should be removed as appropriate.

Appendix A

1. The statements about r/sNA, NTM and Sputum should be removed if appropriate.

Appendix E

1. The PI should acknowledge the first box.

A question was raised regarding what room will toxins be used in? It was noted that the toxins are RG2 as these are not select agents.

Although changes and calcifications are needed as indicated above, the committee agreed the information would not change or affect the risk group determination, therefore the study may continue.

Determination and vote: The committee voted to approved with modifications as indicated above.

Total: 8 For: 8 Against: 0 Abstentions: 0

3. **BH-Hisert-02-26. Katherine Hisert, Md, PhD, MD. New Study Review.
Reviewer: Cristina Penaranda**

Discussion: The reviewer presented the new protocol submission to the committee noting this is one of the PIs from the Janssen protocol submission. The study will involve rDNA, infectious agents, human samples, live animals, flow cytometry and toxins. The PI has submitted the appropriate appendices for this research and has appropriately identified the risk groups and biosafety levels.

Modifications and/or Clarification Requested:

1. Section I.4 Clarify training, indicate which personnel will be working with selected agents/toxins, and clarify the work being conducted for this PI
2. Section I.5 indicate location of work with selected agents/toxins
3. For r/DNA checklist confirm if 4 should be checked (if done in human cells)
4. For r/DNA checklist 7 should not be checked
5. Section II.8, include the name of the plasmid backbone: for example, pCherry3 should be pSMT3-S, with vector risk group 1. Specify M. abscessus transcription factor deletion and complemented strains if applicable.
6. Section III.9.C PI should indicate the strains known or likely to be multi-drug resistant, specify that USA300 is MRSA and the status for the other clinical isolates.
7. Clarify if human materials will be used in mice section. If yes, the box for human materials in section V.11.C needs to be checked, section V.11.H should be completed as well as a handling guide.
8. The box regarding pregnant employees for the Streptococcus pneumoniae handling guide does not need to be checked.

Appendix E

1. The first box should be checked since the toxins used are NOT select agents

Appendix G

1. Update to only include work being conducted.

Determination and vote: The committee voted to approved with modifications as indicated above.

Total: 8 **For: 8** Against: 0 Abstentions: 0

2. DMR APPROVALS:

1. BH-Brown-02-20 PI: Kevin Brown, MD. Triennial Approval 02/04/2026

3. APPROVALS:

None to Report

4. SOPs and POLICIES:

None to Report

5. NEW BUSINESS

None to Report

6. OLD BUSINESS

None to Report

7. EDUCATION:

None to Report

8. MINOR ADMINISTRATIVE:

1. **Note-to-Files (approved by Chairs):**

- None to Report
- 2. **Personnel Updates:**
 - a) BH-Penaranda-08-22 PI: Cristina Penranda, PhD. Addition of Nicole Hayes removal of Ealine Epperson. Approved 2/11/2026.
- 3. **Annual Reviews:**
 - b) BH-Daley-01-21 PI: Charles Daley, MD. Second annual review approved 02/06/2026.
 - c) BH-Onofrei-02-25 PI: Claudia Onofrei, MD. First annual review: removal of Dusanka Mocevic, approved 02/06/2026.
 - d) BH-Meehan-01-22 PI: Richard Meehan, MD. First annual review approved 02/11/2026.
- 4. **Protocol Closures:**
 - e) BH-Gerber-03-19 PI: Anthony Gerber, MD, PhD. Administrative closure 1/27/2026
- 5. **Expiration:**
 - None to Report
- 6. **Memorandums of Understanding (MOUs)**
 - None to Report

9. ADJOURNMENT:

Meeting Adjourned at: 12: 19 pm

10. ATTACHMENTS

- 1. 2/24/2026 IBC Agenda
- 2. 12/16/2025 Minutes
- 3. Submission Materials for section II
- 4. Approved materials for sections III and IV

Respectfully submitted,

Signed by:

Ken Malcolm

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Ken Malcolm, PhD, IBC Chair

DocuSigned by:

Vanessa Rodriguez

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Vanessa Rodriguez, IBC administrator