

**IBC Meeting**  
**July 22, 2025 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)
  - g. Matthew D. Rosenbaum (Animal Expert/Veterinarian)
  - h. Joanne E. Streib (Technical Member)
3. Non Attendance: Peter Farina (Safety Officer)
4. Review and approval of the minutes: 4/22/25

**2. PROTOCOLS AND ADDENDA:**

1. BH-Dooms-05-22. PI: Hans Dooms, PhD – Triennial Review. Reviewer: Ken Malcolm

Cristina added to breakout room at 11:04 am due to a conflict of interest
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Discussion: The reviewer presented the submission to the committee noting the study will involve rDNA, human samples, live animals, and flow cytometry. The PI has submitted the appropriate appendices for this research and has appropriately identified the risk groups and biosafety levels. Replication deficient MSCV will be used and has been appropriately identified as RG2 nothing biosafety level 1 and ABSL 1 and 2 will be used appropriately. The rDNA work fall under sections III-D-2, III-D-3 and III-D-4 of the NIH Guidelines.

**Modifications and/or Clarification Requested:**

1. Revisions to main protocol:
  - i. In Section I.4, include a Training plan.
  - ii. In Section IV.10.E table, add pancreas, as indicated in Appendix A.
  - iii. In Section V.D, in the Other section, add a brief description in the PI Comments if huPBMC (or other cells) are virally transducer.
  - iv. In Section V.F, indicate Yes for “Will an infectious agent be produced in the animal”
  - v. For the MSCV Handling guide, check the box for Shed in Urine and feces.
2. Revisions to Appendix A:
  - i. In Appendix A, uncheck the Infectious Agents box.
  - ii. In B.ii, move this wording to the rDNA section above (B.i).
  - iii. Complete the checklist.
3. On the Lab sign, remove retroviral vectors from the “Infectious agents” section, as this is meant for human pathogens, and use this same wording for

the rDNA section. Remove “DNA plasmids” if only cloning vectors are used, but retain if expression vectors are used.  
Appendix E is not necessary as no select agents will be needed.  
Appendix G is no longer required.

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

Total: 6      For: 6      Against: 0      Abstentions: 0

Cristina Penaranda and Katie Kopf were not present for the discussion or vote.

Cristina Penaranda rejoined the call at 11:16am after the discussion and vote.

2. BH-Scottbrowne-03-19. James Scott-Browne, PhD – Triennial Review. Reviewer: Cristina Penaranda  
Discussion: The reviewer presented the submission to the committee noting the study will involve rDNA, infectious agents, human samples, live animals, gene editing, Lentiviral vector research, and flow cytometry. The PI has submitted the appropriate appendices for this research and has appropriately identified the risk groups and biosafety levels. ABSL 2 will be used appropriately. The rDNA work fall under sections III-D-2, III-D-3 and III-D-4.

#### Modifications and/or Clarification Requested:

1. Revisions to main protocol:
  - i. Need to add a training plan
  - ii. Need to check box 5 in the rDNA section
  - iii. Confirm if human materials will be sorted
  - iv. Check section C in Hazardous materials in live animal section
  - v. Add a description in Hazardous materials in live animal section B
  - vi. The submission indicated that “recombinant viral particles” will be used in mice. If this refers to flu/LCMV, then it is not necessary to check the box since these are covered under “infections agents”. Please add a brief description of experiment (s) in below the box under “proposed activities”
  - vii. Add room number to in Hazardous materials in live animal section E
  - viii. Check the appropriate boxes in the animal handling guides.
2. Revisions to Appendix A:
  - i. Clarify in B(iii) if infected cells will be sorted
3. Revisions to Appendix B:
  - i. In section C add all vector systems
  - ii. Update to indicate enhanced BL2 procedures.
  - iii. Clarify if there is a different generation of lentivirus that can be used.
4. Revisions to Appendix C
  - i. C should be no
  - ii. E should be no
5. Revisions to lab signs.
  - i. add date in the top left box. remove “ecotropic and amphotrophic retroviruses and lentiviruses” from the Infectious Agents section since they are listed in the recombinant DNA section.

- ii. Remove “pregnancy, immunocompromised” from special entry requirements
- iii. add “Don personal protective equipment prior to entry”.

Katie Kopf joined the call at 11:28 am.

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

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

3. BH-Gerber-03-19. Anthony Gerber, MD, PhD- Triennial Review. Reviewer: Cristina Penaranda

Discussion: The reviewer presented the submission to the committee noting the study will involve rDNA, infectious agents, human samples, Lentiviral Vector research, gene editing and flow cytometry. The PI has submitted the appropriate appendices for this research and has appropriately identified the risk groups 2 and biosafety levels 2. The rDNA work fall under sections III-D-2 and III-D-3 of the NIH Guidelines.

Modifications and/or Clarification Requested:

1. Revisions to main protocol:
  - ix. Check off flow cytometry as work being conducted
  - x. Add training plan
  - xi. Add BSL2 to the locations for K718
  - xii. Check box 1 in the rDNA/synthetic nucleic acid table
  - xiii. Section II.8
    1. Replication deficient amphotropic retrovirus need to be conducted under enhanced BL2 procedures
    2. For Cytokines, indicate the gene names
2. Revisions to Appendix A:
  - a. Add BAL and possibly check sorter
3. Appendix E and Appendix F are not necessary as this work will not be conducted.
4. Lab signs need to be updated using the new signs.

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

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

4. BH-Bratcher-08-19. Preston Bratcher, PhD Triennial Review. Reviewer: Ken Malcolm

Discussion: The reviewer presented the submission to the committee noting the study will involve rDNA, infectious agents, human samples, live animals, flow cytometry, and gene editing including CRISPR. It was noted that PI did not check the rDNA box on the form in error noting that they will be using synthetic nucleic acids. The PI has submitted the appropriate appendices for this research and has appropriately identified the risk groups 2 and biosafety levels 2. The rDNA work fall under sections III-D-2 and III-D-3 of the NIH Guidelines.

**Modifications and/or Clarification Requested:**

1. Revisions to main protocol:
  - xiv. Need to indicate rDNA and use of CRISPR
  - xv. Add training plan
  - xvi. Section I.4 check box A for personnel, as appropriate
  - xvii. IN section I.5 add category A as appropriate
  - xviii. Complete sections II.7 and II.8 as appropriate
  - xix. In section III.9 specify the species as well as in section V.11.G if appropriate.
  - xx. Section V.E confirm if animals will be moved to the lab. In V.G, list the specific species for use in animals. On the Handling Guide for MAC, check the precautions boxes as for Mab.
2. Lab signs need to be updated to add the room number each room listed in the main protocol; in the last section add CRISPR-modified epithelial cells.

The committee discussed whether the study can continue the work as previously submitted given the current approval is due to expire prior to the next meeting and determined it was acceptable for the PI to continue work as previously submitted, any new activities included in the submission may not begin until full re-approval is granted.

Determination and vote: The committee voted to defer action.

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

**3. DMR APPROVALS:**

1. BH-Numata-Nakamura-06-21. PI: Mari Numata-Nakamura – addition of Influenza A virus and clade 2.3.4.4B H5N1 high pathogenicity avian influenza (HPAI). Approved 05/01/2025.
2. BH-Malcolm-08-20. PI: Ken Malcolm – Addition of Stenotrophomonas. Approved 06/05/2025.

**4. APPROVALS:**

1. BH-Bridges-04-19. PI: James Bridges, PhD – Triennial review approved 5/05/2025.
2. BH-Taylor-Cousar-02-22. PI: Jennifer Taylor-Cousar, MD – Triennial review approved 05/08/2025.

**5. SOPs and POLICIES:**

None to Report

**6. NEW BUSINESS**

Discuss using SARS-CoV-2 in animal experiments and for in vitro infections.

The committee previously discussed the reclassification of SARS-CoV-2, however now the chairs would like to discuss how this would be conducted in the BRC. Protocols from other institutions discuss using ABSL 2 with enhanced procedures. The chair recommends that the work continue in the 120 room with added PPE if appropriate. The committee's animal expert recommended the same enhanced procedures be used for techs and research

personnel such as double glove and mask. Another option would be to have approved personnel handle the animals, this was noted as a possible option. A question as to whether there would be a restrictions to limit personnel using the equipment to avoid multiple people in the room at one time. It was noted that if it is risk group 2/ABSL 2 it should be handled accordingly. Another question was raised about needed vaccine for SARS-CoV-2, this would be considered.

The committee determined the work should be conducted under the biosafety 2 hood utilizing ABSL 2 precautions with enhanced procedures.

## 7. OLD BUSINESS

None to Report

## 8. EDUCATION:

None to Report

## 9. MINOR ADMINISTRATIVE:

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

None to Report

### 2. Personnel Updates:

- a) BH-Malcolm-08-20 PI: Ken Malcolm, PhD. Removal of Emily Wheeler
- b) BH-Seibold-02-21 PI: Max Seibold, PhD. Addition of Kristin Fluke approved 05/30/25.
- c) BH-Maier-12-20 PI: Lisa Maier, MD, MSPH. Removal of Kristyn MacPhail, Addition of L. Elaine Epperson, approved 06/12/25.
- d) BH-Janssen-03-20. PI: William Janssen, MD. Addition of Malaney Finn, approved 06/24/2025.
- e) BH-Petrache-05-21. PI: Irina Petrache, MD. Addition of Travis Saltzman, approved 06/27/2025.
- f) BH-Janssen-03-20. PI: William Janssen, MD. Addition of Beatrice Kwarteng, Jacob Jaramillo, approved 07/14/2025.

### 3. Annual Reviews:

- a) BH-Manka-02-23. PI: Laurie Manka, MD. Second Annual Review, approved 4/18/25
- b) BH-Solomon-05-21. PI: Joshua Solomon, MD. First Annual Review, approved 5/2/25.
- c) BH-Biobank-03-20. PI: Steve Groshong, MD, PhD. Second Annual Review, approved 5/9/25.
- d) BH-Gally-06-20. PI: Fabienne Gally. PhD. Second Annual Review: remove Briana Henry and Add Emilia Jedryka, approved 05/09/2025.
- e) BH-Radoshevich-03-24. PI: Lilliana Radoshevich, PhD. First Annual Review addition of Jacob Miller and John Patterson removal of Orane Pion-Piola, approved 05/12/2025.
- f) BH-Wechsler-06-20. PI: Michael Wechsler, MD. Second Annual Review, approved 05/30/2025.
- g) BH-Numata-Nakamura-06-21. PI: Mari Numata-Nakamura, MD, PhD, First annual review, removal of Jessica Loeffler. Approved 06/10/2025.

- h) BH-Livecellcore-07-21. PI: Hong Wei Chu, MD. First annual review, removal of Diana Cervantes. Approved 6/24/2025.
- i) BH-Alam-06-21. PI: Rafeul Alam, MD, PhD. First annual review. Approved 06/24/2025.
- 4. Protocol Closures:
  - a) BH-Matsuda-03-20. Closed 06/05/2025
- 5. Expiration:
  - a) None to Report
- 6. Memorandums of Understanding (MOUs)
  - b) None to Report

**10. ADJOURNMENT:**

Meeting Adjourned at: 12:34 PM

**11. ATTACHMENTS**

- 1. 7/22/2025 IBC Agenda
- 2. Minutes from the 4/22/25 IBC meeting
- 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

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*Vanessa Rodriguez*

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Vanessa Rodriguez, IBC administrator