

IBC Meeting
November 18, 2025 11AM, Zoom Virtual Meeting
Minutes

1. CALL TO ORDER:

1. The meeting was called to order at: 11:02 am
2. In Attendance:
 - a. Ken Malcolm (Chair)
 - b. Cristina Penaranda (Co-Chair)
 - c. Doria Cladis (Non-Affiliated community member)
 - d. Vanessa Rodriguez (Member/administrator)
 - e. Katie Kopf (Animal Expert/Veterinarian)
 - f. Joanne E. Streib (Technical Member)
 - g. Peter Farina (Safety Officer)
3. Non Attendance: Matthew D. Rosenbaum (Animal Expert/Veterinarian)
Tom Merry (Non-Affiliated community member)
4. Review and approval of the minutes: 8/26/25

2. PROTOCOLS AND ADDENDA:

1. BH-Downey-12-19. Gregory Downey, MD Triennial Review.

Reviewer: Ken Malcolm

Discussion: The reviewer presented the renewal submission to the committee noting. The study will involve rDNA, infectious agents, human samples, live animals, Flow Cytometry, Lentiviral Vector, and gene editing. The PI has submitted the appropriate appendices for this research and has appropriately identified the risk groups (2) and biosafety levels (2). The study falls under sections III-D and III-D-2 of the NIH Guidelines

Modifications and/or Clarification Requested:

Main Registration form:

- Section I.3 flow cytometry needs to be checked
- Section I.5 Containment Centrifuge in C120 needs to be checked “NO”
- Section II.8.E include genes that are potentially oncogenic and include shRNA and sgRNA targets.
- Section IV Use in Animals for elastase needs to be checked in the table
- Section V.11.C Human materials (elastase) needs to be checked
- Section V.11.D confirm that biohazards will not be used after Smoke exposure; uncheck FlexiVent – Pre. The information in the comment section regarding micro CT after IAV infection should be removed
- Section V.E indicated use of infectious agents and human materials
- Section V.F Indicate the use of lentiviral vectors in animals or modify Appendix B item #9. In addition, reconcile the use of animals from the Section II table with this list. Include shRNA and sgRNA targets, if applicable, in separate field.
- Separate the handling guides for each agent

Appendix A

- Indicate the cell type(s) in the second row.

- In the Analyzers and Sorters columns, the text needs to be replaced with check boxes and check as appropriate

Appendix B

- Question #2, indicate “proprietary” 5 vector “4th gen” system.
- Question #3, should be Yes.
- Question #4, remove tat and rev, according to the manual.
- Question #6, confirm that other genes with oncogenic potential will not be used with the lentiviral transductions.
- Question #9, should be Yes
- Question #10, clarify the use of lentiviral vectors (or transduced cells) in animals. Check Yes if shRNA or sgRNA lentiviral.
- Clarify the use of fluorescent markers and bi-cistronic lentiviral system; the main protocol, Section II, indicates use of fluorescent markers in animals and Appendix B the use of bi-cistronic lentiviral system.

Appendix C- no revisions needed

Lab sign

- Include the date
- Include all of the bacteria list in the protocol; Human materials should read “Human lung tissue and human cell lines; human cells; blood; bronchoalveolar lavage; sputum; elastase”.
- Hepatitis B is recommended for work with blood.
- In the last section of the Lab Sign, please remove Cre, TGFb.

The committee agreed that the study should be granted a 60-day extension in order for the items to be addressed and reviewed by the committee.

Determination and vote: The committee voted to re-consider this submission at an upcoming meeting noting the PI can continue the research as previously approved for an additional 60 days.

Total: 7 For: 7 Against: 0 Abstentions: 0

3. DMR APPROVALS:

- BH-Numata-Nakamura-06-21. PI: Mari Numata-Nakamura, MD, PhD. Addition of Addition of Gamma-irradiated SARS-CoV-2. Approved 10/23/2025.
- BH-Strong-10-19. PI: Michael Strong, PhD. Triennial Review approved 09/26/2025

4. APPROVALS:

- BH-Bratcher-08-19. PI: Preston Bratcher, PhD – Triennial review approved 9/08/2025.
- BH-Chen.e-08-20. PI: Edward Chan, MD – Addition of SARS-CoV-2 approved 10/08/2025.
- BH-Penaranda-08-22. PI: Cristina Penaranda – Triennial Review approved 9/10/25.

5. SOPs and POLICIES:

None to Report

6. NEW BUSINESS

Discussed a plan to move specific studies that have multiple PIs with different scopes on one protocol to separate submissions for each PI.

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-Janssen-03-20 PI: William Janssen, MD. Addition of Austin Thekkumthala approved 9/26/25.

3. Annual Reviews:

a) BH-Lahm-11-21 PI: Tim Lahm, MD. First annual review approved 9/26/2025.

b) BH-Woodcock-09-24 PI: Chen-Shan Woodcock, PhD. First annual review approved 09/26/2025.

c) BH-Taylor-Cousar-09-24 PI: Jennifer Taylor-Cousar, MD. First annual review: Removal of Samantha Johnson and Grant Warren; Addition of Michele Gaffigan. Approved 10/16/2025.

d) BH-Goleva-10-23 PI: Elena Goleva, PhD. Second annual review. Approved 10/16/2025.

4. Protocol Closures:

a) BH-Crooks-09-23 PI James Crooks, PhD. Study closed as of 10/02/2025

5. Expiration:

None to Report

6. Memorandums of Understanding (MOUs)

None to Report

10. ADJOURNMENT:

Meeting Adjourned at: 11:56 am

11. ATTACHMENTS

1. 11/18/2025 IBC Agenda
2. Minutes from the 8/26/25 IBC meeting
3. Submission Materials for section II
4. Approved materials for sections III and IV

Respectfully submitted,

Signed by:

Ken Malcolm

c3F7407F7B7E403...

Ken Malcolm, PhD, IBC Chair

DocuSigned by:

Vanessa Rodriguez

5B864EA6E75044B...

Vanessa Rodriguez, IBC administrator