

U-M Institutional Biosafety Committee
Minutes
Approved at the January 16, 2026, IBC Meeting

Meeting Information:

Date: Friday, December 19, 2025

Time: 1:15-2:30 p.m.

Location: Via conference call (Zoom)

Voting Members Present: Pamela Bennett-Baker, Matt Chapman, Wanlu Du, Chris Fenno, Janet Follo, Huiru Kopera, Joyce Lai, Tom Lanigan, Daniel Lawrence, Patrick Lester, Akira Ono, Stephen Rapundalo, Alex Rickard, Jackie Shields, Andrew Tai, John Thomas, Fei Wen, Christiane Wobus (Chair)

Voting Members Absent: None

Alternate Members Present: Ingrid Bergin (alt. for Lester), Jessica Bunn (alt. for Follo)

IBC Staff Members Present: Jen Harley, Alicia Trombley

Guests Present: Carolyn Kuenz, Eric Robertson, Nicoleen Boyle, Andrew Kennedy, Kathy Ignatoski, Jonah Lee, Pat Ward, Sheya Jones, Sarah Lawson

The meeting was called to order at: 1:15 p.m.

The meeting was adjourned at: 1:46 p.m.

Agenda Items:

1. Updates from the Chair – Christiane Wobus

Dr. Wobus welcomed members to the last meeting of 2025, stating she is looking forward to the upcoming in-person meeting in January.

Jackie Shields told the committee about a new university initiative on research safety and security.

2. Consideration of minutes from the previous meeting

The committee reviewed the minutes from the November 21, 2025, meeting. There were no changes recommended.

Motion: Stephen Rapundalo moved to approve the minutes.

Second: Matt Chapman seconded the motion.

Vote: All in favor.

3. Biosafety Officer Report – Sheya Jones

Ms. Jones stated that no incidents or injuries this month required NIH reporting.

Ms. Jones informed members about the upcoming Research & Academic Safety Fair scheduled for February 10, 2026, from 10:00 a.m. to 2:00 p.m. The event will take place at the Michigan League. Registration information will be shared, and participation is encouraged.

Ms. Jones updated members regarding the Customs and Border Protection Import Workshop which is planned for Spring 2026 (tentatively April). Staff participation is requested, particularly from administrative staff, and those who help with shipping processes. Names of relevant staff should be submitted to EHS to ensure they receive an invitation.

Ms. Jones stated that due to an increase in USDA, CDC, and APHIS inspections, individuals with import permits are encouraged to contact the EHS office to receive support and inspection preparation guidance.

4. Conflict of interest disclosure opportunity

Dr. Wobus asked committee members whether they or their labs were involved with, or were in conflict with, financially or otherwise, any items on today's agenda.

1. Chris Fenno indicated a conflict with application IBCA0000003_AR11 for Dr. Fenno.
2. Alex Rickard indicated a conflict with application IBCA0000003_AR11 for Dr. Fenno and IBCA0000994_AR10 for Dr. Lin.

5. Applications for committee action

BSL2 Applications

The following BSL2 applications were considered and voted upon separately by the committee due to a conflict of interest.

1. IBCA00000003_AR11

Fenno, J – Amendment

Current approval: BSL1 (plasmid vectors and vectorless systems); BSL2 (plasmid vectors in RG2 host and vectorless systems); BSL2 (RG2 bacteria); BSL2 (human-derived substances). No work involving biological toxins, animal-derived substances, animals or plants.

Changes: Added additional strains of *Fusobacterium nucleatum* (BSL2).

Consensus: The committee agreed with the reviewers that the described work is appropriate for BSL2 containment and that BSL2 risk mitigation practices are likewise appropriate.

14. IBCA00000994_AR10

Lin, Nina – Amendment

Current approval: BSL1 (plasmid vectors); BSL1 (RG1 bacteria and fungi); BSL2 (RG2 bacteria); BSL2 (human-derived substances). No work involving biological toxins, animal-derived substances, animals or plants.

Changes: Updated research goals with human-derived substances (BSL2) and added additional RG2 bacteria (BSL2).

Consensus: The committee agreed with the reviewers that the described work is appropriate for BSL2 containment and that BSL2 risk mitigation practices are likewise appropriate.

Motion: Tom Lanigan moved to approve the (2) applications listed above, at the containment levels agreed upon, contingent on satisfactory completion of a laboratory inspection in the past year and upon any other contingencies noted above.

Second: Stephen Rapundalo seconded the motion.

Vote: All in favor, with Chris Fenno and Alex Rickard recused.

The following BSL2 applications were considered by the committee and voted upon:

1. *This application was handled separately due to a conflict of interest.*

2. IBCA00000022_AR03

Narayan, Alison – Renewal

Current approval: BSL1 (plasmid vectors); BSL2 (RG2 bacteria); BSL2 (TTX and Saxitoxin). No work involving human- or animal-derived substances, animals or plants.

Changes: Added additional plasmid vectors (BSL1).

Consensus: The committee agreed with the reviewers that the described work is appropriate for BSL1 and BSL2 containment and that BSL2 risk mitigation practices are likewise appropriate.

3. IBCA00000057_AR13

Kahlenberg, J Michelle – Amendment

Current approval: BSL1 (plasmid vectors and vectorless systems); BSL2 (lentivirus and MSCV vectors); BSL2 (RG2 bacteria); BSL2 (LPS); BSL1 (human-derived substances: saliva); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered vectorless systems or LPS); ABSL2 for the duration (mice administered Staph aureus). No work involving animal-derived substances or plants.

Changes: Added new gene elements in plasmid vectors (BSL1).

Consensus: The committee agreed with the reviewers that the described work is appropriate for BSL1 containment.

4. IBCA00000290_AR07

Collins, Kathleen – Renewal

Current approval: BSL1 (plasmid vectors); BSL2 (retrovirus and adenovirus vectors; plasmid vectors with HIV and SIV genes); BSL2 (HIV); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL2 for the duration (mice administered rDNA modified human-derived substances). No work involving biological toxins, animal-derived substances, or plants.

Changes: Added work with vectorless systems (BSL1) and animal-derived substances from ruminants (BSL1). Removed work with animals.

Consensus: The committee agreed with the reviewers that the described work is appropriate for BSL1 and BSL2 containment and that BSL2 risk mitigation practices are likewise appropriate.

The proposed animal housing containment level is considered appropriate.

5. IBCA00000371_AR04

Kwan, Kenneth – Renewal

Current approval: BSL1 (vectorless systems, plasmid vectors, and AAV vectors); BSL2 (lentiviral vectors); ABSL1 (transgenic mice); ABSL1 (mice administered vectorless systems, lentiviral, AAV, or plasmid vectors). No work involving infectious agents, biological toxins, human- or animal-derived substances, or plants.

Changes: No major changes.

Consensus: The committee agreed with the reviewers that the described work is appropriate for BSL1 and BSL2 containment and that BSL2 risk mitigation practices are likewise appropriate. The proposed animal housing containment level is considered appropriate. Approval is contingent upon minor edits being made to the application.

6. IBCA00000391_AR11

Koschmann, Carl – Renewal

Current approval: BSL1 (plasmid vectors); BSL2 (adenovirus and lentivirus vectors); BSL2 (human-derived substances); ABSL1 (mice administered plasmid vectors, rDNA modified animal cells, lentivirus vectors, or rDNA modified human cells passing infectious agent testing); ABSL2 for 3 days (mice administered adenovirus vectors); ABSL2 for the duration (mice administered rDNA modified human-derived substances). No work involving infectious agents, biological toxins, animal-derived substances, or plants.

Changes: Added work with additional human-derived substances (BSL2).

Consensus: The committee agreed with the reviewers that the described work is appropriate for BSL1 and BSL2 containment and that BSL2 risk mitigation practices are likewise appropriate. The proposed animal housing containment level is considered appropriate. Approval is contingent upon minor edits being made to the application.

7. IBCA00000499_AR05

Wang, Michael – Renewal

Current approval: BSL1 (plasmid vectors and vectorless systems); BSL2 (lentiviral vectors); BSL2 (human- and animal-derived substances from ruminants, swine, and non-human primates); ABSL1 (transgenic rodents). No work involving infectious agents, biological toxins, or plants.

Changes: Added additional plasmid vectors (BSL1).

Consensus: The committee agreed with the reviewers that the described work is appropriate for BSL1 and BSL2 containment and that BSL2 risk mitigation practices are likewise appropriate. The proposed animal housing containment level is considered appropriate.

8. IBCA00000500_AR04

Singer, Kanakadurga – Renewal

Current approval: BSL2 (LPS); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered LPS). No work involving rDNA, infectious agents, animal-derived substances, or plants.

Changes: Added work with adenoviral vectors (BSL2).

Consensus: The committee agreed with the reviewers that the described work is appropriate for

BSL2 containment and that BSL2 risk mitigation practices are likewise appropriate. The proposed animal housing containment level is considered appropriate. Approval is contingent upon minor edits being made to the application.

9. IBCA00000541_AR05

Duncan, Mara – Renewal

Current approval: BSL1 (plasmid and baculovirus vectors; vectorless systems); BSL2 (human-derived substances). No work involving infectious agents, biological toxins, animal-derived substances, animals, or plants.

Changes: Added work with non-K12 E. coli plasmid vectors (BSL1) and updated risk mitigation practices.

Consensus: The committee agreed with the reviewers that the described work is appropriate for BSL1 and BSL2 containment and that BSL2 risk mitigation practices are likewise appropriate.

10. IBCA00000560_AR10

Fox, David – Renewal

Current approval: BSL1 (plasmid vectors and vectorless systems); BSL2 (lentivirus vectors); BSL2 (pertussis toxin and LPS); BSL2 (human-derived substances); BSL2 (animal-derived substances: non-human primates); ABSL1 (transgenic mice); ABSL1 (mice administered LPS or rDNA modified animal cells); ABSL2 for the duration (mice administered human-derived substances or rDNA modified human-derived substances). No work involving infectious agents or plants.

Changes: No major changes.

Consensus: The committee agreed with the reviewers that the described work is appropriate for BSL1 and BSL2 containment and that BSL2 risk mitigation practices are likewise appropriate. The proposed animal housing containment level is considered appropriate.

11. IBCA00000643_AR15

Turner, David – Renewal

Current approval: BSL1 (plasmid vectors and vectorless systems); BSL2 (MoLV vectors); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered plasmid vectors or vectorless systems). No work involving infectious agents, biological toxins, animal-derived substances, or plants.

Changes: No major changes.

Consensus: The committee agreed with the reviewers that the described work is appropriate for BSL1 and BSL2 containment and that BSL2 risk mitigation practices are likewise appropriate. The proposed animal housing containment level is considered appropriate.

12. IBCA00000689_AR06

Lieberman, Andrew – Renewal

Current approval: BSL1 (plasmid vectors, AAV vectors, and vectorless systems); BSL2 (AAV vectors with growth control genes and FIV vectors); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered plasmid vectors, vectorless systems, and AAV vectors); ABSL2 for 3 days (mice administered AAV vectors with growth control genes). No work involving infectious agents, animal-derived substances, or plants.

Changes: Added additional human-derived substances (BSL2).

Consensus: The committee agreed with the reviewers that the described work is appropriate for BSL1 and BSL2 containment and that BSL2 risk mitigation practices are likewise appropriate. The proposed animal housing containment level is considered appropriate. Approval is contingent upon minor edits being made to the application.

13. IBCA00000696_AR07

Jakob, Ursula – Amendment

Current approval: BSL1 (plasmid vectors and vectorless system); BSL2 (plasmid vectors in RG2 host and lentivirus vectors); BSL2 (RG2 bacteria); BSL2 (human-derived substances); ABSL1 (transgenic *C. elegans*); ABSL1 (*C. elegans* administered rDNA modified RG1 bacteria). No work involving biological toxins, animal-derived substances, or plants.

Changes: Added new gene elements in plasmid vectors (BSL1).

Consensus: The committee agreed with the reviewers that the described work is appropriate for BSL1 containment. Approval is contingent upon minor edits being made to the application and favorable review by two reviewers.

14. *This application was handled separately due to a conflict of interest.*

15. IBCA00001135_AR04

Coleman, Rhima – Amendment

Current approval: BSL1 (plasmid vectors); BSL2 (lentivirus vectors); BSL2 (human-derived substances); ABSL2 for the duration (rodents administered human-derived substances or rDNA modified human-derived substances). No work involving infectious agents, biological toxins, animal-derived substances, or plants.

Changes: Updated work with human-derived substances (BSL2).

Consensus: The committee agreed with the reviewers that the described BSL2 risk mitigation practices are appropriate. Approval is contingent upon minor edits being made to the application.

16. IBCA00001495_AR02

Ashton-Miller, James – Renewal

Current approval: BSL2 (human-derived substances); BSL2 (animal-derived substances: sheep, chicken, or turkey). No work involving rDNA, infectious agents, biological toxins, animals or plants.

Changes: Updated work with human-derived substances (BSL2) and animal-derived substance (BSL2), and updated risk mitigation practices.

Consensus: The committee agreed with the reviewers that the described work is appropriate for BSL2 containment and that BSL2 risk mitigation practices are likewise appropriate. Approval is contingent upon minor edits being made to the application.

17. IBCA00001500_AR06

O'Meara, Teresa – Amendment

Current approval: BSL1 (plasmid vectors); BSL2 (rDNA-modified RG2 fungi); BSL2 (RG2 fungi); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL2 for the duration

(mice administered rDNA-modified RG2 fungi). No work involving biological toxins, animal-derived substances, or plants.

Changes: Added additional plasmid vectors (BSL1) and administration of RG2 fungi to mice (ABSL2 for the duration).

Consensus: The committee agreed with the reviewers that the described work is appropriate for BSL1 containment. The proposed animal housing containment level is considered appropriate.

18. IBCA00002023_AR04

Min, Jouha – Renewal

Current approval: BSL1 (plasmid vectors); BSL2 (lentiviral vectors); BSL2 (RG2 bacteria); BSL2 (human-derived substances); ABSL2 for the duration (rabbits and rodents administered RG2 bacteria). No work involving biological toxins, animal-derived substances, or plants.

Changes: Added work with additional human-derived substances (BSL2).

Consensus: The committee agreed with the reviewers that the described work is appropriate for BSL1 and BSL2 containment and that BSL2 risk mitigation practices are likewise appropriate. The proposed animal housing containment level is considered appropriate. Approval is contingent upon minor edits being made to the application.

19. IBCA00002304_AR07

Kaczorowski, Catherine – Amendment

Current approval: BSL1 (plasmid and AAV vectors); BSL2 (lentivirus vectors); BSL2 (tetrodotoxin); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered AAV vectors). No work involving infectious agents, animal-derived substances, or plants.

Changes: Added work with additional human-derived substances (BSL2).

Consensus: The committee agreed with the reviewers that the described work is appropriate for BSL2 containment and that BSL2 risk mitigation practices are likewise appropriate. Approval is contingent upon minor edits being made to the application and favorable review by one reviewer.

20. IBCA00002343_AR03

Wu, Connie – Renewal

Current approval: BSL1 (plasmid vectors and vectorless systems); BSL2 (lentiviral vectors); BSL2 (human-derived substances); ABSL1 (mice administered vectorless systems or rDNA-modified animal cells). No work involving infectious agents, biological toxins, animal-derived substances, or plants.

Changes: Added additional plasmid vectors (BSL1).

Consensus: The committee agreed with the reviewers that the described work is appropriate for BSL1 and BSL2 containment and that BSL2 risk mitigation practices are likewise appropriate. The proposed animal housing containment level is considered appropriate.

21. IBCA00002446_AR02

Hastings, Michelle – Amendment

Current approval: BSL1 (plasmid vectors and vectorless systems); BSL2 (human-derived substances); BSL2 (animal-derived substances: swine); ABSL1 (transgenic mice); ABSL1 (mice

administered vectorless systems). No work involving infectious agents, biological toxins, or plants.

Changes: Updated risk mitigation practices (BSL2).

Consensus: The committee agreed with the reviewers that the described BSL2 risk mitigation practices are appropriate. Approval is contingent upon minor edits being made to the application.

22. IBCA00002531_AR03

Parolia, Abhijit – Amendment

Current approval: BSL1 (vectorless systems, plasmid and phage vectors); BSL2 (retroviral and adenoviral vectors); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered vectorless systems, plasmid vectors, and adenovirus or retrovirus vectors via Category 1 routes; mice and zebrafish administered rDNA-modified animal cells); ABSL2 for 3 days (mice administered adenoviral or retroviral vectors); ABSL2 for the duration (zebrafish administered rDNA-modified human-derived substances; mice administered human-derived substances). No work involving infectious agents, biological toxins, animal-derived substances, or plants.

Changes: Added new gene elements in vectorless systems, phage, and plasmid vectors (BSL1) and in lentiviral and MSCV vectors (BSL2).

Consensus: The committee agreed with the reviewers that the described work is appropriate for BSL1 and BSL2 containment and that BSL2 risk mitigation practices are likewise appropriate. Approval is contingent upon favorable review by one reviewer and favorable re-review by one reviewer.

23. IBCA00002589_AR02

Allada, Ravi – Amendment

Current approval: BSL1 (plasmid vectors); BSL2 (tetrodotoxin); BSL2 (human-derived substances); ABSL1 (transgenic fruit flies); ABSL1 (fruit flies administered plasmid vectors or tetrodotoxin). No work involving infectious agents, animal-derived substances, or plants.

Changes: Added work with lentivirus vectors (BSL2).

Consensus: The committee agreed with the reviewers that the described work is appropriate for BSL2 containment and that BSL2 risk mitigation practices are likewise appropriate. Approval is contingent upon minor edits being made to the application.

24. IBCA00002723_AR04

Wong, Pamela – Amendment

Current approval: BSL1 (vectorless systems); BSL2 (lentiviral vectors); BSL2 (RG2 viruses); BSL1 (Monophosphoryl Lipid A); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered vectorless systems, Monophosphoryl Lipid A, or inactivated SARS-CoV-2 virus); ABSL2 for 21 days (mice administered Influenza A/New Caledonia/20/99); ABSL2 for the duration (mice administered Influenza virus, Influenza H1N1 virus, Influenza A Puerto Rico virus, Vesicular stomatitis virus, SARS-CoV-2, or RSV). No work involving animal-derived substances or plants.

Changes: Proposal to move mice administered SARS-CoV-2 to ABSL1 housing after 14 days.

Consensus: The committee agreed with the reviewers that the proposed animal housing containment level is considered appropriate.

25. IBCA00003076

Takematsu, Eri - Initial Application

Proposed: BSL1 (plasmid vectors and vectorless systems); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL2 for the duration (mice administered human-derived substances). No work involving infectious agents, biological toxins, animal-derived substances, or plants.

Consensus: The committee agreed with the reviewers that the described work is appropriate for BSL1 and BSL2 containment and that BSL2 risk mitigation practices are likewise appropriate. The proposed animal housing containment level is considered appropriate.

26. IBCA00003084

Pedersen, Elisabeth - Initial Application

Proposed: BSL1 (plasmid vectors); BSL2 (lentiviral vectors); BSL2 (human- and animal-derived substances from chickens); ABSL1 (transgenic mice); ABSL1 (mice administered rDNA-modified animal cells); ABSL2 for the duration (mice administered rDNA-modified human-derived substances). No work involving infectious agents, biological toxins, or plants.

Consensus: The committee agreed with the reviewers that the described work is appropriate for BSL1 and BSL2 containment and that BSL2 risk mitigation practices are likewise appropriate. The proposed animal housing containment level is considered appropriate.

27. IBCA00003091

Korley, Frederick - Initial Application

Proposed: BSL2 (human-derived substances); BSL1 (animal-derived substances: swine). No work involving rDNA, infectious agents, biological toxins, animals or plants.

Consensus: The committee agreed with the reviewers that the described work is appropriate for BSL1 and BSL2 containment and that BSL2 risk mitigation practices are likewise appropriate. Approval is contingent upon minor edits being made to the application and favorable re-review by one reviewer.

Motion: Tom Lanigan motioned to approve the (25) IBC applications listed above at the containment levels agreed upon, contingent on satisfactory completion of a laboratory inspection in the past year and upon any other contingencies noted above.

Second: Matt Chapman seconded the motion.

Vote: All in favor.

BSL1 Applications

The following BSL1 applications were considered by the committee and voted upon.

28. IBCA00000653_AR03

O'Brien, Patrick – Renewal

Current approval: BSL1 (plasmid vectors and vectorless systems). No work involving infectious agents, biological toxins, human- or animal-derived substances, animals or plants.

Changes: Added work with non-K12 E. coli plasmid vectors (BSL1).

Consensus: The committee agreed with the reviewers that the described work is appropriate for BSL1 containment.

29. IBCA00002325_AR01

Kim, Jun – Renewal

Current approval: AAV vectors (BSL1); ABSL1 (transgenic mice); ABSL1 (mice administered AAV vectors). No work involving infectious agents, biological toxins, human- or animal-derived substances, or plants.

Changes: No major changes.

Consensus: The committee agreed with the reviewers that the described work is appropriate for BSL1 containment. The proposed animal housing containment level is considered appropriate. Approval is contingent upon favorable review by one reviewer.

30. IBCA00003088

Collins, Gregory - Initial Application

Proposed: ABSL1 (transgenic mice). No work involving rDNA, infectious agents, biological toxins, human- or animal-derived substances, or plants.

Consensus: The committee agreed with the reviewers that the proposed animal housing containment level is considered appropriate.

Motion: Stephen Rapundalo motioned to approve the (3) IBC applications listed above at the containment levels agreed upon.

Second: Matt Chapman seconded the motion.

Vote: All in favor

6. Discussion Items

Item 1. Human Gene Transfer Application – Andrew Tai

HUM00281410

PI: Monalisa Ghosh

Title: A Phase 2, randomized, open-label, controlled study to evaluate the efficacy and safety of rapcabtagene autoleucel versus comparator in participants with severe active Granulomatosis with Polyangiitis (GPA) or Microscopic Polyangiitis (MPA)

Sponsor: Novartis

Andrew Tai described the study for the committee. He and Krishna Rao have reviewed the current submission and express support for approval of this trial. Dr. Tai noted in his review that this is a randomized, open-label, controlled clinical trial of a CD19-targeting CAR-T cell therapy in adults with severe active Granulomatosis with Polyangiitis (GPA) or Microscopic Polyangiitis (MPA). Antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis (AAV) consists of two main diseases, GPA and MPA. B cells are thought to have a key role in the pathogenesis of

AAV. Standard of care therapies, principally glucocorticoids combined with rituximab (anti-CD20), is associated with relapse in 30-50% of patients over 5 years. Repeated courses of treatment can cause serious side effects related to glucocorticoids or to prolonged B-cell depletion leading to increased risk of infections. The primary objective of this trial is to demonstrate superiority of the study agent vs rituximab – the endpoint is event-free survival. The study agent is currently being tested in two phase I/II clinical trials, one for B-cell malignancies and the other for severe, refractory autoimmune diseases. The safety profile is consistent with CD19-targeting CAR-T cell therapies: CRS, IEC-HS, ICANS, infections, cytopenias, genotoxicity/malignancy, infusion reactions and hypersensitivity. The risk of replication competent lentivirus and transmission of infectious agents is very low.

Motion: Tom Lanigan moved to approve the human gene transfer application at BSL2 containment.

Second: Joyce Lai seconded the motion.

Vote: All in favor.

Item 2. VR Lab Safety Training Demo – Alex Rickard

Dr. Rickard chose not to give a full presentation due to the upcoming winter break and instead provided a brief announcement. The EHS Research and Academic Safety Fair will take place in February. Faculty are invited to participate and will be able to try a free immersive training experience on lab safety training for students. This was supported by EHS and The Center for Academic Innovation. Dr. Rickard is currently working with the EHS staff for a rollout. If you are interested in participating, please email Dr. Rickard prior to the event.

7. Matters Arising

There were no matters arising.