

U-M Institutional Biosafety Committee
Minutes
Approved at the September 18, 2026, IBC Meeting

Meeting Information:

Date: Friday, August 21, 2026

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

Location: Via conference call (Zoom)

Voting Members Present: Pamela Bennett-Baker, Matt Chapman, Steven Clark, Wanlu Du, Chris Fenno, Sheya Jones, Joyce Lai, Tom Lanigan, Patrick Lester, Jon Oscherwitz, Stephen Rapundalo, Alex Rickard, Jonny Sexton, Jackie Shields, Andrew Tai, Yifan Wang, Fei Wen, Christiane Wobus (Chair)

Voting Members Absent: Huira Kopera

Alternate Members Present: Ingrid Bergin (alt. for Lester), Jessica Bunn (alt. for Jones), Dalis Collins (alt. for Lester), Crystal O'Donnell (alt. for Jones), Janet Follo (alt. for Jones)

IBC Staff Members Present: Jen Harley, Michael Santiago-Castro, Alicia Trombley

Guests Present: Eric Robertson, Nicoleen Boyle, Em SeGraves, Jonah Lee, Pat Ward, Tara Bradsher, Sarah Lawson, Ingrid Walstad-Terpak, Robertson Davenport

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

The meeting was adjourned at: 2:12 p.m.

Agenda Items:

1. Updates from the Chair – Christiane Wobus

Dr. Wobus stated there were no updates.

2. Consideration of minutes from the previous meeting

The committee reviewed the minutes from the July 17, 2026, meeting. There were no changes recommended.

Motion: Matt Chapman moved to approve the minutes.

Second: Chris Fenno seconded the motion.

Vote: All in favor.

3. Biosafety Officer Report – Sheya Jones

Sheya Jones informed committee members of two exposure incidents that did not involve recombinant DNA. Ms. Jones informed the committee of an upcoming workshop EHS is hosting titled “U.S. Customs and Border Protection Importation of Biological Materials.”

Ms. Jones also noted that the NIH has released the Draft NIH Biosafety Policy for Research Involving Biohazards, with comments on the policy being accepted until October 19, 2026. Discussion ensued regarding the new NIH policy as well as the recently released U.S. Government Policy for Stopping High-Risk Life Sciences Research.

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. Yifan Wang and Christiane Wobus indicated a conflict with application IBCA00002361_AR07 for Dr. Wang.
2. Christiane Wobus indicated a conflict with application IBCA00001550_AR03 for Dr. Zhu.
3. Jon Osherwitz indicated a conflict with application IBCA00000028_AR17 for Dr. Nunez.

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. Tom Lanigan chaired this portion of the meeting.

25. IBCA00001550_AR03

Zhu, Haojie – Renewal

Current approval: BSL2 (human-derived substances); ABSL1 (transgenic mice). No work involving rDNA, 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 BSL2 containment and that BSL2 risk mitigation practices are likewise appropriate. The proposed animal housing containment level is considered appropriate.

29. IBCA00002361_AR07

Wang, Yifan – Amendment

Current approval: BSL1 (plasmid vectors); BSL2 (lentiviral and MSCV vectors, rDNA-modified *Toxoplasma gondii*); BSL2 (RG2 parasites); BSL2 (human-derived substances and animal-derived substances from chickens); ABSL1 (transgenic rodents); ABSL2 for the duration (rodents administered *Toxoplasma gondii* or rDNA-modified *Toxoplasma gondii*). No work involving biological toxins or plants.

Changes: Added work with *Cyclospora cayetanensis* (BSL2) and 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.

Motion: Stephen Rapundalo 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: Matt Chapman seconded the motion.

Vote: All in favor, with Christiane Wobus and Yifan Wang recused.

Christiane Wobus resumed chairing the meeting.

2. IBCA00000028_AR17

Nunez, Gabriel – Renewal

Current approval: BSL1 (plasmid and MoLV vectors); BSL2 (lentiviral vectors and plasmid vectors in RG2 hosts); BSL1 (RG1 bacteria and parasites); BSL2 (RG1 and RG2 bacteria, viruses, fungi, and

parasites); BSL2 (LPS, Monophosphoryl Lipid A); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered LPS, Monophosphoryl Lipid A, or RG1 bacteria); ABSL2 for the duration (mice administered human-derived substances or RG2 infectious agents). No work involving animal-derived substances or plants.

Changes: Updated research goals and 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. The proposed animal housing containment level is considered appropriate.

Motion: Sheya Jones moved to approve the (1) 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, with Jon Osherwitz recused.

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

1. IBCA00000018_AR08

Ganesh, Santhi – Amendment

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

Changes: Added work with additional plasmid vectors (BSL1) and AAV vectors (BSL1) with administration to mice (ABSL1).

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 minor edits being made to the application.

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

3. IBCA00000046_AR22

Lauring, Adam – Amendment

Current approval: BSL1 (plasmid vectors); BSL2 (plasmid, MoLV, lentivirus, rabies, vaccinia/pox, poliovirus, human and murine enterovirus, influenza A virus, RSV, and rotavirus viral vectors); BSL2 (RG2 viruses, Influenza H5 HPAI); BSL2 (human-derived substances); BSL2 (animal-derived substances: swine, ruminants, fowl, and wild vertebrate animals). No work involving biological toxins, animals or plants.

Changes: Added work with seasonal influenza viruses (BSL2) and updated work with animal-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.

4. IBCA00000054_AR13

Lukacs, Nicholas – Amendment

Current approval: BSL2 (RSV and Influenza H1N1); BSL2 (Cholera toxin and LPS); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered Cholera toxin or LPS); ABSL2 for 14 days (mice administered RSV - see approval note); ABSL2 for the duration (mice administered RSV or Influenza H1N1). No work involving rDNA, animal-derived substances, or plants.

Changes: Added work with additional transgenic mice (ABSL1).

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

5. IBCA00000073_AR25

Xu, Zhen – Amendment

Current approval: BSL1 (human-derived substances: decontaminated human skullcap), BSL2 (human-derived substances; animal-derived substances from swine and ruminants); ABSL1 (rodents administered rDNA-modified animal cells; pigs administered animal-derived substances or human-derived substances: decontaminated human skullcap); ABSL2 for the duration (mice administered human-derived substances). No work involving infectious agents, biological toxins, or plants.

Changes: Added additional work with 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.

6. IBCA00000138_AR09

Shavit, Jordan – Renewal

Current approval: BSL1 (plasmid vectors and vectorless systems); BSL2 (RG2 bacteria); BSL2 (LPS); BSL2 (human-derived substances); ABSL1 (transgenic mice and zebrafish); ABSL1 (zebrafish administered LPS); ABSL2 for the duration (zebrafish administered RG2 bacteria). No work involving 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.

7. IBCA00000162_AR06

Squarize, Cristiane – Renewal

Current approval: BSL1 (plasmid vectors); BSL2 (lentiviral and MoLV vectors); BSL2 (human- and animal-derived substances from pigs); ABSL1 (transgenic mice); ABSL2 for the duration (mice administered human-derived substances or rDNA-modified human-derived substances). No work involving infectious agents, biological toxins, 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 and favorable review by one reviewer.

8. IBCA00000269_AR04

Allen, Benjamin – Renewal

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

Changes: Added new gene elements in plasmid vectors (BSL1), additional human cells (BSL2), and additional transgenic mice (ABSL1).

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 and favorable review by one reviewer.

9. IBCA00000424_AR05

Boyle, Alan – Renewal

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

Changes: Updated research goals with human-derived substances (BSL2) and removed work with lentivirus vectors.

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.

10. IBCA00000453_AR19

Chen, Yuqing – Amendment

Current approval: BSL1 (plasmid and AAV vectors; vectorless systems); BSL2 (adenovirus, lentivirus, and MoLV vectors); BSL2 (RG2 bacteria); BSL2 (LPS and Diphtheria toxin); BSL2 (human-derived substances); ABSL1 (transgenic rodents and rabbits); ABSL1 (mice administered Diphtheria toxin, vectorless systems, or plasmid vectors; mice and rabbits administered AAV vectors, LPS or rDNA modified animal cells; rats administered plasmid vectors or rDNA modified animal cells; rabbits administered vectorless systems); ABSL2 for 3 days (rodents and rabbits administered adenovirus vectors; rabbits and mice administered AAV vectors with growth control genes; rabbits administered retrovirus vectors); ABSL2 for the duration (rodents and rabbits administered rDNA modified human cells, mice and rabbits administered human-derived substances, mice and rabbits administered RG2 bacteria). No work involving animal-derived substances or plants.

Changes: Added work with animal-derived substances from non-human primates (BSL2) with administration to mice and rabbits (ABSL2 for 3 days).

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.

11. IBCA00000691_AR07

Hollon, Todd – Amendment

Current approval: BSL1 (plasmid vectors); BSL2 (lentivirus vectors); BSL2 (human-derived substances); ABSL2 for the duration (mice administered 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 BSL2 containment and that BSL2 risk mitigation practices are likewise appropriate. Approval is contingent upon minor edits being made to the application.

12. IBCA00000700_AR10

D'Silva, Nisha – Amendment

Current approval: BSL1 (plasmid, phage, AAV vectors, and AAVrg vectors; vectorless systems); BSL2 (adenovirus and lentivirus vectors); BSL1 (E. coli (genetically crippled strains)); BSL2 (RG2 bacteria); BSL1 (cholera toxin subunit B); BSL2 (LPS); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered cholera toxin subunit B, AAV vectors, AAVrg vectors, or rDNA

modified animal cells); ABSL2 for the duration (mice administered human-derived substances or rDNA modified human-derived substances). No work involving animal-derived substances or plants.

Changes: Added administration of vectorless systems to mice (ABSL1).

Consensus: The committee agreed with the reviewers that the proposed animal housing containment level is considered appropriate. Approval is contingent upon minor edits being made to the application.

13. IBCA00000843_AR05

Parent, Carole – Renewal

Current approval: BSL1 (plasmid and AAV vectors); BSL2 (MSCV vectors); BSL2 (RG2 fungi); BSL2 (Pertussis toxin, Cholera toxin, LPS, Phalloidin); BSL2 (human-derived substances). No work involving animal-derived substances, animals, 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.

14. IBCA00000863_AR05

Bachman, Michael – Renewal

Current approval: BSL2 (plasmid vectors and vectorless systems); BSL2 (RG2 bacteria); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL2 for the duration (mice administered RG2 bacteria or rDNA modified RG2 bacteria). No work involving biological toxins, animal-derived substances, or plants.

Changes: Added work with additional plasmid vector (BSL2) and updated risk mitigation practices (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.

15. IBCA00000868_AR05

Ludlow, Andrew – Renewal

Current approval: BSL1 (plasmid and AAV vectors; vectorless systems); BSL2 (AAV vectors with growth control genes, lentivirus, MSCV, and MoLV vectors); BSL2 (human-derived substances); ABSL1 (transgenic rodents); ABSL1 (mice administered rDNA modified animal cells or vectorless systems); ABSL2 for the duration (mice administered human-derived substances or rDNA modified human-derived substances). 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. Approval is contingent upon minor edits being made to the application.

16. IBCA00000872_AR12

Tessier, Peter – Renewal

Current approval: BSL1 (vectorless systems, phage, and plasmid vectors); BSL2 (lentiviral vectors); BSL2 (Pertussis toxin); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered vectorless systems or Pertussis toxin). No work involving infectious agents, 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 favorable re-review by one reviewer.

17. IBCA00000934_AR04**Simmons, Lyle – Renewal**

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

Changes: Added work with additional RG2 bacteria (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.

18. IBCA00000985_AR12**Li, Peng – Amendment**

Current approval: BSL1 (plasmid and AAV vectors); BSL2 (HSV and rabies vectors; AAV vectors with growth control genes); BSL1 (Cholera toxin subunit B and 192-IgG Saporin); BSL2 (LPS); ABSL1 (transgenic mice); ABSL1 (mice administered Cholera toxin subunit B, Saporin, LPS, AAV vectors, or rabies virus vectors); ABSL2 for 3 days (mice administered HSV vectors). No work involving infectious agents, human- or animal-derived substances, or plants.

Changes: Added new gene elements in AAV vectors (BSL2) and work with an additional AAV vector (BSL1) with administration to mice (ABSL1) and AAV vector with growth control genes (BSL2) with administration to mice (ABSL1 when administered via category 1 ROAs and ABSL2 for 3 days when administered via category 2 ROAs). Also added administration of rDNA modified animal cells to mice (ABSL1).

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. IBCA00001041_AR06**Kondapalli, Kalyan – Amendment**

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

Changes: Added new gene elements in plasmid vectors (BSL1) and work with AAV vectors (BSL2) and vectorless systems (BSL1). Updated research goals with human-derived substances (BSL2) and risk mitigation practices (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 minor edits being made to the application.

20. IBCA00001070_AR14**Truttmann, Matthias – Amendment**

Current approval: BSL1 (vectorless systems, plasmid and phage vectors); BSL2 (lentiviral and AAV vectors); BSL2 (RG1 and RG2 bacteria and fungi); BSL1 (animal-derived substances from llamas and alpacas); BSL2 (human-derived substances); ABSL1 (transgenic mice and *C. elegans*); ABSL1 (*C. elegans* administered *Enterococcus faecalis*; llamas and alpacas administered vectorless systems; mice administered vectorless systems); ABSL2 for 3 days (mice administered AAV vectors); ABSL2 for the duration (*C. elegans* or mice administered RG2 bacteria; mice administered human-derived substances). No work involving 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 containment.

21. IBCA00001140_AR09

Iwase, Shigeki – Amendment

Current approval: BSL1 (plasmid and baculovirus vectors; vectorless systems); BSL2 (retrovirus vectors); BSL2 (RG2 viruses); BSL2 (tetrodotoxin); BSL2 (human-derived substances); ABSL1 (transgenic rodents); ABSL1 (rodents administered plasmid vectors and vectorless systems); ABSL2 for the duration (mice administered RG2 viruses). No work involving animal-derived substances or plants.

Changes: Updated research goals with human-derived substances and risk mitigation practices (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, favorable review by one reviewer, and favorable re-review by one reviewer.

22. IBCA00001146_AR10

Wang, Wenjing – Amendment

Current approval: BSL1 (plasmid and AAV vectors); BSL2 (lentiviral vectors); BSL2 (prion-like alpha synuclein fibrils); BSL2 (human-derived substances). No work involving biological toxins, animal-derived substances, animals or plants.

Changes: Added work with additional plasmid vectors (BSL1), and new gene elements in AAV vectors (BSL1) and in lentiviral 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.

23. IBCA00001197_AR04

Bridwell-Rabb, Jennifer – Amendment

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

Changes: Added work with additional plasmid vector (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.

24. IBCA00001546_AR03

Udager, Aaron – Renewal

Current approval: BSL1 (plasmid vectors); BSL2 (adenoviral, lentiviral and AAV vectors); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered rDNA-modified animal cells); ABSL2 for 3 days (mice administered AAV, lentiviral, or adenoviral vectors); ABSL2 for the duration (mice administered human-derived substances or rDNA-modified human-derived substances). 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.

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

26. IBCA00001677_AR05

O'Dwyer, David – Renewal

Current approval: BSL2 (RG2 bacteria); BSL2 (LPS and Diphtheria toxin); BSL2 (human- and animal-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered Diphtheria toxin or LPS); ABSL2 for the duration (mice administered human-derived substances or RG2 bacteria). No work involving rDNA or plants.

Changes: Added work with 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. The proposed animal housing containment level is considered appropriate. Approval is contingent upon minor edits being made to the application.

27. IBCA00001710_AR02

DeSantis, Morgan – Renewal

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

Changes: Added work with additional baculovirus vectors (BSL1) and additional human cells (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 minor edits being made to the application.

28. IBCA00001830_AR11

Shureiqi, Imad – Amendment

Current approval: BSL1 (vectorless systems, plasmid, and AAV vectors); BSL2 (adenoviral, lentiviral, and AAV vectors with growth control genes); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered vectorless systems, rDNA-modified animal cells, or AAV vectors); ABSL2 for 3 days (mice administered AAV vectors with growth control genes); ABSL2 for the duration (mice administered human-derived substances or 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 BSL2 containment and that BSL2 risk mitigation practices are likewise appropriate.

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

30. IBCA00002368_AR04

Miller, Jason – Renewal

Current approval: BSL1 (plasmid, AAV, and baculovirus vectors); BSL2 (lentivirus, adenovirus, and AAV vectors); BSL2 (human-derived substances); BSL1 (animal-derived substances from ruminants and swine); ABSL1 (transgenic mice). No work involving infectious agents, biological toxins, or plants.

Changes: Added new gene elements in plasmid (BSL1), AAV (BSL2), lentivirus (BSL2), and adenovirus vectors (BSL2), work with vectorless systems (BSL1), and administration of AAV vectors to mice (ABSL1 and ABSL2 for 3 days).

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.

31. IBCA00002441_AR01

Wolf, Matthias – Renewal

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

Changes: Added new gene elements in vectorless systems (BSL1) and lentiviral vectors (BSL2) and updated risk mitigation practices (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.

32. IBCA00002462_AR01

Kodati, Shilpa – Renewal

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

Changes: Added additional work with human-derived substances (BSL2), and updated risk mitigation practices (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.

33. IBCA00002531_AR04

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 plasmid vectors (BSL1), retrovirus vectors (BSL2), and vectorless systems (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.

34. IBCA00002589_AR04

Allada, Ravi – Amendment

Current approval: BSL1 (plasmid vectors); BSL2 (lentivirus 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 AAV vectors (BSL1) with administration mice (ABSL1). Also added work with transgenic mice (ABSL1).

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.

35. IBCA00002618_AR02

Kargbo-Hill, Sarah – Amendment

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

Changes: Added work with animal-derived substances from swine (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.

36. IBCA00002824_AR04

Grohar, Patrick – Amendment

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

Changes: Added new gene elements in plasmid vectors (BSL1) and work with lentivirus vectors (BSL2) and vectorless systems (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. Approval is contingent upon minor edits being made to the application and favorable review by one reviewer.

37. IBCA00002880_AR01

Dang, Louis – Amendment

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

Changes: Added new gene elements in 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.

38. IBCA00002925_AR02

Missmer, Stacey – Amendment

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

Changes: Updated risk mitigation practices.

Consensus: The committee agreed with the reviewers that the described BSL2 risk mitigation practices are appropriate.

39. IBCA00003226

McCoy, Sara - Initial Application

Proposed: BSL1 (plasmid vectors and vectorless system); BSL2 (AAV vectors); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered plasmid vectors or rDNA-modified animal cells); ABSL2 for 3 days (mice administered AAV vectors); ABSL2 for the duration (mice administered human-derived substances or rDNA-modified human cells). 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. Approval is contingent upon minor edits being made to the application and favorable re-review by one reviewer.

40. IBCA00003230

Bell, Hannah - Initial Application

Proposed: BSL1 (plasmid vectors and vectorless systems); BSL2 (lentivirus vectors); BSL2 (human-derived substances); 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, 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. Approval is contingent upon minor edits being made to the application.

Motion: Stephen Rapundalo motioned to approve the (37) 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: Patrick Lester seconded the motion.

Vote: All in favor, with Chris Fenno recused.

BSL1 Applications

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

41. IBCA00000845_AR05

Chang, Cheong-Hee – Renewal

Current approval: BSL2 (*Listeria monocytogenes*); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL2 for the duration (rDNA modified *Listeria monocytogenes*). No work involving biological toxins, animal-derived substances, or plants.

Changes: Removed work with infectious agents and human-derived substances.

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

42. IBCA00002133_AR02

Li, Shiyong – Renewal

Current approval: BSL1 (AAV vectors); ABSL1 (rats 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 minor edits being made to the application.

43. IBCA00002447_AR02

He, Ping – Renewal

Current approval: BSL1 (plasmid vectors); BSL1 (tobacco rattle virus vectors); BSL1 (*Fusarium oxysporum*, *Pseudomonas syringae*, and RG1 viruses); BL1-P (transgenic arabidopsis, cotton, *Nicotiana benthamiana*, and pepper). No work involving biological toxins, human- or animal-derived substances, or animals.

Changes: No major changes.

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

44. IBCA00002490_AR02

Barroso Pereira, Filipa – Renewal

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

Changes: Added new gene elements in plasmid vectors.

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

45. IBCA00002517_AR02**Marand, Alexandre – Renewal**

Current approval: BSL1 (plasmid vectors); BL1-P (transgenic plants); BL1-P (plants administered plasmid vectors). No work involving infectious agents, biological toxins, human- or animal-derived substances, or animals.

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. The proposed plant containment level is considered appropriate. Approval is contingent upon minor edits being made to the application.

46. IBCA00003161**Cuarenta, Amelia - Initial Application**

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

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.

Motion: Tom Lanigan motioned to approve the (6) IBC applications listed above at the containment levels agreed upon.

Second: Stephen Rapundalo seconded the motion.

Vote: All in favor

6. Discussion Items**Item 1. Human Gene Transfer Application – Andrew Tai****HUM00295214****PI: Monalisa Ghosh**

Title: 2026.077_A Phase 3, Randomized, Open-Label, Multicenter Study Evaluating the Efficacy of KITE-753 Versus Axicabtagene Ciloleucel in Participants with Relapsed or Refractory Large B-Cell Lymphoma After First-Line Therapy

Sponsor: Kite Pharma

Andrew Tai described the study for the committee. He has reviewed the current submission and expresses support for approval of this trial. Dr. Tai noted in his review that the disease of interest in this study is large B-cell lymphoma (LBCL). This is a phase 3 study evaluating the efficacy of a dual CD19/CD20-targeting CAR-T cell therapy vs axicabtagene ciloleucel in adult patients with relapsed/refractory large B-cell lymphoma (LBCL) after one line of systemic therapy. Preclinical studies show that the CAR-T cell product can recognize and eliminate tumor cell lines expressing CD19, CD20, or both antigens. This is not a first-in-human study. As of Nov 2025, 30 participants with LBCL have been enrolled with a safety profile typical of CAR-T cell therapy with AEs including CRS, ICANS/neurotoxicity, infections, hypogammaglobulinemia, and cytopenias. Other risks include IEC-HS and the risk of T-cell malignancy.

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

Second: Sheya Jones seconded the motion.

Vote: All in favor.

Item 2. Human Gene Transfer Application – Andrew Tai

HUM00295793

PI: Frederick Askari

Title: A Phase 1/2 Clinical Study to Evaluate Safety, Tolerability, Biological Activity, and Initial Efficacy of Prime Editing (PM577a) for the Treatment of Wilson Disease (WD) in Adult and Adolescent Participants with at Least One Allele Harboring the p.H1069Q Mutation in ATP7B

Sponsor: Prime Medicine

Andrew Tai described the study for the committee. He has reviewed the current submission and expresses support for approval of this trial. Dr. Tai noted in his review that Wilson disease (WD) is a rare genetic disorder of copper metabolism caused by loss-of-function mutations in the ATP7B gene, which encodes a copper-transporting P-type ATPase. This leads to a defect in copper excretion into bile, resulting in tissue copper overload. This leads to a wide spectrum of symptoms, most notably neuropsychiatric and hepatic. Lifelong treatment of WD is necessary. Many patients progress despite standard of care treatment. Liver transplantation is curative, but it is associated with substantial risk and reserved only for those with the most severe/advanced disease. This is a first in human, phase 1/2, single-arm, open-label study of Prime Editing for participants with WD. The study agent is a liver-targeted lipid nanoparticle (LNP) that delivers a set of factors for Prime Editing designed for genetic correction of a specific mutation that accounts for 30-40% of WD-associated alleles in the United States. As this is a first-in-human study, no clinical data are available for review. Potential risks include infusion-related reactions, hepatotoxicity, immune responses to the LNP, coagulation disturbances, extrahepatic biodistribution including risk of germline transmission, genotoxicity, and copper deficiency. Dr. Tai recommended approval contingent upon a satisfactory revision to Question 23.1. The study PI and team must demonstrate knowledge of significant adverse effects to participants, not simply refer to protocol sections.

Motion: Tom Lanigan moved to approve the human gene transfer application at BSL1 containment. contingent on satisfactory completion of the changes notes above.

Second: Sheya Jones seconded the motion.

Vote: All in favor.

7. Matters Arising

There were no matters arising.