

U-M Institutional Biosafety Committee
Minutes
Approved at the April 17, 2026, IBC Meeting

Meeting Information:

Date: Friday, February 20, 2026

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

Location: Via conference call (Zoom)

Voting Members Present: Pamela Bennett-Baker, Matt Chapman, Wanlu Du, Chris Fenno, Sheya Jones, Huiira Kopera, Joyce Lai, Tom Lanigan, Patrick Lester, Akira Ono, Jon Oscherwitz, Alex Rickard, Jackie Shields, Andrew Tai, John Thomas, Fei Wen

Voting Members Absent: Daniel Lawrence, Stephen Rapundalo, Christiane Wobus (Chair)

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

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

Guests Present: Eric Robertson, Nicoleen Boyle, Andrew Kennedy, Jonah Lee, Sarah Lawson

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

The meeting was adjourned at: 2:27 p.m.

Agenda Items:

1. Updates from the Chair – Tom Lanigan (in place of Christiane Wobus)

There were no updates from the chair.

2. Consideration of minutes from the previous meeting

The committee reviewed the minutes from the January 16, 2026, meeting. There were no changes recommended.

Motion: Sheya Jones moved to approve the minutes.

Second: Huiira Kopera seconded the motion.

Vote: All in favor.

3. Biosafety Officer Report – Sheya Jones

Ms. Jones reported on an exposure case that did not involve recombinant DNA.

Ms. Jones informed members that EHS posted a position for assistance with laboratory inspections. The posting has closed and the selection process is ongoing.

4. Conflict of interest disclosure opportunity

Dr. Lanigan 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 applications IBCA00000548_AR06 for Dr. Hu and IBCA00001391_AR07 for Dr. Tenuta.
2. Alex Rickard indicated a conflict with application IBCA00001391_AR07 for Dr. Tenuta.

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.

17. IBCA00000548_AR06

Hu, Jan – Renewal

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

27. IBCA00001391_AR07

Tenuta, Livia – Amendment

Current approval: BSL2 (RG2 bacteria and fungi); BSL2 (human-derived substances); BSL1 (animal-derived substances from ruminants); ABSL1 (rats administered RG2 bacteria and fungi). No work involving rDNA, biological toxins, 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.

Motion: Sheya Jones motioned 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: Huiira Kopera seconded the motion.

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

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

1. IBCA00000038_AR04

Lowenstein, Pedro – Renewal

Current approval: BSL1 (plasmid and AAV vectors); BSL2 (adenovirus and lentivirus vectors); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (rodents administered plasmid vectors, adenovirus vectors, or rDNA modified animal cells); ABSL2 for 3 days (rodents administered adenovirus vectors; rats administered retrovirus 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: Added new gene elements in AAV vectors (BSL1 and BSL2) with administration to mice (ABSL1 if administered via category 1 route of administration, ABSL2 for 3 days if administered via category 2 route of administration).

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.

2. IBCA0000056_AR10

Sherman, David – Renewal

Current approval: BSL1 (plasmid vectors); BSL2 (RG2 bacteria and fungi); BSL2 (microcystin and anatoxin A). No work involving human- or 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.

3. IBCA00000189_AR03

Bielas, Stephanie – Renewal

Current approval: BSL1 (plasmid vectors); BSL2 (adenovirus vectors); BSL2 (human-derived substances); ABSL1 (transgenic mice). 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.

4. IBCA00000209_AR04

Varani, James – Renewal

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

5. IBCA00000210_AR19

Shea, Lonnie – Amendment

Current approval: BSL1 (vectorless systems, plasmid, AAV, and MSCV vectors); BSL2 (lentiviral, MoLV, and HSV1 vectors); BSL2 (*Listeria monocytogenes*); BSL2 (LPS, Cholera toxin, Diphtheria toxin, and Pertussis toxin); BSL2 (human- and animal-derived substances); ABSL1 (transgenic rodents); ABSL1 (rodents administered vectorless systems or rDNA-modified animal cells; mice administered AAV vectors, LPS, retroviral vectors, Pertussis toxin, or Diphtheria toxin); ABSL2 for 3 days (mice administered retroviral or HSV vectors); ABSL2 for the duration (rodents administered human-derived substances or rDNA-modified human-derived substances; mice administered *Listeria monocytogenes* or Cholera toxin). No work involving 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.

6. IBCA00000233_AR05

Murphy, Geoffrey – Renewal

Current approval: BSL1 (plasmid and AAV vectors); BSL2 (lentiviral vectors); BSL2 (Diphtheria toxin, Tetrodotoxin); ABSL1 (transgenic mice); ABSL1 (mice administered AAV vectors, lentiviral

vectors, or Diphtheria toxin). No work involving infectious agents, human- or animal-derived substances, or plants.

Changes: Added new gene elements in AAV vectors (BSL1), work with human-derived substances (BSL2), 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. The proposed animal housing containment level is considered appropriate.

7. IBCA00000265_AR05

Paulson, Henry – Renewal

Current approval: BSL1 (plasmid vectors, AAV vectors, and vectorless systems); BSL2 (lentivirus vectors); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered AAV vectors and vectorless systems).

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.

8. IBCA00000310_AR05

Stockbridge, Randy – Renewal

Current approval: BSL1 (plasmid vectors); BSL2 (plasmid vectors in RG2 host); BSL2 (RG2 bacteria). No work involving biological toxins, human- or 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.

9. IBCA00000354_AR03

Rajapakse, Indika – Renewal

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

Changes: Added work with 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.

10. IBCA00000396_AR05

Li, Qing – Renewal

Current approval: BSL1 (plasmid vectors and MSCV vectors); BSL2 (lentivirus and MSCV vectors); BSL2 (LPS); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered LPS and rDNA modified animal cells); ABSL2 for the duration (mice administered human-derived substances and rDNA modified human-derived substances). 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 review from one reviewer.

11. *This application was tabled.*

12. IBCA00000474_AR06

Pinsky, David – Renewal

Current approval: BSL1 (plasmid vectors and vectorless systems); BSL2 (lentivirus vectors); BSL2 (LPS); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (rodents administered LPS; mice administered vectorless systems); ABSL2 for the duration of the experiment (mice administered human derived substances). No work involving infectious agents, animal-derived substances, or plants.

Changes: No longer administering human-derived substances or vectorless systems to mice.

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 from one reviewer.

13. IBCA00000484_AR13

Zou, Weiping – Renewal

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

14. IBCA00000498_AR04

Andjelkovic-Zochowska, Anuska – Renewal

Current approval: BSL1 (plasmid vectors); BSL2 (human-derived substances); ABSL1 (transgenic mice). 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.

15. IBCA00000520_AR04

Sekiguchi, JoAnn – Renewal

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

Changes: Added new gene elements in lentiviral vectors (BSL2) and work with 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.

16. IBCA00000544_AR03

Thompson, Debra – Renewal

Current approval: BSL1 (plasmid, baculovirus, AAV and phage vectors); BSL2 (lentiviral vectors); BSL2 (human- and animal-derived substances from NHP); BSL1 (animal-derived substances from cows); ABSL1 (transgenic mice); ABSL1 (mice administered AAV vectors); ABSL2 for 3 days (mice administered lentiviral vectors). No work involving infectious agents, biological toxins, or plants.

Changes: 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. The proposed animal housing containment level is considered appropriate.

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

18. IBCA00000556_AR04

Palmbos, Phillip – Renewal

Current approval: BSL1 (plasmid vectors and vectorless systems); BSL2 (adenoviral and lentiviral vectors); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL2 for 3 days (mice administered 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. Approval is contingent upon minor edits being made to the application.

19. IBCA00000595_AR05

Eniola-Adefeso, Lola – Renewal

Current approval: BSL2 (Klebsiella pneumoniae); BSL2 (LPS); BSL2 (human-derived substances); BSL2 (animal-derived substances: swine); ABSL1 (transgenic rodents); ABSL1 (mice administered LPS); ABSL2 for the duration (mice administered Klebsiella pneumoniae). No work involving rDNA 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. Approval is contingent upon minor edits being made to the application.

20. IBCA00000685_AR05

Tiquia-Arashiro, Sonia – Renewal

Current approval: BSL2 (RG2 bacteria). No work involving rDNA, biological toxins, human- or animal-derived substances, animals 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.

21. IBCA00000825_AR06

Lee, Jun Hee – Renewal

Current approval: BSL1 (plasmid and AAV vectors); BSL2 (plasmid, adenovirus, lentivirus and AAV vectors); BSL2 (human-derived substances); ABSL1 (transgenic mice and fruit flies); ABSL1 (mice administered AAV vectors, plasmid vectors, or rDNA-modified animal cells); ABSL2 for 3 days (mice administered AAV vectors or adenovirus vectors); ABSL2 for the duration (mice administered 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 favorable re-review from one reviewer.

22. IBCA00000832_AR04

Garcia, Gonzalo – Renewal

Current approval: BSL1 (plasmid vectors); BSL2 (lentivirus vectors); BSL2 (human-derived substances); ABSL1 (transgenic mice). 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.

23. IBCA00000834_AR05

Keane, Sarah – Renewal

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

Changes: Added work with 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. Approval is contingent upon minor edits being made to the application.

24. IBCA00000915_AR05

Wahl, Daniel – Amendment

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

Changes: Updated risk mitigation practices.

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

25. IBCA00001009_AR08

Hammer, Gary – Amendment

Current approval: BSL1 (plasmid and AAV vectors); BSL2 (lentivirus vectors and AAV vectors with tetanus toxin gene); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered AAV vectors 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, 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.

26. IBCA00001025_AR12

Hogan, Simon – Amendment

Current approval: BSL1 (plasmid vectors and vectorless systems); BSL2 (retrovirus vectors); BSL2 (Diphtheria toxin, Pertussis toxin, LPS, Cholera toxin, and Staphylococcal enterotoxins); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered LPS, rDNA modified animal cells, Diphtheria toxin, Pertussis toxin, Cholera toxin); ABSL2 for 3 days (mice administered Staphylococcal enterotoxins); ABSL2 for the duration (mice administered human-derived substances). No work involving infectious agents, animal-derived substances, or plants.

Changes: Updated work with Staphylococcal enterotoxins (BSL2) with administration to mice (ABSL2 for 3 days if administered through oral gavage or ABSL1 if routes being used do not pose risk of shedding the toxin). Added work with Staph aureus (BSL2) with administration to mice (ABSL2 for the duration).

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, favorable review from one reviewer, and favorable re-review from one reviewer.

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

28. IBCA00001808_AR02

Soellner, Matt – Amendment

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

Changes: Added work with Cholera toxin (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. IBCA00001811_AR02

Turcu, Adina – Renewal

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 work is appropriate for BSL2 containment and that BSL2 risk mitigation practices are likewise appropriate.

30. IBCA00002280_AR01

Thompson, Andrea – Renewal

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

Changes: Added work with additional plasmid vectors (BSL1), additional transgenic mice (ABSL1), 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. The proposed animal housing containment level is considered appropriate. Approval is contingent upon favorable re-review from one reviewer.

31. IBCA00002301_AR01

Prensner, John – Renewal

Current approval: BSL1 (plasmid vectors and vectorless systems); BSL2 (lentiviral and adenoviral

vectors); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered vectorless systems, lentiviral vectors, plasmid vectors or rDNA-modified animal cells); ABSL2 for 3 days (mice administered adenoviral 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: 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.

32. IBCA00002311_AR01

Nidetz, Rob - LNF BSL2 Facility – Renewal

Current approval: BSL2 (RG2 infectious agents); BSL2 (human-derived substances). No work involving rDNA, biological toxins, animal-derived substances, animals 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.

33. IBCA00002334_AR01

Davis, Frank – Renewal

Current approval: BSL1 (AAV vectors); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered AAV vectors). 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.

34. IBCA00002337_AR02

Lorberbaum, David – Renewal

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

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

35. IBCA00002355_AR01

Chen, You-Shin – Renewal

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

36. IBCA00002358_AR03

Niederer, Rachel – Renewal

Current approval: BSL1 (plasmid vectors and vectorless systems); BSL2 (Cholera toxin); BSL2 (human-derived substances). No work involving infectious agents, 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.

37. IBCA00002361_AR06

Wang, Yifan – Renewal

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 new gene elements in 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.

38. IBCA00002397_AR07

Li, Jiahe – Amendment

Current approval: BSL1 (plasmid vectors); BSL2 (lentivirus vectors and plasmid vectors in RG2 host); BSL1 (*Bacillus subtilis*, *Veillonella atypica*, and *E. coli* K12 (genetically crippled strains), *E. coli* EcAZ, *E. coli* Nissle); BSL2 (*E. coli* (pathogenic strains), *Klebsiella pneumoniae*, and *Salmonella enterica* (Typhimurium)); BSL2 (LPS); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered LPS, rDNA modified animal cells, plasmid vectors, RG1 bacteria, or rDNA modified RG1 bacteria); ABSL2 for the duration (mice administered human-derived substances, rDNA modified human-derived substances, rDNA modified human-derived substances, rDNA modified RG2 bacteria, or *E. coli* (pathogenic strains)). No work involving animal-derived substances or plants.

Changes: Added new gene elements in plasmid vectors (BSL1) and RG2 plasmid vector host (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.

39. IBCA00002421_AR04

Zhu, Guizhi – Amendment

Current approval: BSL1 (plasmid vectors and vectorless systems); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered vectorless systems 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, biological toxins, animal-derived substances, or plants.

Changes: Added work with Pertussis toxin (BSL2) with administration to mice (ABSL1).

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 favorable re-review from one reviewer.

40. IBCA00002459_AR04

Linghu, Changyang – Renewal

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

Changes: Added new gene elements in plasmid vectors (BSL1), work with FIV and HIV vectors (BSL2), work with human hair, administration of rDNA modified animal cells to mice (ABSL1), administration of retrovirus vectors to mice (ABSL2 for 3 days), and administration of rDNA modified human-derived substances (ABSL2 for the duration).

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.

41. IBCA00002827_AR04

Hepler, Chelsea – Amendment

Current approval: BSL1 (plasmid vectors); BSL2 (lentivirus and MSCV 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 plasmid vectors (BSL1) and 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. Approval is contingent upon minor edits being made to the application.

42. IBCA00003084_AR01

Pedersen, Elisabeth – Amendment

Current approval: 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.

Changes: Added administration of human-derived substances to mice (ABSL2 for the duration).

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

43. IBCA00003107

Sauler, Maor - Initial Application

Proposed: BSL1 (vectorless systems); BSL2 (human-derived substances); ABSL1 (transgenic mice). 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.

44. IBCA00003123

Mourani, Peter - Initial Application

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

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: Sheya Jones motioned to approve the (41) 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.

BSL1 Applications

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

45. IBCA00000342_AR10

Henke, Peter – Renewal

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

Changes: No major changes.

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

46. IBCA00002895_AR01

Biggs, Bradley – Amendment

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 Aerobic lignin-degrading microbes (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.

Motion: Sheya Jones motioned to approve the (2) IBC applications listed above at the containment levels agreed upon.

Second: Alex Rickard seconded the motion.

Vote: All in favor

Tabled Applications

The following applications were tabled.

11. IBCA00000452_AR09

Gudjonsson, Johann – Renewal

Current approval: BSL1 (plasmid vectors); BSL2 (lentivirus vectors); BSL2 (Papillomaviruses); BSL2 (LPS); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered LPS); ABSL2 for the duration (mice administered human-derived substances or Papillomaviruses). No work involving animal-derived substances or plants.

Changes: Updated genetic elements and risk mitigation practices (BSL2). Removed work with LPS and papillomaviruses.

Discussion: The committee reviewed this renewal application involving lentiviral vector work and identified deficiencies in the answers regarding viral biology and risk assessment. It was determined that the PI and lab personnel must complete the Working Safely with Viral Vectors training and demonstrate in the renewal application a clearer understanding of associated risks before lentiviral work can be approved. Until then, the laboratory will be asked to stop lentiviral work.

Consensus: Tabled.

6. Discussion Items

Item 1. Human Gene Transfer Application – Andrew Tai**HUM00208096****PI: Carl Koschmann****Title:** A Combination Therapy Trial using an Adaptive Platform Design for Children and Young Adults with Diffuse Midline Gliomas (DMGs) including Diffuse Intrinsic Pontine Gliomas (DIPGs) at Initial Diagnosis, Post-Radiation Therapy and at Time of Progression**Sponsor:** Oncoceutics, Inc.

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 brain tumors are the leading cause of cancer death in children in the United States and Europe. 80% of brainstem gliomas in children are diffuse intrinsic pontine gliomas (DIPG) with a median survival of less than 1 year. There are no approved drug therapies for DIPG. Standard of care is radiation therapy, but this is typically palliative. Over 90% of gliomas have mutations that inactivate the retinoblastoma (Rb)/p16 pathway. The study agent is a “conditionally replicative adenovirus” (CRAAd) that has been genetically modified to efficiently replicate in cells with an inactive retinoblastoma (Rb) pathway but not in cells with an intact Rb pathway. Preclinical studies have shown oncolytic activity against a variety of human glioma cell lines *in vitro* and in xenograft models. The most frequently reported AEs to date have been CNS disorders overlapping with expected signs/symptoms of the CNS tumor (e.g. seizure, encephalopathy, headache). There have been no deaths due to drug-related AEs and no unanticipated significant safety concerns.

Motion: Sheya Jones moved to approve the human gene transfer application at BSL2 containment.

Second: Chris Fenno seconded the motion.

Vote: All in favor.

7. Matters Arising

There were no matters arising.