U-M Institutional Biosafety Committee Minutes

Date:

Friday, June 20, 2025
1:15-2:30 p.m., via conference call (Zoom)
Approved at the July 18, 2025, IBC meeting.

Attendance:

Role	Name	Present
IBC Voting Member	Pamela Bennett-Baker	X
IBC Voting Member	Matt Chapman	X
IBC Voting Member	Wanlu Du	
IBC Voting Member	Chris Fenno	X
IBC Voting Member	Janet Follo	
IBC Voting Member	Huira Kopera	X
IBC Voting Member	Joyce Lai	X
IBC Voting Member	Tom Lanigan (Associate Chair)	X
IBC Voting Member	Daniel Lawrence	X
IBC Voting Member	Patrick Lester	X
IBC Voting Member	Akira Ono (on sabbatical)	
IBC Voting Member	Stephen Rapundalo	X
IBC Voting Member	Alexander Rickard	
IBC Voting Member	Jackie Shields	X
IBC Voting Member	Andrew Tai	X
IBC Voting Member	John Thomas	X
IBC Voting Member	Fei Wen	X
IBC Voting Member	Christiane Wobus (Chair)	X
Alternate Members	Ingrid Bergin (alt. for Lester)	X
Alternate Members	Jessica Bunn (alt. for Follo)	X
Alternate Members	Dalis Collins (alt. for Lester)	X
Alternate Members	Crystal O'Donnell (alt. for Follo)	X
IBC Staff	Jen Harley	X
IBC Staff	Michael Santiago-Castro	X
IBC Staff	Alicia Trombley	
Guest	Andrew Kennedy	X
Guest	Carolyn Kuenz	X
Guest	Sarah Lawson	X
Guest	Jonah Lee	X
Guest	Danielle Sheen	X
Guest	Diane Wilson	X

The meeting was called to order at 1:17 pm.

Agenda Items

1. Updates from the Chair – Christiane Wobus

Dr. Wobus stated there were no updates.

2. Consideration of minutes from the May 16, 2025, IBC meeting

The committee reviewed the minutes from the May 16, 2025, 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 – Crystal O'Donnell (in place of Janet Follo)

Reported to NIH OSP - potential rDNA exposure:

The incident occurred in a BSL2 laboratory space when a student was removing a rubber stopper from a waste container outside of the biosafety cabinet. When the stopper was removed, a small amount of material from inside the waste container splashed the student in the face, with some potentially entering his eye. The waste container contained bleach and various types of cells some of which had been transduced with recombinant DNA. The student flushed his eyes for 15 minutes and called Occupational Health Services (OHS) who recommended no further action at the time. The student was not wearing a lab coat, safety glasses, or a face shield at the time of the incident. They had completed the required training. EHS made recommendations to the lab including that proper eye protection be worn especially when handling large volumes. The cell culture waste contained bleach and it is likely that the biological material was inactivated.

Two other incidents not involving recombinant DNA were reported to EHS and follow up is occurring on both.

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.

Christiane Wobus indicated a conflict with application IBCA0000011_AR11 for Dr. Wang.

Chris Fenno indicated a conflict with application IBCA00001391_AR06 for Dr. Tenuta.

5. BSL2 Applications

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

Due to a conflict of interest, Tom Lanigan chaired this portion of the meeting:

40. IBCA00002361_AR04, Wang, Yifan – Amendment

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

Changes: Added work with rDNA-modified Toxoplasma gondii (BSL2) with administration to rodents (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.

Motion: Huira Kopera 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: Crystal O'Donnell seconded the motion.
Vote: All in favor, with Christiane Wobus recused.

Christiane Wobus resumed chairing the meeting.

41. IBCA00001391_AR06, Tenuta, Livia – Renewal

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: 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 minor edits being made to the application.

Motion: Tom Lanigan 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: Joyce Lai seconded the motion.
Vote: All in favor, with Chris Fenno recused.

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

1. **IBCA00000032_AR09, O'Konek, Jessica – Renewal**

Current approval: BSL1 (vectorless systems); BSL1 (Monophosphoryl Lipid A); BSL2 (Cholera toxin); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered Monophosphoryl Lipid A, vectorless systems, or Cholera 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.

2. **IBCA00000046_AR20**, **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 new gene elements in plasmid vectors (BSL2), work with Hepatitis E (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.

3. **IBCA00000118_AR04**, **Veatch, Sarah – Renewal**

Current approval: BSL1 (plasmid vectors); BSL2 (MoLV and lentiviral vectors); BSL2 (human- and animal-derived substances). No work involving infectious agents, biological toxins, animals or plants.
Changes: Added new gene elements in lentiviral vectors (BSL2) and removed work with animal-derived substances.
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.

4. **IBCA00000137_AR12**, **Baker Jr, James – Renewal**

Current approval: BSL1 (vectorless systems); BSL2 (lentivirus vectors); BSL2 (RG2 viruses); BSL1 (Monophosphoryl lipid A); BSL2 (Staphylococcal enterotoxins); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered vesicular stomatitis virus, inactivated SARS-CoV-2, Influenza A (Puerto Rico virus), Monophosphoryl lipid A, or vectorless systems); ABSL2 for 14 days (mice administered Influenza virus or Influenza H1N1 virus where no infection present); ABSL2 for the duration (mice administered Influenza virus, Influenza H1N1 virus, Influenza A (Puerto Rico virus), Respiratory syncytial virus, or Human metapneumovirus). No work involving animal-derived substances or plants.
Changes: Removed work with rDNA, respiratory syncytial virus, and inactivated SARS-CoV-2.
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. **IBCA00000164_AR07, Tronson, Natalie – Renewal**

Current approval: BSL1 (AAV vectors); BSL1 (Saporin); BSL2 (LPS); ABSL1 (transgenic mice); ABSL1 (mice administered AAV vectors or LPS; rats administered AAV vectors, saporin, or LPS). No work involving infectious agents, human- or animal-derived substances, or plants.
Changes: Added new gene elements in AAV 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. The proposed animal housing containment level is considered appropriate. Approval is contingent upon minor edits being made to the application.

6. **IBCA00000172_AR06**, **Feldman, Eva – Renewal**

Current approval: BSL1 (plasmid vectors); BSL2 (adenovirus, lentivirus, and AAV vectors); BSL2 (Staph aureus); BSL2 (LPS); BSL2 (human-derived substances); ABSL1 (transgenic rodents); ABSL1 (rats administered adenovirus, AAV, and lentivirus vectors; mice administered LPS; mice administered retrovirus vectors or adenovirus vectors via intrathecal ROA); ABSL2 for 3 days (mice administered lentivirus and adenovirus vectors; rats administered rDNA modified animal cells); ABSL2 for the duration (rodents administered rDNA modified human-derived substances). No work involving infectious agents, animal-derived substances, or plants.
Changes: Changed work with AAV vectors without toxic or growth control genes from BSL2 to 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. Approval is contingent upon minor edits being made to the application.

7. **IBCA00000190_AR04**, **Talpaz, Moshe – Renewal**

Current approval: BSL1 (plasmid vectors); BSL2 (lentiviral, MSCV, and MoLV vectors); BSL2 (human-derived substances); 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, animal-derived substances, or plants.
Changes: Added work with additional 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. Approval is contingent upon favorable review from a vet reviewer.

8. **IBCA00000318_AR09**, **Schmidt, Thomas – Renewal**

Current approval: BSL1 (plasmid vectors); BSL1 (RG1 bacteria); BSL2 (RG2 bacteria); BSL2 (human-derived substances); ABSL1 (mice administered RG1 bacteria or rDNA-modified RG1 bacteria); ABSL2 for the duration (mice administered human-derived substances, RG2 bacteria, or rDNA-modified RG2 bacteria). No work involving 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.

9. **IBCA00000324_AR06**, **Hatch, Nan – Renewal**

Current approval: BSL1 (plasmid vectors); BSL2 (adenovirus, lentivirus, and MoLV vectors); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL2 for 3 days (rodents administered retrovirus 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.

10. **IBCA00000340_AR06**, **Baker, Brendon – Renewal**

    Current approval: BSL1 (plasmid vectors); BSL2 (lentivirus vectors); BSL2 (human-derived substances); ABSL1 (transgenic mice); 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 and favorable re-review from a vet reviewer.

11. **IBCA00000388_AR10**, **Gallagher, Katherine – Renewal**

    Current approval: BSL1 (plasmid and AAV vectors); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered AAV vectors); 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 an additional AAV serotype (BSL1) and adenovirus vectors (BSL2) with administration to mice (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.

12. **IBCA00000389_AR03**, **Hayes, Daniel – 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: 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. Approval is contingent upon favorable review from one additional scientific reviewer.

13. **IBCA00000400_AR09**, **Moon, James – Renewal**

    Current approval: BSL1 (vectorless systems, plasmid, and AAV vectors); BSL2 (lentiviral vectors); BSL2 (LPS, Pertussis toxin, Diphtheria toxin); BSL1 (CTB, Monophosphoryl Lipid A); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered Monophosphoryl Lipid A, AAV vectors, LPS, CTB, Diphtheria toxin, Pertussis toxin, rDNA-modified animal cells, or vectorless systems); ABSL2 for the duration (mice administered human-derived substances). No work involving infectious agents, animal-derived substances, 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.

14. **IBCA00000401_AR07**, **Tsai, Billy – Renewal**

Current approval: BSL1 (plasmid and non-infectious human papillomavirus vectors); BSL2 (Dengue virus vectors and lentivirus vectors); BSL2 (SARS-CoV-2); BSL2 (human- and animal-derived substances from non-human primates). No work involving infectious agents, biological toxins, animals 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.

15. **IBCA00000449_AR06**, **Holinstat, Michael – Renewal**

Current approval: BSL2 (human-derived substances); BSL2 (animal-derived substances: non-human primates); ABSL1 (transgenic mice); ABSL2 for the duration (mice administered human-derived substances). No work involving rDNA, infectious agents, biological toxins, 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.

16. **IBCA00000476_AR04**, **Padmanabhan, Vasantha – Amendment**

Current approval: BSL1 (plasmid vectors); BSL2 (human-derived substances and animal-derived substances from sheep). No work involving infectious agents, biological toxins, animals or plants.
Changes: Removed work with plasmid vectors and updated risk mitigation practices.
Consensus: The committee agreed with the reviewers that the described BSL2 risk mitigation practices are appropriate.

17. **IBCA00000515_AR05**, **Freeman, Zachary - Transgenic Animal Model Core Facility – Renewal**

Current approval: BSL1 (plasmid and AAV vectors; vectorless systems); BSL2 (AAV vectors with toxic or growth control genes); ABSL1 (transgenic rodents); ABSL1 (rodents administered AAV vectors, vectorless systems, or rDNA modified animal cells). No work involving infectious agents, biological toxins, human- or animal-derived substances, or plants.
Changes: Added additional AAV vectors (BSL1) and AAV vectors with toxic or growth control genes (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.

18. **IBCA00000540_AR03**, **Higgins, Peter – Amendment**

    Current approval: BSL1 (plasmid vectors and vectorless systems); BSL2 (lentivirus vectors); BSL2 (Salmonella enterica (Typhimurium)); BSL2 (human-derived substances); ABSL2 for the duration (mice administered Salmonella enterica (Typhimurium)). No work involving biological toxins, animal-derived substances, or plants.
    Changes: Updated necropsy procedures and risk mitigation practices.
    Consensus: The committee agreed with the reviewers that the described BSL2 risk mitigation practices are appropriate.

19. **IBCA00000549_AR09**, **Helms, Adam – Renewal**

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

20. **IBCA00000583_AR11**, **Hankenson, Kurt – Amendment**

    Current approval: BSL1 (plasmid vectors and vectorless systems); BSL2 (adenovirus, lentivirus, and plasmid vectors); BSL2 (human-derived substances); BSL1 (animal-derived substances: ruminants and swine); ABSL1 (transgenic mice); ABSL1 (mice administered vectorless systems); ABSL2 for 3 days (mice administered adenovirus vectors); 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).
    Consensus: The committee agreed with the reviewers that the described work is appropriate for BSL1 containment.

21. *This application was tabled***.**

22. **IBCA00000756_AR12**, **Wigginton, Krista – Amendment**

    Current approval: BSL1 (vectorless systems); BSL2 (plasmid and influenza viral vectors vectors); BSL1 (RG1 viruses); BSL2 (RG2 viruses and bacteria); BSL2 (human- and animal-derived substances from non-human primates). No work involving biological toxins, animals, or plants.
    Changes: Added new gene elements in vectorless systems (BSL1) and work with P. syringae (BSL2) and removed work with RG2 bacteria.
    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 re-review by one scientific reviewer and one EHS biosafety reviewer.

23. IBCA00000816_AR03, **Dawid, Suzy – Amendment**

Current approval: BSL1 (plasmid vectors); BSL2 (plasmid vectors in RG2 host and vectorless systems); BSL2 (Streptococcus pneumoniae); BSL2 (human-derived substances); ABSL2 for the duration (mice administered Streptococcus pneumoniae or rDNA modified Streptococcus pneumoniae). No work involving biological toxins, animal-derived substances, or plants.
Changes: Added work with Streptococcus anginosus (BSL2) with administration to mice in both recombinant and non-recombinant form (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.

24. IBCA00000843_AR03, **Parent, Carole – Amendment**

Current approval: BSL1 (plasmid vectors); BSL2 (MSCV vectors); BSL2 (Pertussis toxin, Cholera toxin, LPS, Phalloidin); BSL2 (human-derived substances). No work involving infectious agents, animal-derived substances, animals or plants.
Changes: Added work with AAV vectors (BSL1).
Consensus: The committee agreed with the reviewers that the described work is appropriate for BSL1 containment.

25. IBCA00000886_AR04, **Brooks Herzog, Susan – Amendment**

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

26. IBCA00000926_AR05, **Carruthers, Vernon – Amendment**

Current approval: BSL1 (plasmid, cosmid, and baculovirus vectors); BSL2 (lentivirus and MSCV vectors; plasmid vectors in RG2 host); BSL1 (RG1 parasites); BSL2 (Toxoplasma gondii); BSL2 (human-derived substances); ABSL2 for the duration (mice administered Toxoplasma gondii or rDNA modified RG2 cells). No work involving biological toxins, animal-derived substances, or plants.
Changes: Added work with AAV vectors (BSL1).
Consensus: The committee agreed with the reviewers that the described work is appropriate for BSL1 containment.

27. IBCA00000972_AR08, **Burgess, Christian – Amendment**

Current approval: BSL1 (AAV vectors); BSL2 (rabies virus vectors); BSL1 (cholera toxin subunit B); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered cholera toxin subunit B, rabies virus vectors, AAV vectors, or rDNA modified human-derived substances). No work involving infectious agents, animal-derived substances, or plants.
Changes: Added work with canine adenovirus vectors (BSL1) with administration to mice (ABSL1) and removed work with human-derived substances.

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.

28. **IBCA00001009_AR06**, **Hammer, Gary – Amendment**

    Current approval: BSL1 (plasmid vectors); BSL2 (lentivirus vectors); BSL2 (human-derived substances); 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, animal-derived substances, or plants.
    Changes: Added new gene elements in plasmid vectors (BSL1 and BSL2) and work with AAV vectors (BSL1 and BSL2) with administration 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.

29. **IBCA00001332_AR04**, **Khoriaty, Rami – Amendment**

    Current approval: BSL1 (plasmid, AAV, and MSCV vectors); BSL2 (lentivirus vectors and AAV vectors with growth control genes); BSL2 (LPS); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered LPS, plasmid vectors, AAV vectors, rDNA modified animal cells, or lentivirus vectors); ABSL2 for 3 days (mice administered lentivirus vectors); ABSL2 for the duration (mice administered human-derived substances or rDNA modified human-derived substances). No work involving infectious agents, animal-derived substances, or plants.
    Changes: Added additional transgenic mice (ABSL1).
    Consensus: The committee agreed with the reviewers that the proposed animal housing containment level is considered appropriate.

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

31. **IBCA00001395_AR04**, **McConnell, Daniel - Central Ligand Assay Satellite Services Laboratory (CLASS) – 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.

32. **IBCA00001401_AR03**, **Lalancette, Claudia - BRCF Epigenomics Core – Renewal**

    Current approval: BSL1 (vectorless systems); BSL2 (human-derived substances). No work involving 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 BSL1 and BSL2 containment and that BSL2 risk mitigation practices are likewise appropriate.

33. IBCA00002105_AR01, Zaman, Luis – Renewal

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

34. IBCA00002130_AR02, Ma, Peter – Amendment

Current approval: BSL1 (plasmid vectors and vectorless systems); BSL2 (human-derived substances); ABSL1 (mice administered plasmid vectors or vectorless systems; rabbits administered vectorless systems). No work involving infectious agents, biological toxins, animal-derived substances, or plants.
Changes: Added administration of plasmid vectors to rats (ABSL1).
Consensus: The committee agreed with the reviewers that the proposed animal housing containment level is considered appropriate.

35. IBCA00002144_AR01, Spriggs, Chelsey – Renewal

Current approval: BSL1 (plasmid vectors and vectorless systems); BSL2 (animal parvoviruses); BSL2 (human- and animal-derived substances from non-human primates). No work involving biological toxins, animals or plants.
Changes: Added new gene elements in plasmid vectors (BSL1), Merkel cell polyomavirus vectors (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.

36. IBCA00002200_AR04, Lee, Tzumin – Renewal

Current approval: BSL1 (plasmid vectors and vectorless systems); BSL2 (lentivirus vectors); ABSL1 (transgenic fruit flies, mice, and zebrafish); ABSL1 (mice administered lentivirus or plasmid vectors; fruit flies administered plasmid vectors; zebrafish administered vectorless systems 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.

37. IBCA00002206_AR01, Savier, Elise – Renewal

Current approval: BSL1 (canine adenovirus and AAV vectors); BSL2 (rabies viral vectors); ABSL1 (transgenic mice); ABSL1 (mice or tree shrews administered CAV, AAV, or rabies viral 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.

38. **IBCA00002307_AR06Cornett, Ashley - EPIC 7T Small Animal MRI Core – Amendment**

Current approval: BSL2 (human-derived substances); BSL2 (animal-derived substances: sheep); BSL1 (animal-derived substances: swine). No work involving rDNA, infectious agents, biological toxins, animals or plants.
Changes: Added MRI scanning of additional human-derived tissues (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.

39. **IBCA00002351_AR02**, **Hoang, Thanh – Amendment**

Current approval: BSL1 (plasmid and AAV vectors); BSL2 (lentivirus vectors and AAV vectors with growth control genes); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL2 for 3 days (mice administered AAV vectors). No work involving infectious agents, biological toxins, animal-derived substances, or plants.
Changes: Changed administration of AAV vectors from ABSL2 for 3 days to ABSL1.
Consensus: The committee agreed with the reviewers that the proposed animal housing containment level is considered appropriate.

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

41. **IBCA00002500_AR05**, **Kozik, Ariangela – Amendment**

Current approval: BSL2 (plasmid vectors and vectorless systems); BSL1 (RG1 bacteria); BSL2 (RG2 bacteria); BSL2 (LPS); BSL2 (human-derived substances). No work involving animal-derived substances, animals or plants.
Changes: 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.

42. **IBCA00002812_AR01**, **Fung, Herman – Amendment**

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 additional plasmid vector host (BSL1).
Consensus: The committee agreed with the reviewers that the described work is appropriate for BSL1 containment.

Motion: Tom Lanigan motioned to approve the (39) 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: Crystal O'Donnell seconded the motion.
Vote: All in favor.

6. BSL1 Applications

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

43. IBCA00000177_AR04, Wierzbicki, Andrzej – Renewal

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

44. IBCA00001399_AR04, Beard, Daniel – Renewal

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

45. *This application was tabled*.

Motion: Tom Lanigan motioned to approve the **(2)** IBC applications listed above at the containment levels agreed upon.
Second: John Thomas seconded the motion.
Vote: All in favor.

7. Tabled Applications

The following applications were tabled:

21. IBCA00000650_AR03, Brenner, Chad – Amendment

Current approval: BSL1 (plasmid vectors and vectorless systems); BSL2 (lentivirus and MoLV vectors); BSL2 (human-derived substances); ABSL1 (transgenic mice); 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 animal-derived substances from non-human primates (BSL2).
Consensus: Tabled. PI still needs to return the application with requested revisions.

45. IBCA00002142_AR01, Clack, Herek – Renewal

Current approval: BSL1 (bacteriophage). No work involving rDNA, biological toxins, human- or animal-derived substances, animals or plants.

Changes: Added work with additional bacteriophage strains (BSL1) and work with P. syringae (BSL2).
Consensus: Tabled.
Discussion: The committee discussed the application involving research with Pseudomonas syringae and bacteriophages. Concerns were raised over the application's clarity, consistency, and safety classification. The application underwent multiple revisions through the review process. There was uncertainty over the biosafety level designation for P. syringae. The inclusion of bacteriophages in the infectious agents section was questioned as these viruses do not affect humans or animals. Committee members agreed that the application is not ready for approval and should be tabled until clearer information is provided regarding who is performing the work and where, biosafety levels, and experimental plans, particularly any involving aerosols.

8. Discussion Items

1. Human Gene Transfer – Andrew Tai presenting

Jacqueline Madison – HUM00273326
Title: A Phase 1 Study of NKX019, a CD19 Chimeric Antigen Receptor Natural Killer (CAR NK) Cell Therapy, in Subjects with Autoimmune Disease
Sponsor: Nkarta, Inc.

Andrew Tai described the study and his review findings for the committee. This is a phase 1, open-label, dose finding and expansion study of an allogeneic CD19 CAR-NK cell therapy product in adults with systemic lupus erythematosus (SLE) and active lupus nephritis (LN) or in adults with primary membranous nephropathy (pMN). Participants in this trial must have had inadequate response or intolerance to treatment. Unlike CAR-T cell therapies, CAR-NK cells do not expand significantly in vivo. This may result in lower rates of certain adverse events (e.g., cytokine release syndrome and immune effector cell-associated neurotoxicity syndrome) and NK cells do not cause graft-versus-host disease. The vector is being used to transduce cells ex vivo and is not being given to study participants directly. Dr. Tai noted the U-M IBC previously reviewed and approved another phase I clinical trial with the same agent earlier this year. Dr. Tai said he recommends approval of this trial at BSL2.

Motion: Matt Chapman moved to approve the human gene transfer application at BSL2 containment.
Second: Joyce Lai seconded the motion.
Vote: All in favor.

2. Human Gene Transfer – Andrew Tai presenting

Scott Schuetze – HUM00272973
Title: 2025.054: Expanded Access Protocol for Product which does not conform to the TECELRA® (afamitresgene autoleucel, suspension for intravenous infusion) Commercial Release Specification (ADP-0044-999)
Sponsor: Adaptimmune LLC

Andrew Tai described the study and his review findings for the committee, including adverse events observed in similar clinical trials, peptide cross-reactivity, and persistence

of the study agent. He noted that this is an expanded access protocol for patients prescribed this FDA-approved autologous T cell therapy where the manufactured product does not meet the commercial release specification and remanufacturing is not feasible or clinically appropriate. This product is indicated for treatment of adult patients with unresectable or metastatic synovial sarcoma who have received prior systemic therapy, certain specific HLA haplotypes, and whose tumor expresses the MAGE-A4 antigen. Dr. Tai said he recommends approval of this trial at BSL2.

Motion: Matt Chapman moved to approve the human gene transfer application at BSL2 containment.
Second: Crystal O'Donnell seconded the motion.
Vote: All in favor.

9. Matters Arising

Jackie Shields noted the email sent by the IBC this week to principal investigators within the U-M IBC community alerting them to the June 18 notice issued by NIH regarding termination of funding for dangerous gain-of-function research. It is not expected that any research at U-M would fit that definition, though a link to the DURC-PEPP Self Assessment was included as a resource for researchers. Any work identified through the assessment will be reviewed by the Institutional Review Entity and the IBC and ORSP staff would work with the PI to notify NIH if that is needed.

The meeting was adjourned at 2:24 pm.