

U-M Institutional Biosafety Committee
Draft Minutes
Approved at the November 21, 2025, IBC Meeting

Meeting Information:

Date: Friday, October 17, 2025

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

Location: Via conference call (Zoom)

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

Voting Members Absent: Janet Follo, Andrew Tai, Christiane Wobus (Chair)

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

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

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

The meeting was called to order at: 1:16 p.m.

The meeting was adjourned at: 1:53 p.m.

Agenda Items:

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

Jackie Shields said the IBC team is putting together a brief survey which will be sent out to members in the coming weeks. The survey will ask for feedback on current processes and for ideas about changes to consider when the replacement of eResearch is implemented.

Ms. Shields reminded members of the NIH Biosafety Modernization Initiative and the option of providing comments to NIH by email at SciencePolicy@od.nih.gov.

2. Consideration of minutes from the previous meeting

The committee reviewed the minutes from the September 19, 2025, meeting. There were no changes recommended.

Motion: Stephen Rapundalo moved to approve the minutes.

Second: Chris Fenno seconded the motion.

Vote: All in favor.

3. Biosafety Officer Report – Jessica Bunn (in place of Janet Follo)

Jessica Bunn introduced Sheya Jones who has been hired into the position of Biosafety Manager in EHS. This position became available when Janet Follo accepted the position of EHS Associate Director earlier this year. Ms. Jones previously worked at U-M on the EHS Biosafety team from 2012 to 2021, and everyone at the meeting welcomed her back.

Nicolene Boyle described an incident that happened in late September and is being reported to NIH Office of Science Policy. A researcher was performing tumor monitoring of a mouse that had been administered B16F10 melanoma cells. During the tumor examination the mouse bit the researcher who was wearing a single pair of gloves, and the skin was broken from the bite. The researcher followed proper procedure, washing the bite area with soap and water and flushing the wound for 15 minutes. They contacted OHS the next day; no treatment or vaccination was recommended.

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. Alex Rickard indicated a conflict with application IBCA0000021_AR05 for Dr. VanEpps.

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.

2. IBCA0000021_AR05

VanEpps, J – Amendment

Current approval: BSL1 (plasmid vectors); BSL1 (Bacillus subtilis); BSL2 (RG2 bacteria); BSL2 (human- and animal-derived substances from swine); ABSL2 for the duration (pigs, rabbits, and rats administered RG2 bacteria). No work involving biological toxins 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.

Motion: Matt Chapman 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: Huiira Kopera seconded the motion.

Vote: All in favor, with Alex Rickard recused.

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

1. IBCA0000011_AR16

Wobus, Christiane – Amendment

Current approval: BSL1 (vectorless systems, plasmid, and baculoviral vectors); BSL2 (lentiviral vectors); BSL2 (RG2 viruses and bacteria); BSL2 (LPS); BSL2 (human- and animal-derived substances from non-human primates); ABSL1 (transgenic mice); ABSL2 for the duration (mice administered human-derived substances or RG2 infectious agents). No work involving 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.

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

3. IBCA00000028_AR16**Nunez, Gabriel – Amendment**

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); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered LPS 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: Added work with Monophosphoryl Lipid A (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.

4. IBCA00000054_AR12**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. IBCA00000057_AR12**Kahlenberg, J Michelle - Amendment**

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

Changes: Added new gene elements in lentiviral 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.

6. IBCA00000073_AR21**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- and animal-derived substances from swine and ruminants (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.

7. IBCA00000081_AR10**Nemzek, Jean – Amendment**

Current approval: BSL1 (E. coli K12); BSL2 (pathogenic E. coli, Staphylococcus aureus); BSL2 (LPS); BSL2 (human- and animal-derived substances from swine); ABSL1 (transgenic mice); ABSL1 (mice

administered LPS); ABSL2 for the duration (mice administered pathogenic E. coli; pigs administered Staphylococcus aureus). No work involving rDNA or plants.

Changes: Added work with Moloney murine leukemia virus (BSL1).

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

8. IBCA00000096_AR11

Knight, Jason – Amendment

Current approval: BSL1 (AAV vectors); BSL2 (RG2 bacteria); BSL2 (LPS); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered LPS or AAV vectors); ABSL2 for the duration (mice administered human-derived substances or Klebsiella pneumoniae). No work involving 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. This application was favorably reviewed contingent upon minor edits.

9. IBCA00000132_AR05

Kelts, Jessica – Amendment

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

Changes: Added work with recombinant 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. This application was favorably reviewed contingent upon minor edits.

10. IBCA00000157_AR05

Laouar, Yasmina – Amendment

Current approval: BSL1 (AAV vectors and vectorless systems); BSL2 (MSCV vectors); BSL2 (RG2 bacteria, Cytomegalovirus, and Leishmania major); BSL2 (Pertussis toxin and LPS); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered Pertussis toxin, LPS, rDNA modified animal cells, or AAV vectors); ABSL2 for 3 days (mice administered retrovirus vectors); ABSL2 for the duration (mice administered human-derived substances, RG2 bacteria, Cytomegalovirus, or Leishmania major). No work involving animal-derived substances or plants.

Changes: Added work with heat-killed mycobacterium tuberculosis (BSL1) with administration to mice (ABSL1). They also updated work with AAV vectors with growth control genes to 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. This application was favorably reviewed contingent upon favorable review by one reviewer.

11. IBCA00000282_AR06

Carty, Shannon – Renewal

Current approval: BSL1 (plasmid vectors, MSCV vectors, and vectorless systems); BSL2 (lentiviral vectors and plasmid vectors in RG2 host); BSL2 (Influenza H1N1 virus, Listeria monocytogenes, and Lymphocytic choriomeningitis virus); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered rDNA modified animal cells or vectorless systems); ABSL2 for the duration (mice administered rDNA modified RG2 bacteria, Influenza H1N1 virus, or Lymphocytic choriomeningitis virus). No work involving biological toxins, animal-derived substances, or plants.

Changes: Added administration of non-recombinant *Listeria monocytogenes* to mice (ABSL2 for the duration) and removed work with Influenza H1N1 virus. No longer administering vectorless systems to animals. Changed vectorless systems 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. This application was favorably reviewed contingent upon minor edits.

12. IBCA00000308_AR10

Lin, Jiandie – Renewal

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

Changes: Added new gene elements in plasmid vectors (BSL1), adenovirus vectors (BSL2), and AAV vectors (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. The proposed animal housing containment level is considered appropriate. This application was favorably reviewed contingent upon minor edits.

13. IBCA00000393_AR09

Weiss, Stephen – Renewal

Current approval: BSL1 (plasmid vectors and vectorless systems); BSL2 (adenoviral, lentiviral, and MoLV vectors); BSL2 (LPS and Cholera toxin); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered LPS or rDNA-modified animal cells); ABSL2 for the duration (mice administered 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. IBCA00000406_AR05

Franceschi, Renny – Renewal

Current approval: BSL1 (plasmid vectors and vectorless systems); BSL2 (lentivirus and adenovirus 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 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. This application was favorably reviewed contingent upon minor edits and favorable re-review by one reviewer.

15. IBCA00000410_AR04

Putnam, Andrew – Renewal

Current approval: BSL1 (plasmid vectors); BSL2 (lentiviral vectors); BSL2 (human-derived substances); 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.

16. IBCA00000416_AR05

Telesnitsky, Alice – Renewal

Current approval: BSL1 (plasmid vectors and vectorless systems); BSL2 (plasmid vectors with viral genes, MoLV, lentiviral and XMRV viral vectors); BSL1 (Moloney murine leukemia virus); BSL2 (RG2 viruses); BSL2 (human- and animal-derived substances from non-human primates); BSL1 (animal-derived substances from chickens). No work involving biological toxins, 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. This application was favorably reviewed contingent upon minor edits.

17. IBCA00000461_AR03

Rae, James – Renewal

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: 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. This application was favorably reviewed contingent upon favorable re-review by one reviewer.

18. IBCA00000514_AR06

Leopold, Judith – Renewal

Current approval: BSL1 (plasmid vectors and vectorless systems); BSL2 (lentivirus vectors); BSL2 (human-derived substances); 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: 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.

19. IBCA00000540_AR04

Higgins, Peter – Renewal

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: Added new gene elements in vectorless systems (BSL1), work with animal-derived substances from swine (BSL1), and 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.

20. IBCA00000659_AR05**Martens, Eric – Amendment**

Current approval: BSL1 (plasmid vectors); BSL2 (plasmid vectors in RG2 host); BSL1 (RG1 bacteria and viruses); BSL2 (RG2 bacteria); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL2 for the duration (mice administered human-derived substances, RG2 infectious agents, or rDNA-modified bacteria). No work involving biological toxins, animal-derived substances, or plants.

Changes: Added work with additional RG1 bacteria (BSL1) and RG2 bacteria (BSL2) with administration to mice (ABSL2 for the duration), 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.

21. IBCA00000695_AR04**Koutmou, Kristin – Amendment**

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

Changes: Added work with Epstein-Barr virus cell lines (BSL2) and 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. This application was favorably reviewed contingent upon minor edits.

22. IBCA00000932_AR09**Raphael, Yehoash – Amendment**

Current approval: BSL1 (AAV vectors); BSL2 (vectorless systems, adenoviral, and AAV vectors with growth control genes); BSL2 (Diphtheria toxin); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice or guinea pigs administered rDNA-modified animal cells, vectorless systems, plasmid vectors, AAV vectors, or adenoviral vectors; mice administered Diphtheria toxin); ABSL2 for 3 days (guinea pigs administered lentiviral vectors); ABSL2 for the duration (mice or guinea pigs administered human-derived substances). No work involving infectious agents, animal-derived substances, or plants.

Changes: Added new gene elements in AAV vectors (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. This application was favorably reviewed contingent upon favorable re-review by two reviewers.

23. IBCA00000934_AR03**Simmons, Lyle – Amendment**

Current approval: BSL1 (vectorless systems, plasmid, and phage 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 new gene elements in plasmid vectors and vectorless systems (BSL1), and additional plasmid vector hosts (BSL1). Removed work with RG2 plasmid vectors.

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

24. IBCA00001405_AR05**Tripathi, Ashootosh - Natural Products Discovery Core – Renewal**

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

Changes: Added additional strains of *Streptococcus pneumoniae* (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. This application was favorably reviewed contingent upon favorable re-review by one reviewer.

25. IBCA00001450_AR02

Beehner, Jacinta – Renewal

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

26. IBCA00001512_AR02

Alumkal, Joshi – Renewal

Current approval: BSL1 (plasmid vectors and vectorless systems); BSL2 (lentivirus vectors); BSL2 (human-derived substances); 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, animal-derived substances, or plants.

Changes: Added work with 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. This application was favorably reviewed contingent upon favorable re-review by one reviewer.

27. IBCA00001528_AR05

Sexton, Jonathan – Renewal

Current approval: BSL1 (plasmid vectors); BSL2 (lentiviral vectors); BSL2 (RG2 viruses); BSL2 (human-derived substances); ABSL2 for the duration (mice administered RG2 viruses). 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. This application was favorably reviewed contingent upon favorable review by one reviewer and re-review by one reviewer.

28. IBCA00001569_AR02

Alteri, Christopher – 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: 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. This application was favorably reviewed contingent upon minor edits.

29. IBCA00002090_AR01

Sick, Volker – Renewal

Current approval: BSL1 (RG1 fungi); BSL2 (RG2 fungi and 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 BSL1 and BSL2 containment and that BSL2 risk mitigation practices are likewise appropriate.

30. IBCA00002174_AR02

Giles, Erin – 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. This application was favorably reviewed contingent upon favorable re-review by one reviewer.

31. IBCA00002175_AR01

Labaki, Wassim – 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. IBCA00002215_AR03

Coronel, Maria – Amendment

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

Changes: Added work with LPS (BSL2) with administration to mice (ABSL1), administration of rDNA modified human-derived substances to rodents (ABSL2 for the duration), rDNA modified animal cells to mice (ABSL1), and administration of non-recombinant human-derived substances to rats (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. This application was favorably reviewed contingent upon minor edits.

33. IBCA00002270_AR03

Morales-Hernandez, Antonio – Renewal

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

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

34. IBCA00002276_AR03**Janssen, Erin – Renewal**

Current approval: BSL1 (plasmid vectors); BSL2 (LPS); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered LPS). No work involving infectious agents, 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. This application was favorably reviewed contingent upon minor edits.

35. IBCA00002285_AR03**Kresty, Laura – Renewal**

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

36. IBCA00002361_AR05**Wang, Yifan – Renewal**

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

Changes: Added new gene elements in plasmid vectors (BSL1) and work with animal-derived substances from chickens (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.

37. IBCA00002500_AR06**Kozik, Ariangela – Amendment**

Current approval: BSL1 (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 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. This application was favorably reviewed contingent upon minor edits.

38. IBCA00002902_AR01**Lifshitz, Jonny – Amendment**

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

Changes: Updated risk mitigation practices (BSL2).

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

39. IBCA00003009**Garbincius, Joanne - Initial Application**

Proposed: BSL1 (plasmid vectors, AAV vectors, and vectorless systems); BSL2 (adenovirus and lentivirus 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.

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. This application was favorably reviewed contingent upon favorable re-review by one reviewer.

40. IBCA00003073**Madison, Annelise - 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. This application was favorably reviewed contingent upon minor edits and favorable re-review by one reviewer.

Motion: Matt Chapman 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: Huiru Kopera seconded the motion.

Vote: All in favor.

BSL1 Applications

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

41. IBCA00001100_AR04**Leventhal, Daniel – Amendment**

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

Changes: Added work with canine adenovirus vectors (BSL1) with administration to rats (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. This application was favorably reviewed contingent upon minor edits.

Motion: Matt Chapman motioned to approve the (1) IBC applications listed above at the containment levels agreed upon.

Second: Alex Rickard seconded the motion.

Vote: All in favor

6. Discussion Items**Item 1. Human Gene Transfer Application – Krishna Rao**

HUM00274458**PI: Sami Barmada****Title:** A Phase 1b Open-Label, Multicenter, Dose Escalation Study to Assess the Safety, Tolerability and Pharmacodynamic Effects of a Single Dose of PBFT02 Delivered into The Cisterna Magna (ICM) Of Adult Participants with Frontotemporal Dementia (FTD) And Mutations in The Granulin Precursor (GRN) Or Chromosome 9 Open Reading Frame 72 (C9orf72) Genes**Sponsor:** Passage Bio

Krishna Rao described the study for the committee. He and Andrew Tai have reviewed the current submission and express support for approval of this trial. Dr. Tai noted in his review that Frontotemporal Dementia (FTD) is a syndrome under the broader category of frontotemporal lobar degeneration. A pathologic hallmark of FTD is the abnormal accumulation of misfolded proteins (tau or ubiquitinated TDP-43) in neurons and glial cells. FTD is a progressive and uniformly fatal disease, with death typically occurring with 10 years of clinical presentation. There are no disease-modifying therapies for FTD; treatment consists of supportive care and reducing disease-associated symptomatology. This is a phase 1b, open-level, dose-escalation trial of a single dose of an AAV1 vector encoding the granulin precursor (GRN) injected into the CSF via the cisterna magna in order to increase CNS expression of GRN. GRN is hypothesized to be protective against FTD by promoting lysosomal activity and clearance of misfolded TDP-43.

Preclinical data in rodents and NHPs have shown that ICM injection of the vector increases CNS expression of GRN and attenuates disease in mouse models of FTD. In mice, vector was distributed in the CNS, liver, and kidneys. Vector shedding was observed in urine and feces 5 d after administration, reaching undetectable levels within 60 days. Of note, at higher doses vector administration to adult NHPs was associated with degeneration of dorsal root ganglia and trigeminal ganglia sensory neuron cell bodies with secondary degeneration of their associated axons in the majority of animals at day 90; these findings were not associated with observed abnormalities on physical or neurological exam. Anti-human GRN antibodies developed in NHPs, but this is not expected to develop in haploinsufficient humans.

This agent has been administered elsewhere to 7 participants with FTD-GRN. Two had SAEs of asymptomatic venous sinus thrombosis and one had asymptomatic but significant transaminase elevation (hepatotoxicity). The protocol was modified to reduce the dose by 50% and to increase immunosuppression with corticosteroids. GRN levels were found to be elevated above the healthy adult mean in the CSF for the duration of follow-up (up to 18 months). Risks include hepatotoxicity, dorsal root ganglion toxicity (also observed in other AAV gene therapy trials), venous sinus thrombosis (currently unclear whether this is related to the study agent or the injection procedure), cardiomyopathy, insertional mutagenesis. Participants will be monitored closely for nerve toxicity (neurologic examinations and nerve conduction studies). GRN overexpression has been observed in a variety of tumors; although it is not a known oncogene, there is a theoretical risk of cancer progression.

Motion: Stephen Rapundalo moved to approve the human gene transfer application at BSL1 containment.

Second: Pam Bennett-Baker seconded the motion.

Vote: All in favor.

Item 2. Human Gene Transfer Application – Krishna Rao**HUM00277979****PI: Leslie Fecher****Title:** UMCC 2025.XXX: open-label, randomized, Ph. 3 trial to evaluate efficacy, safety, and tolerability

of IMA203 versus investigator's choice of treatment in pts with previously treated, unresectable or metastatic cutaneous melanoma (ACTengine® IMA203-301)

Sponsor: Immatics US, Inc.

Krishna Rao described the study for the committee. He and Andrew Tai have reviewed the current submission and express support for approval of this trial. Dr. Tai noted in his review that this is a trial to evaluate IMA203 versus investigator's choice of treatment in HLA-A*02:01-positive patients with previously treated unresectable or metastatic cutaneous melanoma. The therapeutic approach is to introduce an engineered TCR that recognizes a specific HLA-A*02:01 restricted tumor antigen called PRAME-004. This TCR is highly specific for this tumor antigen peptide with no anticipated off-target peptides expressed in humans. The replication-defective, third-generation, self-inactivating lentiviral vector backbone has been used by other clinical trials. The vector is used for ex vivo transduction of activated autologous T cells. No vector is administered directly to participants. As of August 2024, 70 patients have been treated with IMA203 as monotherapy in a dose-finding study. Adverse events have included CRS and ICANS. Other potential risks include on-target toxicity in normal tissues containing melanoma cells, unexpected off-target toxicity, HLH/MAS, T-cell malignancy, cytopenias from lymphodepletion, and toxicities from IL-2 given post-IMA203 administration.

Motion: Krishna Rao moved to approve the human gene transfer application at BSL2 containment.

Second: Stephen Rapundalo seconded the motion.

Vote: All in favor.

7. Matters Arising

There were no matters arising.