**U-M Institutional Biosafety Committee**
**Draft Minutes**
Approved at the September 19, 2025, IBC Meeting

## Meeting Information:

**Date:** Friday, August 15, 2025
**Time:** 1:15-2:30 p.m.
**Location:** Via conference call (Zoom)

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

**Voting Members Absent:** Wanlu Du, Jackie Shields, Andrew Tai, Christiane Wobus (Chair)

**Alternate Members Present:** Jessica Bunn (alt. for Follo), Dalis Collins (alt. for Lester), Crystal O'Donnell (alt. for Follo), Krishna Rao (alt. for Tai)

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

**Guests Present:** Nicoleen Boyle, Kathy Ignatoski, Andrew Kennedy, Carolyn Kuenz, Sarah Lawson, Jonah Lee, Eric Robertson, Diane Wilson

**The meeting was called to order at:** 1:15 p.m.
**The meeting was adjourned order at:** 1:45 p.m.

## Agenda Items:

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

Dr. Lanigan stated there were no updates.

### 2. Consideration of minutes from the previous meeting

The committee reviewed the minutes from the July 18, 2025, meeting. There were no changes recommended.

> **Motion:** Stephen Rapundalo moved to approve the minutes.
> **Second:** Matt Chapman seconded the motion.
> **Vote:** All in favor.

### 3. Biosafety Officer Report – Janet Follo

Ms. Follo stated there were no updates.

### 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. Daniel Lawerence indicated a conflict with application IBCA0000011_AR11 for Dr. Ginsburg.
2. Chris Fenno indicated a conflict with application IBCA0000046_AR15 for Dr. Bottino.

3. Alex Rickard indicated a conflict with application IBCA0001018_AR07 for Dr. Dick.

**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.*

**12. IBCA00000457_AR06**
**Ginsburg, David – Renewal**
**Current approval:** BSL1 (plasmid and phage vectors); BSL2 (lentivirus vectors); BSL2 (Shiga toxin and LPS); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered plasmid vectors, phage vectors, Shiga toxin, or LPS); ABSL2 for the duration (mice administered human-derived substances). No work involving infectious agents, animal-derived substances, or plants.
**Changes:** Added work with additional plasmid vector (BSL1).
**Consensus:** The committee agreed with the reviewers that the described work is appropriate for BSL1 and BSL2 containment and that BSL2 risk mitigation practices are likewise appropriate. The proposed animal housing containment level is considered appropriate.

**19. IBCA00001018_AR09**
**Bottino, Marco – Amendment**
**Current approval:** BSL2 (RG2 bacteria); BSL2 (LPS); BSL2 (human-derived substances); ABSL1 (immunodeficient mice); ABSL1 (rats administered LPS); ABSL2 for the duration (dogs and mice administered human-derived substances; rats administered RG2 bacteria). No work involving animal-derived substances or plants.
**Changes:** Added work with animal-derived substances from swine (BSL2).
**Consensus:** The committee agreed with the reviewers that the described work is appropriate for BSL2 containment and that BSL2 risk mitigation practices are likewise appropriate. Approval is contingent upon minor edits being made to the application.

**36. IBCA00002911**
**Dick, Gregory - Initial Application**
**Proposed:** BSL2 (Microcystis aeruginosa); BSL2 (Microcystin). No work involving rDNA, human- or 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. Approval is contingent upon minor edits being made to the application and favorable re-review from one reviewer.

> **Motion:** Huira Kopera moved to approve the (3) applications listed above, at the containment levels agreed upon, contingent on satisfactory completion of a laboratory inspection in the past year and upon any other contingencies noted above.
> **Second:** Stephen Rapundalo seconded the motion.
> **Vote:** All in favor, with Dan Lawrence, Chris Fenno, and Alex Rickard recused.

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

**1. IBCA00000028_AR15**
**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 Helicobacter hepaticus (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.

**2. IBCA00000145_AR04**
**Wang, Shaomeng – Amendment**
**Current approval:** BSL1 (plasmid vectors); BSL2 (lentiviral vectors); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (rodents administered rDNA-modified animal cells); ABSL2 for the duration (rodents administered rDNA-modified human-derived substances). No work involving infectious agents, biological toxins, animal-derived substances, or plants.
**Changes:** Added new gene elements in lentiviral vectors (BSL2) and administration of 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. Approval is contingent upon minor edits being made to the application, favorable review from one reviewer, and favorable re-review from one reviewer.

**3. IBCA00000168_AR03**
**Devlin, Maureen – 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.

**4. IBCA00000225_AR04**
**Pipe, Steven – Renewal**
**Current approval:** BSL1 (plasmid vectors); BSL2 (human- and animal-derived substances from non-human primates); ABSL1 (transgenic mice); ABSL1 (mice administered plasmid 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.

**5. IBCA00000281_AR06**
**Ragsdale, Stephen – Renewal**
**Current approval:** BSL1 (plasmid vectors); BSL1 (RG1 bacteria); BSL2 (RG2 bacteria); BSL2 (human-derived substances). No work involving biological toxins, animal-derived substances, animals or plants.
**Changes:** Added new gene elements in plasmid vectors (BSL1), additional RG1 bacteria (BSL1), and additional RG2 bacteria (BSL2).
**Discussion:** Alex Rickard raised a question about Dr. Ragsdale's description of a "swagelok pressure relief valve with a needle inserted into a rubber stopper" to prevent gas pressure from exceeding glass container limits. Matt Chapman confirmed this is safety practice used when growing bacteria in glass containers due to the potential explosion risk. Nicoleen Boyle stated she was comfortable with the

application's description and would continue working with the Ragsdale lab to ensure their risk mitigation practices are appropriate.
**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.

**6. IBCA00000320_AR06**
**Duncan, Robert – Renewal**
**Current approval:** BSL1 (plasmid and AAV vectors); BSL2 (adenovirus vectors, lentivirus vectors, and AAV vectors with growth control genes); BSL2 (herpes simplex viruses); BSL2 (human-derived substances); BSL2 (animal-derived substances: non-human primates and fowl); ABSL1 (transgenic mice); ABSL1 (guinea pigs administered rDNA modified animal cells); ABSL2 for the duration (guinea pigs administered human-derived substances or rDNA modified human-derived substances). No work involving biological toxins or plants.
**Changes:** Updated risk mitigation practices. No longer working with animal-derived substances from fowl or infectious agents.
**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. IBCA00000322_AR07**
**Duan, Bo – Renewal**
**Current approval:** BSL1 (AAV vectors); BSL2 (lentivirus and rabies vectors); BSL1 (Cholera toxin subunit B); BSL2 (Diphtheria toxin, LPS, and tetrodotoxin); ABSL1 (transgenic mice); ABSL1 (mice administered AAV vectors, rabies vectors, retrovirus vectors, Cholera toxin subunit B, LPS, or Diphtheria toxin). No work involving infectious agents, human- or animal-derived substances, or plants.
**Changes:** No major changes.
**Consensus:** The committee agreed with the reviewers that the described work is appropriate for BSL1 and BSL2 containment and that BSL2 risk mitigation practices are likewise appropriate. The proposed animal housing containment level is considered appropriate. Approval is contingent upon minor edits being made to the application.

**8. IBCA00000364_AR08**
**Merajver, Sofia – Renewal**
**Current approval:** BSL1 (plasmid vectors); BSL2 (adenoviral and lentiviral vectors); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL2 for 3 days (mice administered rDNA-modified animal cells or adenoviral vectors); ABSL2 for the duration (mice or rats 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) with administration to mice (ABSL1), and work with transgenic rats (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.

**9. IBCA00000412_AR07**
**Pal, Dinesh – Renewal**
**Current approval:** BSL1 (AAV vectors); BSL1 (Saporin); BSL2 (Tetrodotoxin); ABSL1 (transgenic rodents); ABSL1 (rats administered AAV vectors, Saporin, or Tetrodotoxin and mice administered AAV

vectors or Tetrodotoxin). No work involving infectious agents, human- or animal-derived substances, or plants.
**Changes:** No major changes.
**Consensus:** The committee agreed with the reviewers that the described work is appropriate for BSL1 and BSL2 containment and that BSL2 risk mitigation practices are likewise appropriate. The proposed animal housing containment level is considered appropriate. Approval is contingent upon minor edits being made to the application and favorable review from one reviewer.

**10. IBCA00000423_AR04**
**Luker, Gary – Renewal**
**Current approval:** BSL1 (plasmid vectors and vectorless systems); BSL2 (adenovirus, MoLV, lentivirus, and MSCV vectors); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered rDNA modified animal cells or rDNA modified human cells that have been documented by a vendor or validated testing to be pathogen free); 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 immunocompromised mice (ABSL2).
**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.

**11. IBCA00000434_AR05**
**Wilcox, Ryan – Renewal**
**Current approval:** BSL1 (plasmid vectors); BSL2 (adenoviral and lentiviral vectors); BSL2 (Diphtheria toxin); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered rDNA-modified animal cells or Diphtheria toxin); 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.

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

**13. IBCA00000494_AR04**
**Morgan, Meredith – Renewal**
**Current approval:** BSL1 (plasmid vectors and vectorless systems); BSL2 (MoLV and lentiviral 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 lentiviral 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. The proposed animal housing containment level is considered appropriate.

**14. IBCA00000553_AR11**
**Wiley, John – Amendment**
**Current approval:** BSL1 (vectorless systems, plasmid and AAV vectors); BSL2 (lentiviral, rabies, pseudorabies, and AAV vectors with growth control genes); BSL1 (RG1 bacteria); BSL2 (LPS and Lipotaechoic Acid); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (rodents administered LPS, RG1 bacteria, vectorless systems, Lipotaechoic Acid, or AAV vectors); ABSL2 for 3 days (mice administered lentiviral, rabies or pseudorabies viral vectors); ABSL2 for the duration (rodents administered rDNA-modified RG1 bacteria or human-derived substances). No work involving animal-derived substances or plants.
**Changes:** Added work with transgenic rats (ABSL1).
**Consensus:** The committee agreed with the reviewers that the proposed animal housing containment level is considered appropriate.

**15. 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 removed work with RG2 bacteria.
**Changes for August agenda:** Updated work with P. syringae (BSL1).
**Consensus:** The committee agreed with the reviewers that the described work is appropriate for BSL1 containment. Approval is contingent upon favorable re-review by one reviewer.

**16. IBCA00000886_AR05**
**Brooks Herzog, Susan – Amendment**
**Current approval:** BSL2 (human-derived substances); ABSL1 (transgenic mice). No work involving rDNA, infectious agents, biological toxins, animal-derived substances, or plants.
**Changes:** Added work with animal-derived substances from ruminants and swine (BSL1).
**Consensus:** The committee agreed with the reviewers that the described work is appropriate for BSL1 containment.

**17. IBCA00000971_AR05**
**Waldhaus, Joerg – Amendment**
**Current approval:** BSL2 (Diphtheria toxin); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered Diphtheria toxin). No work involving rDNA, infectious agents, animal-derived substances, or plants.
**Changes:** Added work with 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.

**18. IBCA00000993_AR06**
**Hammoud, Saher – Amendment**
**Current approval:** BSL1 (plasmid vectors and vectorless systems); BSL2 (lentivirus vectors); BSL2 (Diphtheria toxin); BSL2 (human-derived substances); BSL2 (animal-derived substances: ruminants); ABSL1 (transgenic mice); ABSL1 (mice administered Diphtheria toxin or rDNA modified animal cells; cows administered vectorless systems); ABSL2 for 3 days (mice administered lentivirus vectors); ABSL2 for the duration (mice administered human-derived substances). No work involving infectious agents or plants.

**Changes:** Updated research goals for work with human-derived substances (BSL2).
**Consensus:** The committee agreed with the reviewers that the described BSL2 risk mitigation practices are appropriate.

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

**20. IBCA00001341_AR02**
**Hanson, Phyllis – 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 non-K-12 plasmid vectors (BSL1), new gene elements in plasmid vectors (BSL1), and work with Toxoplasma gondii (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.

**21. IBCA00001379_AR02**
**Koutmos, Markos – Renewal**
**Current approval:** BSL1 (plasmid and baculovirus vectors; vectorless systems); BSL2 (lentivirus vectors). No work involving infectious agents, biological toxins, human- or animal-derived substances, animals or plants.
**Changes:** Added new gene elements in plasmid and baculovirus vectors (BSL1), an additional plasmid vector (BSL1), and work with 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.

**22. IBCA00001399_AR05**
**Beard, Daniel – Amendment**
**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:** 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. Approval is contingent upon favorable re-review by one reviewer.

**23. IBCA00001417_AR03**
**Stringer, Kathleen - NMR Metabolomics Core – Renewal**
**Current approval:** BSL2 (LPS); BSL2 (human- and animal-derived substances from non-human primates and swine). No work involving rDNA, infectious agents, 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. Approval is contingent upon minor edits being made to the application.

**24. IBCA00001889_AR01**
**Salami, Simpa – Renewal**
**Current approval:** BSL1 (vectorless systems); 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.

**25. IBCA00002023_AR03**
**Min, Jouha – Amendment**
**Current approval:** BSL1 (plasmid vectors); BSL2 (lentiviral vectors); BSL2 (RG2 bacteria); BSL2 (human-derived substances); ABSL2 for the duration (rabbits and rodents administered RG2 bacteria). No work involving biological toxins, animal-derived substances, or plants.
**Changes:** Added administration of MRSA to mice (ABSL2 for the duration).
**Consensus:** The committee agreed with the reviewers that the proposed animal housing containment level is considered appropriate.

**26. IBCA00002138_AR01**
**Wider, Joseph – Renewal**
**Current approval:** BSL2 (animal-derived substances from swine). 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.

**27. 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 and P. syringae (BSL1).
**Consensus:** The committee agreed with the reviewers that the described work is appropriate for BSL1 containment.

**28. IBCA00002168_AR02**
**Carpenter, Eileen – 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.

**29. IBCA00002191_AR03**
**Decker, Joseph – Renewal**
**Current approval:** BSL1 (plasmid, AAV, and MSCV vectors; vectorless systems); BSL2 (lentivirus vectors); BSL2 (LPS); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered rDNA modified animal cells, vectorless systems, or plasmid vectors); ABSL2 for the duration (mice administered rDNA modified human-derived substances). No work involving infectious agents, or animal-derived substances, or plants.
**Changes:** Added work with additional human-derived substances (BSL2), administration of non-primary human cell lines 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.

**30. IBCA00002205_AR02**
**Decker, Ann – Renewal**
**Current approval:** 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 rDNA, infectious agents, biological toxins, animal-derived substances, or plants.
**Changes:** No major changes.
**Consensus:** The committee agreed with the reviewers that the described work is appropriate for BSL2 containment and that BSL2 risk mitigation practices are likewise appropriate. The proposed animal housing containment level is considered appropriate.

**31. IBCA00002215_AR02**
**Coronel, Maria – Renewal**
**Current approval:** 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 plasmid and cosmid vectors (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. Approval is contingent upon favorable review by one reviewer and favorable re-review by one reviewer.

**32. IBCA00002285_AR02**
**Kresty, Laura – Amendment**
**Current approval:** BSL1 (vectorless systems); BSL2 (lentivirus vectors); BSL2 (Cholera toxin); BSL2 (human-derived substances). No work involving infectious agents, animal-derived substances, animals or plants.
**Changes:** Added work with 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.

**33. IBCA00002421_AR03**
**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 new gene elements in vectorless systems (BSL1) and additional transgenic mice (ABSL1).
**Consensus:** The committee agreed with the reviewers that the described work is appropriate for BSL1 containment. The proposed animal housing containment level is considered appropriate.

**34. IBCA00002527_AR02**
**Srinivasan, Sharan – Amendment**
**Current approval:** BSL1 (AAV, plasmid vectors and vectorless systems); BSL2 (human-derived substances); ABSL1 (transgenic mice); ABSL1 (mice administered plasmid vectors and vectorless systems). No work involving infectious agents, biological toxins, animal-derived substances, or plants.

**Changes:** Added new gene elements in AAV vectors (BSL1).
**Consensus:** The committee agreed with the reviewers that the described work is appropriate for BSL1 containment.

**35. IBCA00002886_AR01**
**Huycke, Tyler – Amendment**
**Current approval:** BSL1 (plasmid, AAV, and RCAS vectors); BSL2 (lentivirus vectors); BSL2 (human-derived substances); BSL1 (animal-derived substances: fowl); ABSL1 (transgenic mice). No work involving infectious agents, biological toxins, or plants.
**Changes:** Added work with Diphtheria 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 minor edits being made to the application and favorable re-review from one reviewer.

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

**37. IBCA00003031**
**Skiba, Meredith - Initial Application**
**Proposed:** BSL1 (plasmid, baculoviral vectors, and vectorless systems); BSL2 (Pertussis toxin); BSL2 (human-derived substances). No work involving infectious agents, animal-derived substances, animals or plants.
**Consensus:** The committee agreed with the reviewers that the described work is appropriate for BSL1 and BSL2 containment and that BSL2 risk mitigation practices are likewise appropriate.

**38. IBCA00003032**
**Deininger, Michael - Initial Application**
**Proposed:** BSL1 (plasmid vectors and vectorless systems); BSL2 (adenovirus vectors, MoLV vectors, lentivirus vectors, and AAV vectors with growth control genes); 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.
**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.

**39. IBCA00003041**
**Barnett, Katherine - Initial Application**
**Proposed:** BSL1 (plasmid vectors and vectorless systems); BSL2 (lentivirus vectors); BSL2 (Influenza A, Puerto Rico Virus and SARS-CoV-2); BSL2 (Lipotaechoic Acid and LPS); BSL2 (human-derived substances); BSL2 (animal-derived substances: non-human primates); ABSL1 (transgenic mice); ABSL2 for the duration (mice administered RG2 viruses). No work involving 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.

> **Motion:** Stephen Rapundalo motioned to approve the (36) 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:** Alex Rickard seconded the motion.

**Vote:** All in favor.

BSL1 Applications

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

**40. IBCA00000175_AR03**
**Schwendeman, Steven – Renewal**
**Current approval:** ABSL1 (transgenic rodents). 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.

**41. IBCA00000280_AR04**
**Cartee, Greg – Renewal**
**Current approval:** BSL1 (plasmid and AAV vectors; vectorless systems); ABSL1 (transgenic rats); ABSL1 (rats administered AAV vectors or vectorless systems). No work involving infectious agents, biological toxins, human- or animal-derived substances, or plants.
**Changes:** Added work with an additional AAV vector (BSL1) and new gene elements in vectorless systems (BSL1).
**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.

**42. IBCA00002490_AR01**
**Barroso Pereira, Filipa – Amendment**
**Current approval:** BSL1 (plasmid and YAC vectors; vectorless systems). No work involving infectious agents, biological toxins, human- or animal-derived substances, animals or plants.
**Changes:** Added work with additional 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.

**43. IBCA00002992_AR01**
**McLaughlin, Maeve – Amendment**
**Current approval:** BSL1 (plasmid vectors). No work involving infectious agents, biological toxins, human- or animal-derived substances, 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 containment.

**44. IBCA00003033**
**Hays, Michelle - Initial Application**
**Proposed:** BSL1 (plasmid and YAC vectors; other non-viral vectors; vectorless systems). No work involving infectious agents, biological toxins, human- or animal-derived substances, animals or plants.
**Consensus:** The committee agreed with the reviewers that the described work is appropriate for BSL1 containment.

**Motion:** Akira Ono motioned to approve the (5) IBC applications listed above at the containment levels agreed upon.

**Second:** Stephen Rapundalo seconded the motion.
**Vote:** All in favor

## 6. Discussion Items

### Item 1. Human Gene Transfer Application – Krishna Rao

**HUM00271508**
**PI: Marcus Geer**
**Title:** 2025.055: A Phase 1b/2 Study of GC012F (AZD0120), a Chimeric Antigen Receptor T-cell (CAR T) Therapy Targeting CD19 and B-cell Maturation Antigen (BCMA) in Subjects with Relapsed/Refractory Multiple Myeloma (RRMM)
**Sponsor:** AstraZeneca Pharmaceuticals

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 phase 1b/2 open label, nonrandomized clinical trial of a CAR-T cell therapy targeting CD19 and BCMA in adults with relapsed/refractory multiple myeloma (RRMM) with evidence of progressive disease despite at least 3 prior lines of therapy. MM is a malignant plasma cell disorder and accounts for 17% of hematological malignancies. Although the development of multiple therapeutic agents has resulted in improved overall survival, MM is currently not considered curable with a 5-year survival rate of 54%. The study agent is a CAR-T cell product expressing dual anti-CD19 and anti-BCMA CAR. BCMA is expressed on normal and malignant plasma cells. While CAR-T cell therapy targeting BCMA alone has efficacy in treatment of MM, the addition of CD19 targeting is anticipated to target MM progenitor cells and reduce BCMA-negative escape. Preclinical data have demonstrated CAR binding to target proteins, *in vitro* and *in vivo* cytotoxicity, and cytokine/antigen-dependent proliferation. Possible adverse events include cytopenias, hypogammaglobulinemia, immune cell toxicities, T-cell malignancies, infusion-related reactions or hypersensitivity reactions. To date, AEs in clinical trials of this agent for RRMM have included mostly CRS and cytopenias; no immune cell neurologic AEs have been reported to date. High objective response rates have been observed.

**Motion:** Stephen Rapundalo moved to approve the human gene transfer application at BSL2 containment.
**Second:** Janet Follo seconded the motion.
**Vote:** All in favor.

## 7. Matters Arising

There were no matters arising.