INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Thursday, August 21, 2025**
Time:	11:00 am Mountain Time
Location:	Zoom Teleconference
Institution:	Intermountain Health - Salt Lake City, Salt Lake City, UT
Principal Investigator:	**Pankhuri Gupta MD**
Protocol:	Allogene Therapeutics, **ALLO-329-101**
NCT Number:	NCT07085104
Meeting Type:	Initial Review of Protocol and Site
Title:	A Phase 1 Study Evaluating The Safety And Preliminary Efficacy of ALLO-329, A Dual Anti-CD19 / Anti-CD70 Allogeneic CAR T Cell Product In Autoimmune Disease (Resolution)

1. Call to order:

The Meeting was called to order at 11:00 am Mountain Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Five voting members were present, including two local members unaffiliated with the institution. Also present were three Institutional Representatives and IBC Services staff. The Chair declared that a quorum was present.

4. Conflict of Interest:

The Chair requested that voting members report any conflict of interest regarding this meeting. No conflicts of interest were reported.

5. Public posting:

An Institutional Representative confirmed that notice of the meeting was publicly posted. No public comments were received by the site or the Committee regarding this review.

6. Review of proposed research:

The Chair provided an overview of the protocol.

The Chair provided an overview of the biosafety risk assessment for the protocol.

7. Determination for biosafety level and period of IBC oversight:

The Committee determined that **BSL-2 containment facilities and practices** are required for ALLO-329, since it consists of primary human cells modified using CRISPR-Cas and a recombinant adeno-associated viral vector.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of ALLO-329 locally**, provided that other biosafety criteria for study closure are also met.

8. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 5 NO: 0 ABSTAIN: 0

9. Review of Principal Investigator qualifications:

Points of Discussion:

1. An Institutional Representative confirmed that the Principal Investigator has experience in the clinical trial field and is in the process of updating her curriculum vitae.
2. The Committee recommended that the Institution submit an updated CV for the Principal Investigator that includes relevant clinical trial experience.

The Committee reviewed and accepted the qualifications of the Principal Investigator.

10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Points of Discussion:

1. The Committee recommended that a small sharps container be placed within the Biological Safety Cabinet (BSC) during study agent preparation for immediate disposal of used needles and vials, per best biosafety practices.
2. The Committee recommended that the last sentence in Biosafety SOP Section 3.3 be revised to read as, "A sharps container is located within the BSC for immediate disposable of used study agent vials and needles."
3. An Institutional Representative confirmed that some dosing areas in the [redacted] location have multiple chairs that can be separated with a curtain, but noted that it is highly likely that only the subject being dosed will be in the room.
4. An Institutional Representative confirmed that the study agent-specific Biohazard Sign will most likely be placed on the door to the [redacted] location where the subject will be dosed.
5. An Institutional Representative confirmed that the black chair in the [redacted] location is designed to be easily cleaned and decontaminated with an effective disinfectant.
6. An Institutional Representative confirmed that the biohazard labeling outside of the biohazardous waste rooms is per the Institution's standard. The Committee found this acceptable.
7. An Institutional Representative confirmed that oxygen levels are not monitored in the room where the study agent will be stored. While this is not a specific biosafety-related issue, the Committee wished to note this in the minutes.
8. The Committee discussed the type of containment that will be used to transport prepared syringes from the [redacted] to the dosing room. An Institutional Representative noted that current policy dictates that hazards be placed in a sealed baggie and that a tote is also available for transportation. The Committee noted that the standard internal transport containment that is used may differ between a chemical hazard and a biohazard.
9. The Committee recommended that prepared syringes placed in a biohazard-labeled baggie be placed within a durable, leak-proof container such as a Ziploc- or Tupperware-style container. Alternatively, if the tote that the [redacted] has available is durable and leak-proof, the Committee noted that this may also be acceptable.
10. The Committee recommended that the Institution submit a photo of the internal transport container that will be used to transport the prepared syringe from the [redacted] to the dosing room. The Committee also recommended that this internal transport container be labeled on the outside with a biohazard symbol, per best biosafety practices.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representatives.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 5 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 11:28 am Mountain Time.

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: **Thursday, August 21, 2025**
Time: 11:00 am Mountain Time
Location: Zoom Teleconference
Institution: Intermountain Health - Salt Lake City, Salt Lake City, UT
Principal Investigator: **Brad Hunter MD, MPH**
Protocol: Eureka Therapeutics, Inc., **ETUS20GPC3AR124**
NCT Number: NCT04864054
Meeting Type: Initial Review of Protocol and Site
Title: An open-label, dose escalation, multi-center phase I/II clinical trial of ECT204 T-Cell therapy in adults with Advanced Hepatocellular Carcinoma (HCC).

1. Call to order:

The Meeting was called to order at 11:29 am Mountain Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Five voting members were present, including two local members unaffiliated with the institution. Also present were three Institutional Representatives and IBC Services staff. The Chair declared that a quorum was present.

4. Conflict of Interest:

The Chair requested that voting members report any conflict of interest regarding this meeting. No conflicts of interest were reported.

5. Public posting:

An Institutional Representative confirmed that notice of the meeting was publicly posted. No public comments were received by the site or the Committee regarding this review.

6. Review of proposed research:

The Chair provided an overview of the protocol.

The Chair provided an overview of the biosafety risk assessment for the protocol.

7. Determination for biosafety level and period of IBC oversight:

The Committee determined that **BSL-2 containment facilities and practices** are required for ECT204, since it consists of autologous T cells modified by a lentiviral vector

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of ECT204 locally**, provided all other criteria for study closure are met.

8. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 5 NO: 0 ABSTAIN: 0

9. Review of Principal Investigator qualifications:

The Committee reviewed and accepted the qualifications of the Principal Investigator.

10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Points of Discussion:

1. The Committee recommended that second to last sentence in Biosafety SOP Section 3.3 be revised to read as, " The appropriate volume…transfer device, which is removed and the syringe is capped prior to discarding it and the needle-free transfer device into a sharps or biohazardous waste container."
2. An Institutional Representative confirmed that the study agent infusion bag will be thawed in a waterbath on a separate cart in the dosing room. The Committee recommended that the Institution submit a photo of the cart/waterbath setup to IBC Services.
3. An Institutional Representative confirmed that the biohazard labeling outside of the biohazardous waste rooms is per the Institution's standard. The Committee found this acceptable.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representatives.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 5 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 11:41 am Mountain Time.

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Thursday, September 25, 2025**
Time:	2:00 pm Mountain Time
Location:	Zoom Teleconference
Institution:	Intermountain Health - Salt Lake City, Salt Lake City, UT
Principal Investigator:	**Brad Hunter, MD, MPH**
Protocol:	Regeneron Pharmaceuticals, **27T51-01**
NCT Number:	NCT06469281
Meeting Type:	Initial Review of Protocol and Site
Title:	A Phase 1a/1b Study of 27T51, an anti-MUC16 CAR T cell drug product administered alone or in combination for participants with recurrent or refractory epithelial ovarian, primary peritoneal, or fallopian tube cancer

1. Call to order:

The Meeting was called to order at 2:07 pm Mountain Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Five voting members were present, including two local members unaffiliated with the institution. Also present were three Institutional Representative and IBC Services staff. The Chair declared that a quorum was present.

4. Conflict of Interest:

The Chair requested that voting members report any conflict of interest regarding this meeting. No conflicts of interest were reported.

5. Public posting:

The Institutional Representative confirmed that notice of the meeting was publicly posted. No public comments were received by the site or the Committee regarding this review.

6. Review of proposed research:

The Chair provided an overview of the protocol.

The Chair provided an overview of the biosafety risk assessment for the protocol.

7. Determination for biosafety level and period of IBC oversight:

The Committee determined that **BSL-2 containment facilities and practices** are required for 27T51 since it consists of autologous T cells modified by a replication-defective and self-inactivating lentiviral vector.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of 27T51 locally**, provided all other biosafety criteria for study closure are also met.

8. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 5 NO: 0 ABSTAIN: 0

9. Review of Principal Investigator qualifications:

The Committee reviewed and accepted the qualifications of the Principal Investigator.

10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Points of Discussion:

1. The Committee recommended that prefilled eyewash bottles be made available in rooms without eyewash stations. The Committee recommended that the institution follow up with IBC Services on this so that site documents can be revised accordingly.
2. The Committee recommended that the zip code on the site map for the [redacted] be replaced with the accurate one.
3. An Institutional Representative confirmed that per sponsor approval, a Biological Safety Cabinet (BSC) will not be used for study agent preparation.
4. An Institutional Representative confirmed that all biohazardous waste containers are labeled with biohazard symbols.
5. An Institutional Representative confirmed that the study agent will be transported between locations in a vehicle by trained staff at the [redacted]. The Committee recommended that an external transport section be added to Section 3.4 of the Biosafety SOP to reflect this.
6. An Institutional Representative stated that biohazardous waste containers are not available in the dosing rooms on the [redacted] The Committee recommended that a biohazardous waste container be made available in these rooms during subject dosing and that new photos, showing the biohazardous waste containers, be provided to IBC Services.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representatives.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 5 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 2:25 pm Mountain Time.

[5] Alternate Member

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Friday, October 24, 2025**
Time:	11:00 am Mountain Time
Location:	Zoom Teleconference
Institution:	Intermountain Health - Salt Lake City, Salt Lake City, UT
Principal Investigator:	**Brad Hunter, MD, MPH**
Protocol:	Janssen Research & Development, LLC, **90014496LYM1001**
NCT Number:	NCT05421663
Meeting Type:	Initial Review of Protocol and Site
Title:	A Phase 1b/2 Multicenter, Open-label, Study of JNJ-90014496, an Autologous CD19/CD20 Bispecific CAR-T Cell Therapy in Adult Participants with B-cell Non-Hodgkin Lymphoma

1. Call to order:

The Meeting was called to order at 11:19 am Mountain Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Five voting members were present, including two local members unaffiliated with the institution. Also present were four Institutional Representatives and IBC Services staff. The Chair declared that a quorum was present.

4. Conflict of Interest:

The Chair requested that voting members report any conflict of interest regarding this meeting. No conflicts of interest were reported.

5. Public posting:

An Institutional Representative confirmed that notice of the meeting was publicly posted. No public comments were received by the site or the Committee regarding this review.

6. Review of proposed research:

The Chair provided an overview of the protocol.

The Chair provided an overview of the biosafety risk assessment for the protocol.

7. Determination for biosafety level and period of IBC oversight:

The Committee determined that **BSL-2 containment facilities and practices** are required for JNJ-90014496, since it consists of autologous T cells modified by a recombinant, replication-defective lentiviral vector.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of JNJ-90014496 locally**, provided all other criteria for study closure are met.

8. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 5 NO: 0 ABSTAIN: 0

9. Review of Principal Investigator qualifications:

The Committee reviewed and accepted the qualifications of the Principal Investigator.

10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Points of Discussion:

1. An Institutional Representative confirmed that prefilled disposable eyewash bottles are not available in the preparation/dosing rooms but there are plumbed eyewash stations located on the same floor in the event of an eye exposure. The Committee found this to be acceptable.
2. The Committee discussed the use of 10% bleach solution, noting that bleach is considered corrosive and recommended that staff wear eye protection when preparing the solution. The Committee also recommended that 10% bleach solution only be used for clean-up of spills in the water bath.
3. The Committee recommended that PDI Super Sani-Cloth wipes be used for clean-up of large spills instead of bleach and that Section 5.1.4b of the Biosafety SOP be revised to indicate this.
4. The Committee recommended that applicable site photos be updated to indicate this protocol.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representatives.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 5 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 11:29 am Mountain Time.

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Friday, October 24, 2025**
Time:	11:00 am Mountain Time
Location:	Zoom Teleconference
Institution:	Intermountain Health - Salt Lake City, Salt Lake City, UT
Principal Investigator:	**Brad Hunter, MD, MPH**
Protocol:	Lyell Immunopharma, Inc., **LYL314-102**
NCT Number:	NCT05421663
Meeting Type:	Initial Review of Protocol and Site
Title:	A phase 3 randomized controlled trial of Rondecabtagene Autoleucel, a dual-targeting CD19/CD20 CAR T-Cell product candidate, versus investigator's choice of CD19 CAR T-Cell therapy in patients with relapsed or refractory large B-Cell Lymphoma in the second-line setting (PiNACLE-H2H)

1. Call to order:

The Meeting was called to order at 11:00 am Mountain Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Five voting members were present, including two local members unaffiliated with the institution. Also present were four Institutional Representatives and IBC Services staff. The Chair declared that a quorum was present.

4. Conflict of Interest:

The Chair requested that voting members report any conflict of interest regarding this meeting. No conflicts of interest were reported.

5. Public posting:

An Institutional Representative confirmed that notice of the meeting was publicly posted. No public comments were received by the site or the Committee regarding this review.

6. Review of proposed research:

The Chair provided an overview of the protocol.

The Chair provided an overview of the biosafety risk assessment for the protocol.

7. Determination for biosafety level and period of IBC oversight:

The Committee determined that **BSL-2 containment facilities and practices** are required for LYL314, since it consists of autologous T cells modified by a recombinant, replication-defective lentiviral vector.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of LYL314 locally**, provided all other criteria for study closure are met.

8. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 5 NO: 0 ABSTAIN: 0

9. Review of Principal Investigator qualifications:

The Committee reviewed and accepted the qualifications of the Principal Investigator.

10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Points of Discussion:

1. An Institutional Representative confirmed that prefilled disposable eyewash bottles are not available in the preparation/dosing rooms but there is a plumbed eyewash station located on the same floor that staff could reach within 10 seconds in the event of an eye exposure. The Committee found this to be acceptable.
2. The Committee recommended that the [redacted] site map be updated to indicate the location of the plumbed eyewash station.
3. The Committee discussed the use of 10% bleach solution, noting that bleach is considered corrosive and recommended that staff wear eye protection when preparing the solution. The Committee also recommended that 10% bleach solution only be used for clean-up of spills in the water bath.
4. The Committee recommended that PDI Super Sani-Cloth wipes be used for clean-up of large spills instead of bleach and that Section 5.1.4b of the Biosafety SOP be revised to indicate this.
5. The Committee recommended that Biosafety SOP Section 3.5 be revised to replace “luer port” with “luer lock port.”

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representatives.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 5 NO: 0 ABSTAIN:

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 11:19 am Mountain Time.

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Monday, October 27, 2025**
Time:	2:00 pm Mountain Time
Location:	Zoom Teleconference
Institution:	Intermountain Health - St. George Regional Hospital, St. George, UT
Principal Investigator:	**Terence Rhodes, MD, PhD**
Protocol:	Replimune, Inc., **RP1-104**
NCT Number:	NCT06264180
Meeting Type:	Continuing Review of Protocol and Site
Title:	A Randomized, Controlled, Multicenter, Phase 3 Clinical Study Comparing Vusolimogene Oderparepvec in Combination with Nivolumab Versus Treatment of Physician's Choice in Patients with Advanced Melanoma That Has Progressed on an Anti-PD-1 and an Anti-CTLA-4 Containing Treatment Regimen (IGNYTE-3)

1. Call to order:

The Meeting was called to order at 2:03 pm Mountain Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Four voting members were present, including one local member unaffiliated with the institution. Also present were three Institutional Representatives and IBC Services staff. The Chair declared that a quorum was present.

4. Conflict of Interest:

The Chair requested that voting members report any conflict of interest regarding this meeting. No conflicts of interest were reported.

5. Public posting:

An Institutional Representative confirmed that notice of the meeting was publicly posted. No public comments were received by the site or the Committee regarding this review.

6. Approval of previous meeting minutes:

Minutes Approved - YES: 3 NO: 0 ABSTAIN: 1

7. Review of proposed research:

The Chair provided an overview of the protocol and status of the study.

The Chair provided an overview of changes since the last review.

8. Determination for biosafety level and period of IBC oversight:

The Committee previously determined that **BSL-2 containment facilities and practices** are required for RP1 since it is based on a recombinant herpes simplex virus-1 administered in a clinical setting. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **6 months after the last subject's last dose of RP1 locally,** provided that other biosafety criteria for study closure are also met. The Committee reaffirmed this determination.

9. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 3 NO: 0 ABSTAIN: 1

10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Points of Discussion:

1. An Institutional Representative confirmed that the study agent is stored in the freezer, which is labelled with a biohazard symbol.
2. The Committee recommended that all biohazardous waste containers be lidded when not in use.
3. The Committee recommended that an updated photo of the sticker showing when the Biological Safety Cabinet (BSC) was last certified be provided to IBC Services.
4. The Committee recommended that plumbed eyewashes be flushed at least monthly and that the institution follow up with IBC Services on the current frequency.
5. The Committee recommended that pre-filled disposable eyewash bottles be made available in the preparation and dosing rooms during study agent handling activities.
6. An Institutional Representative confirmed that the dosing room has a hard-sided, non-sharps biohazardous waste container and that only Personal Protective Equipment (PPE) is disposed of in the biohazardous waste bag as shown in site photos. The Committee recommended that the institution provide IBC Services with a photo of the hard-sided biohazardous waste container in the dosing room.
7. The Committee discussed the study agent transport container, noting that the bag provides secondary containment, but the container itself is not lidded. The Committee recommended that the institution obtain a hard-sided container with a closeable lid for study agent transport. The Committee also recommended that the container be labelled with a biohazard symbol and that absorbent material be placed inside the plastic bag during transport and that a new photo, showing the labelled container with a lid, be provided to IBC Services.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representatives.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 3 NO: 0 ABSTAIN: 1

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 2:22 pm Mountain Time.

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Friday, December 5, 2025**
Time:	11:00 am Mountain Time
Location:	Zoom Teleconference
Institution:	Intermountain Health - Salt Lake City, Salt Lake City, UT
Principal Investigator:	**Daanish Hoda, MD**
Protocol:	Kite Pharma, Inc., **KT-US-728-0204**
NCT Number:	NA
Meeting Type:	Initial Review of Protocol and Site
Title:	A phase 1 open-label, multiregional, multicenter, basket study evaluating the safety and efficacy of KITE-363, an autologous anti-CD19/CD20 CAR T-cell therapy in participants with relapsed/refractory autoimmune neurologic diseases.

1. Call to order:

The Meeting was called to order at 11:00 am Mountain Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Five voting members were present, including two local members unaffiliated with the institution. Also present were two Institutional Representatives and IBC Services staff. The Chair declared that a quorum was present.

4. Conflict of Interest:

The Chair requested that voting members report any conflict of interest regarding this meeting. No conflicts of interest were reported.

5. Public posting:

An Institutional Representative confirmed that notice of the meeting was publicly posted. No public comments were received by the site or the Committee regarding this review.

6. Review of proposed research:

The Chair provided an overview of the protocol.

The Chair provided an overview of the biosafety risk assessment for the protocol.

7. Determination for biosafety level and period of IBC oversight:

The Committee determined that **BSL-2 containment facilities and practices** are required for KITE-363 since it consists of primary human cells modified using a recombinant lentiviral vector.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of KITE-363 locally**, provided that all other criteria for study closure are met.

8. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 5 NO: 0 ABSTAIN: 0

9. Review of Principal Investigator qualifications:

The Committee reviewed and accepted the qualifications of the Principal Investigator.

10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Points of Discussion:

1. The Committee recommended that "IV push infusion" be removed from Biosafety SOP Section 3.5 as this is not applicable.
2. The Committee recommended that the brackets referring to wipes and paper towels be removed from Biosafety SOP Section 5.1.6.
3. The Committee recommended that the reference to the eyewash in the [redacted] be removed from the [redacted] site map as this is not accurate.
4. An Institutional Representative confirmed that prefilled disposable eyewash bottles are not available in the preparation/dosing rooms but there are plumbed eyewash stations located on that same floor. The Committee found this to be acceptable.
5. An Institutional Representative confirmed that PDI Super Sani-Cloth wipes are used for spill clean-up. The Committee recommended that the Site Inspection Checklist (#19) be revised to reflect this.
6. The Committee discussed how disposable PPE is handled after use. An Institutional Representative stated that PPE that is not visibly soiled is disposed of as garbage and is not placed into a biohazardous waste container. The Committee recommended that all disposable PPE be discarded into biohazardous waste containers per best biosafety practices.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representatives.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 5 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 11:16 am Mountain Time.