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.

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Wednesday, March 11, 2026**
Time:	2:00 pm Mountain Time
Location:	Zoom Teleconference
Institution:	Intermountain Health - Salt Lake City, Salt Lake City, UT
Principal Investigator:	**Catherine J. Bakewell, MD, RhMSUS**
Protocol:	Novartis Research and Development, **CYTB323I12201**
NCT Number:	NCT06868290
Meeting Type:	Continuing Review of Protocol and Site
Title:	A Phase 2, randomized, open-label, controlled study to evaluate the efficacy and safety of rapcabtagene autoleucel versus comparator in participants with severe active Granulomatosis with Polyangiitis (GPA) or Microscopic Polyangiitis (MPA)

1. Call to order:

The Meeting was called to order at 2:19 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 one 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. Approval of previous meeting minutes:

Minutes Approved - YES: 5 NO: 0 ABSTAIN: 0

7. Review of proposed research:

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

The Chair noted 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 YTB323, since it consists of autologous T cells modified by a lentiviral vector. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **3 months after the last subject's last dose of YTB323 locally**, provided all other criteria for study closure are 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: 5 NO: 0 ABSTAIN: 0

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 Institutional Representative stated that a Biological Safety Cabinet (BSC) is not used for study agent preparation for this protocol.
2. The Institutional Representative stated that the preparation/dosing rooms have wall mounted sharps containers.
3. The Institutional Representative stated that biohazardous waste containers, large enough for PPE disposal, are taken into the preparation/dosing rooms at the time of study agent handling. The Committee recommended that photos of these biohazardous waste containers be provided to IBC Services.
4. The Committee noted that DOT/IATA training for one of the study staff members expires in March 2026. The Committee recommended that training be completed prior to the expiration date and that the new certification be provided to IBC Services once available.

11. Site requirements:

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

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 2:23 pm Mountain Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Version 01-US-CH-IL.01, dated 06-12-2025
Investigator's Brochure, Edition 10, dated 06-27-2025
Novartis T-Charge, Product Handling Manual, Version 2.0, dated 06-25-2025
Safety Summary Statement for Biological Entities, dated 12-10-2020
Research Modification Evaluation, Protocol, Version 01-US-CH-IL.01
Research Modification Evaluation, Investigator's Brochure, Edition 10
Research Modification Evaluation, Novartis T-Charge, Product Handling Manual, Version 2.0
Research Modification Evaluation, Safety Summary Statement for Biological Entities, dated 12-10-2020
Biological Risk Assessment and Summary, updated 07-29-2025
Site Map, ARC, dated 12-19-2025
Site Map, East 8, 8th Floor, dated 06-13-2025
Site Inspection Checklist, expires 09-11-2027, updated 01-23-2026
Photos, dated 01-28-2026
Biohazard Sign, dated 02-16-2025
SOP, Biosafety for YTB323, dated 02-16-2025
Training, Shipping Certification, expires 2026, 2027
CRRF, dated 01-08-2026
Prior Meeting Minutes, Initial, dated 03-11-2025

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Wednesday, March 11, 2026**
Time:	2:00 pm Mountain Time
Location:	Zoom Teleconference
Institution:	Intermountain Health - Salt Lake City, Salt Lake City, UT
Principal Investigator:	**Catherine J. Bakewell, MD, RhMSUS**
Protocol:	Novartis Research and Development, **CYTB323K12201**
NCT Number:	NCT06655896
Meeting Type:	Continuing Review of Protocol and Site
Title:	A Phase II, multi-part, five-year, randomized, open-label, assessor-blinded, active-controlled, multicenter study to evaluate the efficacy and safety of rapcabtagene autoleucel versus rituximab treatment in participants with severe refractory diffuse cutaneous systemic sclerosis

1. Call to order:

The Meeting was called to order at 2:15 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 one 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. Approval of previous meeting minutes:

Minutes Approved - YES: 5 NO: 0 ABSTAIN: 0

7. Review of proposed research:

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

The Chair noted 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 YTB323, since it consists of autologous T cells modified by a lentiviral vector. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **3 months after the last subject's last dose of YTB323 locally**, provided all other criteria for study closure are 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: 5 NO: 0 ABSTAIN: 0

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 Institutional Representative stated that a Biological Safety Cabinet (BSC) is not used for study agent preparation for this protocol. The Committee recommended that the BSC certification be removed from site documents.
2. The Institutional Representative stated that the preparation/dosing rooms have wall mounted sharps containers.
3. The Institutional Representative stated that biohazardous waste containers, large enough for PPE disposal, are taken into the preparation/dosing rooms at the time of study agent handling. The Committee recommended that photos of these 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 Representative.

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 2:18 pm Mountain Time.

15. Post-meeting note: The Committee noted that DOT/IATA training for one of the study staff members expires in March 2026. The Committee recommended that training be completed prior to the expiration date and that the new certification be provided to IBC Services once available.

Documents reviewed:

Agenda
Protocol, Version 03, dated 09-23-2025
Investigator's Brochure, Edition 10, dated 06-27-2025
Novartis T-Charge, Product Handling Manual, Version 2.0, dated 06-25-2025
Safety Summary Statement for Biological Entities, dated 12-10-2020
Research Modification Evaluation, Protocol, Version 03
Research Modification Evaluation, Protocol, Version 02
Research Modification Evaluation, Investigator's Brochure, Edition 10
Research Modification Evaluation, Novartis T-Charge, Product Handling Manual, Version 2.0
Research Modification Evaluation, Safety Summary Statement for Biological Entities, dated 12-10-2020
Biological Risk Assessment and Summary, updated 02-17-2026
Site Map, ARC, dated 12-19-2025
Site Map, East 8, 8th Floor, dated 06-13-2025
Site Inspection Checklist, expires 09-11-2027, updated 01-23-2026
Photos, dated 01-28-2026 (1)
Biohazard Sign, dated 02-16-2025
SOP, Biosafety for YTB323, dated 02-16-2025
Biological Safety Cabinet Certification, expire 01-2026
Training, Shipping Certifications, expire 2026, 2027
CRRF, dated 02-06-2026
Prior Meeting Minutes, Initial, dated 03-11-2025

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Wednesday, March 11, 2026**
Time:	2:00 pm Mountain Time
Location:	Zoom Teleconference
Institution:	Intermountain Health - Salt Lake City, Salt Lake City, UT
Principal Investigator:	**Dany Saad, MD, RhMSUS**
Protocol:	Novartis Research and Development, **CYTB323L12201**
NCT Number:	NCT06665256
Meeting Type:	Continuing Review of Protocol and Site
Title:	A Phase 2, randomized, open-label, controlled study to evaluate the efficacy and safety of rapcabtagene autoleucel versus comparator in participants with severe refractory idiopathic inflammatory myopathies

1. Call to order:

The Meeting was called to order at 2:00 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 one 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. Approval of previous meeting minutes:

Minutes Approved - YES: 5 NO: 0 ABSTAIN: 0

7. Review of proposed research:

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

The Chair noted 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 YTB323, since it consists of autologous T cells modified by a lentiviral vector. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **3 months after the last subject's last dose of YTB323 locally**, provided all other criteria for study closure are 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: 5 NO: 0 ABSTAIN: 0

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 Institutional Representative stated that a Biological Safety Cabinet (BSC) is not used for study agent preparation for this protocol.
2. The Institutional Representative stated that the preparation/dosing rooms have wall mounted sharps containers.
3. The Institutional Representative stated that biohazardous waste containers, large enough for PPE disposal, are taken into the preparation/dosing rooms at the time of study agent handling. The Committee recommended that photos of these 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 Representative.

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 2:14 pm Mountain Time.

15. Post-meeting note: The Committee noted that DOT/IATA training for one of the study staff members expires in March 2026. The Committee recommended that training be completed prior to the expiration date and that the new certification be provided to IBC Services once available.

Documents reviewed:

Agenda
Protocol, Amendment 3, dated 10-07-2025
Investigator's Brochure, Edition 10, dated 06-27-2025
Novartis T-Charge, Product Handling Manual, Version 2.0, dated 06-25-2025
Safety Summary Statement for Biological Entities, dated 12-10-2020
Research Modification Evaluation, Protocol, Amendment 3
Research Modification Evaluation, Protocol, Amendment 2
Research Modification Evaluation, Protocol, Version 01
Research Modification Evaluation, Investigator's Brochure, Edition 10
Research Modification Evaluation, Novartis T-Charge, Product Handling Manual, Version 2.0
Research Modification Evaluation, Safety Summary Statement for Biological Entities, dated 12-10-2020
Biological Risk Assessment and Summary, updated 01-20-2026
Site Map, ARC, dated 12-19-2025
Site Map, East 8, 8th Floor, dated 06-13-2025
Site Inspection Checklist, expires 09-11-2027, updated 01-23-2026
Photos, dated 01-28-2026
Biohazard Sign, dated 02-16-2025
SOP, Biosafety for YTB323, dated 02-16-2025
Training, Shipping Certifications, expire 2026, 2027
CRRF, dated 01-08-2026
Prior Meeting Minutes, Initial, dated 03-11-2025

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Friday, May 22, 2026**
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:	Estrella Immunopharma, Inc., **EBUS22CD19AR100**
NCT Number:	NCT06343311
Meeting Type:	Initial Review of Protocol and Site
Title:	An open-label, dose escalation, multi-center, phase I/II clinical trial of EB103 T-Cell therapy in adults with relapsed/refractory (R/R) B-Cell Non-Hodgkin Lymphoma (NHL)

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 one 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 EB103, since it consists of primary human cells modified using 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 EB103 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:

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 Biosafety SOP Section 3.4.1 be removed, as the study agent is not transported internally.
2. The Institutional Representative could not confirm whether oxygen sensors are installed in the study agent storage room. The Committee recommended that the site confirm this information and follow up with IBC Services.
3. The Institutional Representative confirmed that the study agent is directly transported within a liquid nitrogen dewar from the storage facility to the dosing rooms. The Committee recommended that the transport container visible in the site photos be properly labeled.
4. The Institutional Representative confirmed that containers for non-sharps biohazardous waste disposal are brought inside rooms before the study agent is handled, and are removed from the room after dosing. The Committee recommended that the site submit a photo showing a container within a dosing room, and that site photos be revised with an explanatory note describing this process.
5. The Committee recommended that a biohazard symbol be placed at eye level on doors to rooms where biohazardous waste is stored as a best practice.

11. Site requirements:

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

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 11:18 am Mountain Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Version 5.0, dated 02-24-2026
Investigator's Brochure, Edition 4.0, dated 02-24-2026
Investigational Product Manual, Version 2.0, dated 01-16-2026
Biological Risk Assessment and Summary, dated 05-07-2026
Site Map, East 8, 8th Floor, dated 06-13-2025
Site Map, ARC, dated 04-30-2026
Site Inspection Checklist, expires 09-11-2027, updated 04-30-2026
Photos, dated 04-30-2026
Biohazard Sign, dated 05-11-2026 (1)
SOP, Biosafety for EB103, dated 05-11-2026
Training, Shipping Certifications, expire 2026, 2027
CV, Hunter, B., signed 09-13-2023

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Tuesday, June 30, 2026**
Time:	2:00 pm Mountain Time
Location:	Zoom Teleconference
Institution:	Intermountain Health - Salt Lake City, Salt Lake City, UT
Principal Investigator:	**April Erwin, MD**
Protocol:	TG Therapeutics, Inc., **TG-Azercel-101**
NCT Number:	NCT06680037
Meeting Type:	Initial Review of Protocol and Site
Title:	A Phase 1, Open-label Study to Evaluate the Safety and Clinical Activity of Azercabtagene Zapreleucel in Participants with B-cell Mediated Autoimmune Disorders

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:

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 PBCAR0191 since it consists of primary human cells modified using mRNA and an AAV vector.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of PBCAR0191 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. An Institutional Representative confirmed that the study agent will be prepared in a Biological Safety Cabinet (BSC) in the Inpatient Pharmacy Hazardous Compounding Room. The Committee recommended all applicable site documents be revised to reflect this information.
2. The Committee recommended as a best biosafety practice that a small sharps container be placed within the BSC for immediate disposable of used needles and vials.
3. The Committee recommended that the Preparation Room photograph be updated to include this protocol.
4. An Institutional Representative confirmed that drivers who transport the study agent from the storage location to the institution are appropriately trained and employed by the American Red Cross.

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 2:23 pm Mountain Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Version 4.0, dated 10-18-2025
Investigator's Brochure, Autoimmune Disorders, Version 1.0, dated 01-23-2025
Pharmacy Manual, Version 2.0, dated 04-25-2025
Biological Risk Assessment and Summary, updated 02-10-2026
Site Map, East 8, 8th Floor, dated 06-13-2025
Site Map, ARC, dated 04-30-2026
Site Map, Inpatient Pharmacy LDS Hospital, dated 06-26-2026
Site Inspection Checklist, expires 09-11-2027, updated 05-18-2026
Photos, dated 06-15-2026
Biohazard Sign, dated 05-28-2026
SOP, Biosafety for PBCAR0191, dated 05-28-2026
Biological Safety Cabinet Certification, expires 07-31-2026
Training, Shipping Certifications, expire 2026, 2027
CV, Erwin, A., signed 03-31-2026

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Thursday, July 16, 2026**
Time:	11:00 am Mountain Time
Location:	Zoom Teleconference
Institution:	Intermountain Health - Salt Lake City, Salt Lake City, UT
Principal Investigator:	**Dany Saad, MD, RhMSUS**
Protocol:	Bristol Myers Squibb, **IM065-0002**
NCT Number:	N/A
Meeting Type:	Initial Review of Protocol and Site
Title:	A phase 1, multicenter, open-label study of BMS-986553, CD19 in Vivo Chimeric Antigen Receptor (CAR) T Cells, in participants with refractory autoimmune diseases

1. Call to order:

The Meeting was called to order at 11:01 am 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 two local members unaffiliated with the institution. Also present were one 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-1 containment facilities and practices plus Standard Precautions** are required for BMS-986553 since it consists of lipid nanoparticle (LNP)-encapsulated circRNA administered in a clinical setting.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of BMS-986553 locally**, provided that all 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: 4 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 discussed study agent storage requirements, and noted Sponsor documents indicate it should be stored between -95°C and -65°C, not in liquid nitrogen as suggested in a site photo. The Institutional Representative confirmed that the study agent will be stored in a freezer in the Inpatient Pharmacy, and the Committee recommended that a photo of the freezer be provided to IBC Services.

11. Site requirements:

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

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

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

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Original, dated 03-31-2026
Investigator's Brochure, Version 01, dated 04-02-2026
Pharmacy Manual, Version 1, dated 04-13-2026
Biological Risk Assessment and Summary, dated 06-01-2026
Site Map, East 8, 8th Floor, dated 06-13-2025
Site Map, Inpatient Pharmacy LDS Hospital, dated 07-07-2026
Site Inspection Checklist, expires 09-11-2027, updated 07-07-2026
Photos, dated 07-07-2026
Biohazard Sign, BMS-986553, dated 07-07-2026
SOP, Biosafety for BMS-986553, dated 07-07-2026
Training, Shipping Certification, expires 2026, 2027
CV, Saad, D., signed 04-22-2024

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Monday, August 3, 2026**
Time:	1:00 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:	Continuing 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 1:17 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 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. Approval of previous meeting minutes:

Minutes Approved - YES: 5 NO: 0 ABSTAIN: 0

7. Review of proposed research:

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

The Chair noted 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 27T51 since it consists of autologous T cells modified by a replication-defective and self-inactivating lentiviral vector. The Committee reaffirmed this determination.

The Committee previously 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. 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: 5 NO: 0 ABSTAIN: 0

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 briefly reviewed and confirmed dosing room annotations.
2. The Committee recommended that the Phase 1 Clinic Site Map be revised to include the correct ZIP code (84143).

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 1:27 pm Mountain Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Version 3.0, dated 02-07-2024
Investigator's Brochure, Edition 2, dated 04-28-2026
Cellular Laboratory Receipt, Preparation, and Infusion Manual, Version 6.0, dated 03-11-2026
Research Modification Evaluation, Investigator's Brochure, Edition 2
Research Modification Evaluation, Cellular Laboratory Receipt, Preparation, and Infusion Manual, Version 6.0
Research Modification Evaluation, Cellular Laboratory Receipt, Preparation, and Infusion Manual, Version 5.0
Research Modification Evaluation, Cellular Laboratory Receipt, Preparation, and Infusion Manual, Version 4.0
Biological Risk Assessment and Summary, updated 07-15-2026
Site Map, East 8, 8th Floor, dated 07-16-2026
Site Map, Phase 1 Clinic Floorplan, dated 07-16-2026
Site Map, ARC, dated 04-30-2026
Site Inspection Checklist, expires 09-11-2027, updated 07-16-2026
Photos, dated 07-16-2026
Biohazard Sign, 27T51, dated 09-12-2025
SOP, Biosafety for 27T51, dated 10-29-2025
Training, Shipping Certifications, expire 2026, 2027
CRRF, dated 06-01-2026
Prior Meeting Minutes, Initial, dated 09-25-2025

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Monday, August 3, 2026**
Time:	1:00 pm 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:	Continuing 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 1:00 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 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. Approval of previous meeting minutes:

Minutes Approved - YES: 5 NO: 0 ABSTAIN: 0

7. Review of proposed research:

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

The Chair noted 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 ALLO-329, since it consists of primary human cells modified using CRISPR-Cas and a recombinant adeno-associated viral vector. The Committee reaffirmed this determination.

The Committee previously 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. 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: 5 NO: 0 ABSTAIN: 0

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 discussed the proposal to prepare the study agent on a countertop in the dosing room instead of in a biosafety cabinet in the pharmacy, and found this to be acceptable.
2. The Committee briefly reviewed and confirmed dosing room annotations.
3. The Committee recommended that the study agent be transported in a secondary bag containing absorbent material, within a hard-sided container with a sealable lid, and that a photo of the container be provided to IBC Services.
4. The Committee recommended that the Phase 1 Clinic Site Map be revised to include the correct ZIP code (84143).

11. Site requirements:

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

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 1:16 pm Mountain Time.

15. Post-meeting notes: None.

Documents reviewed:
Agenda
Protocol, Amendment 3, dated 08-13-2025
Investigator's Brochure, Edition 2.1, dated 07-24-2025
Investigational Product Manual, Version 2.0, dated 10-29-2025
Research Modification Evaluation, Protocol, Amendment 3
Research Modification Evaluation, Investigator's Brochure, Edition 2.1
Research Modification Evaluation, Investigational Product Manual, Version 2.0
Research Modification Evaluation, Study agent preparation from BSC to Countertop, dated 07-16-2026
Biological Risk Assessment and Summary, updated 03-03-2026
Site Map, East 8, 8th Floor, dated 07-16-2026
Site Map, Loveland Clinic, 7th Floor, dated 07-16-2026
Site Map, Phase 1 Clinic Floorplan, dated 07-16-2026
Site Inspection Checklist, expires 09-11-2027, updated 07-16-2026
Photos, dated 07-16-2026
Biohazard Sign, dated 07-16-2026
SOP, Biosafety for ALLO-329, dated 07-16-2026
Training, Shipping Certifications, expire 2026, 2027
CRRF, dated 05-07-2026
Prior Meeting Minutes, Initial, dated 08-21-2025

INTERMOUNTAIN MEDICAL CENTER INSTITUTIONAL BIOSAFETY COMMITTEE MEETING MINUTES

Meeting Date:	**Tuesday, August 25, 2026**
Time:	8:30 am Mountain Time
Location:	Microsoft Teams Meeting
Institution:	Intermountain Health - Salt Lake City, Salt Lake City, UT
Principal Investigator:	Bradley Hunter, MD, MPH
Protocol:	Autolus Inc., TAUTO1-OS1
NCT Number:	NCT06799221
Meeting Type:	Initial Review of Protocol and Site
Study Title:	Expanded Access Program (EAP) for Obecabtagene Autoleucel (obe-cel) Out-of-specification (OOS) in Adult Patients with Acute Lymphoblastic Leukemia

1. Call to order:

The meeting was called to order at 8:35 am Mountain Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Three voting members were present, including one member unaffiliated with the institution. Also present were two study representatives and IBC 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. 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.

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

The Committee determined that BSL-2 containment facilities and practices are required for Obecabtagene Autoleucel OOS, since it consists of primary human cells modified using a recombinant, replication-deficient lentiviral vector.

The Committee determined that IBC oversight will continue for 3 months after the last participant's last infusion of Obecabtagene Autoleucel OOS locally, provided that other biosafety criteria for study closure are also met.

The Committee voted on the determined biosafety level and period of IBC oversight.

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

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

7. Review of Principal Investigator qualifications:

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

8. Review of proposed facilities and practices:

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

Points of Discussion:

1. The study representatives confirmed participants could receive the study agent in an outpatient setting or as an inpatient if they experienced a reaction that required hospitalization.
2. The Committee recommended that the study application be updated to clarify that Intermountain BMT nurses are administering the study agent.
3. The Committee recommended that the versions of the study documents referenced in the application be corrected.

9. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the study representatives.

Points of Discussion:

1. The Committee recommended [redacted] be removed from the study personnel until training can be completed.
2. The Committee recommended it be verified by study personnel that the nurses administering the study agent are current on Bloodborne Pathogens training and Hepatitis B attestation.

10. Vote on the Protocol and Site:

The Committee voted for the following determination on the Protocol and Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

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

11. Advice to the Institution: None.

12. Meeting adjourned: The meeting was adjourned at 8:59 am Mountain Time.

Documents reviewed:
Agenda
Protocol, Version 1.0, dated 22-Nov-2024
Investigator's Brochure, Version 7.0, dated 15-May-2026
Product Handling Manual (US), Version 2.0
Participant Information Sheet and Informed Consent Form, Version Final 1.2, dated 14-Jan-2025
Study Application, Version 1.1

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Wednesday, October 28, 2026**
Time:	1:30 pm Mountain Time
Location:	Zoom Teleconference
Institution:	Intermountain Health - Salt Lake City, Salt Lake City, UT
Principal Investigator:	**Pankhuri Gupta, MD**
Protocol:	Fate Therapeutics, Inc., **FT819-201**
NCT Number:	NCT07570862
Meeting Type:	Initial Review of Protocol and Site
Title:	A Phase 2, Open-Label, Single-Arm Trial of FT819 in Participants With Refractory Moderate-to-Severe Systemic Lupus Erythematosus With Lupus Nephritis

1. Call to order:

The Meeting was called to order at 1:30 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 five 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 FT819 since it consists of primary human cells modified by recombinant plasmids and a CRISPR/Cpf1 ribonucleoprotein (RNP) complex.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of FT819 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:

The Committee reviewed the qualifications of the Principal Investigator and had no concerns.

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 Biosafety SOP Section 5.1.4b be revised by removing the duplicate “ii” sentence.
2. The Committee recommended that Biosafety SOP Section 5.1.4c.ii be revised by replacing “3.6.3” with “3.6.2.”
3. The Committee noted that a study staff member's IATA/Shipping training expires in October 2026 and recommended that the training be completed prior to the expiration date.
4. An Institutional Representative stated that the Loveland Clinic will not be used for this protocol. The Committee recommended that all site documents be revised accordingly to reflect this.
5. The Committee discussed the use of bleach alternatives for spill clean-up and noted that other disinfectants can be used if they are effective against the study agent and manufacturer instructions for use are followed. The Committee recommended that site documents be revised to indicate that EPA registered hospital disinfectants or 10% bleach solution may be used for spill clean-up.

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 1:48 pm Mountain Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Version 2.3 (US only), dated 10-07-2026
Investigator's Brochure, Version 13.0, dated 08-17-2026
Pharmacy Manual, Version 3.0, dated 02-23-2026
Biological Risk Assessment and Summary, updated 10-22-2026
Site Map, Phase 1 Clinic Floorplan, dated 10-21-2026
Site Map, Loveland Clinic, 7th Floor, dated 10-21-2026
Site Map, East 8, 8th Floor, dated 10-21-2026
Site Map, ARC, dated 10-21-2026
Site Inspection Checklist, expires 09-11-2027, updated 10-22-2026
Photos, dated 10-21-2026
Biohazard Sign, FT819, dated 10-23-2026
SOP, Biosafety for FT819, dated 10-23-2026
Training, Shipping Certifications, expire 2026, 2027
CV, Gupta, P., signed 12-03-2024