INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Tuesday, July 14, 2026**
Time:	3:00 pm Central Time
Location:	Zoom Teleconference
Institution:	The West Clinic, Germantown, TN
Principal Investigator:	**Bradley G Somer, MD, MD, MBA**
Protocol:	ImmunityBio, Inc., **ResQ132EX-NMIBC**
NCT Number:	NCT06810141
Meeting Type:	Continuing Review of Protocol and Site
Title:	Expanded Access Use of Recombinant Bacillus Calmette-Guérin in Non-muscle Invasive Bladder Cancer

1. Call to order:

The Meeting was called to order at 3:14 pm Central 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 rMBCG since it consists of an attenuated mycobacterium administered in a clinical setting. 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 rMBCG 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 noted that one of the Biological Safety Cabinet (BSC) Certifications indicated that the Site Installation Test failed. The Committee also noted that each BSC indicated that the exhaust airflow monitor should be replaced.
2. An Institutional Representative confirmed that the BSCs were recently recertified and passed certification, but they have not yet received the certifications from the certifying company. The Committee recommended that these newer BSC Certifications be provided to IBC Services when they become available.
3. An Institutional Representative noted that the BSCs are certified on an annual basis but agreed to verify this information.
4. The Committee recommended that 24/7 emergency contact information be posted on the study agent storage units.

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 3:19 pm Central Time.

15. Post-meeting notes: The Chair noted that the spills and exposures plan in the Biosafety SOP is misnumbered and should be revised to be Section 5.

Documents reviewed:

Agenda
Protocol, Version 3.0, dated 02-12-2025
Investigator's Brochure, Version 1.0, dated 02-19-2025
Pharmacy Manual, Version 1, dated 02-11-2025
TICE BCG Package Insert, dated 08-2022
Biological Risk Assessment and Summary, dated 07-21-2025
Site Map, Germantown, dated 07-31-2025
Site Inspection Checklist, expires 10-04-2026, updated 07-08-2026
Photos, Germantown, dated 03-25-2026
Biohazard Sign, rMBCG, dated 07-29-2025
Biological Safety Cabinet Certifications, dated 12-11-2025
SOP, Biosafety for rMBCG, dated 08-08-2025
Training, Shipping Certification, expires 07-18-2027
CRRF, dated 05-08-2026
Prior Meeting Minutes, Initial, dated 08-04-2025

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Monday, August 4, 2025**
Time:	3:00 pm Central Time
Location:	Zoom Teleconference
Institution:	The West Clinic, Germantown, TN
Principal Investigator:	**Bradley G. Somer, MD, MBA**
Protocol:	ImmunityBio, Inc., **ResQ132EX-NMIBC**
NCT Number:	NCT06810141
Meeting Type:	Initial Review of Protocol and Site
Title:	Expanded Access Use of Recombinant Bacillus Calmette-Guérin in Non-muscle Invasive Bladder Cancer

1. Call to order:

The Meeting was called to order at 3:00 pm Central 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 was 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 rMBCG since it consists of an attenuated mycobacterium administered in a clinical setting.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of rMBCG 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: 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 the removal of bladder contents after subject dosing. The Committee noted that sponsor documents indicate that "voided urine should be disinfected for 15 minutes with an equal volume of household bleach before flushing." The Committee noted that it would be difficult to calculate the volume of urine in order to determine how much bleach to add.
2. The Committee found the institution's plan for draining contents of the subject's bladder via catheter into a container containing 8 mL of household bleach to be acceptable. The Committee recommended that Biosafety SOP, Section 3.5.1 be revised by removing "Alternatively, the subject will void into a toilet …".
3. The Committee recommended that Biosafety SOP Section 5.2.4 be revised to indicate that in the event of an eye exposure, an exposed person will be escorted to the closest plumbed eyewash and that the affected eye should be rinsed for up to 15 minutes.
4. The Institutional Representative confirmed that the study agent will be stored in a refrigerator, as shown in site photos. The Committee recommended that the site photos (slide 3) be revised to indicate that what is shown is a storage refrigerator, not freezer.
5. The Committee noted that IATA/Shipping training for a staff member expires on August 9, 2025 and recommended that the training be completed prior to the expiration date and that the new certification be provided to IBC Services.
6. The Institutional Representative confirmed that the Biological Safety Cabinets (BSCs) used for study agent preparation are recertified semi-annually and were recently re-certified in June 2025. The Committee recommended that the BSC certifications be provided to IBC Services when available.
7. The Committee recommended that prefilled disposable eyewash bottles be made available in the preparation room and that Site Inspection Checklist (#22) be revised to indicate this.

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 3:18 pm Central Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Version 3.0, dated 02-12-2025
Investigator's Brochure, Version 1.0, dated 02-19-2025
Pharmacy Manual, Version 1, dated 02-11-2025
TICE BCG Package Insert, dated 08-2022
Biological Risk Assessment and Summary, dated 07-21-2025
Site Map, dated 07-31-2025
Site Inspection Checklist, expires 10-04-2026, updated 07-30-2025
Photos, dated 07-31-2025
Biohazard Sign, rMBCG, dated 07-29-2025
Biological Safety Cabinet Certifications, dated 12-06-2024
SOP, Biosafety for rMBCG, dated 07-31-2025

Training, Shipping Certification, expires 08-09-2025
CV, Somer, B, signed 05-20-2025

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Tuesday, July 14, 2026**
Time:	3:00 pm Central Time
Location:	Zoom Teleconference
Institution:	The West Clinic, Germantown, TN
Principal Investigator:	**Axel Grothey, MD**
Protocol:	Replimune, Inc., **RP2-003**
NCT Number:	NCT05733598
Meeting Type:	Continuing Review of Protocol and Site
Title:	A Phase 2, Open-label, Multicenter Study Investigating RP2 Oncolytic Immunotherapy in Combination with Second-line Therapy in Patients with Locally Advanced Unresectable, Recurrent and/or Metastatic Hepatocellular Carcinoma

1. Call to order:

The Meeting was called to order at 3:00 pm Central 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 RP2 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 **3 months after the last subject's last dose of RP2 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 noted that one of the Biological Safety Cabinet (BSC) Certifications indicated that the Site Installation Test failed. The Committee also noted that each BSC indicated that the exhaust airflow monitor should be replaced.
2. An Institutional Representative confirmed that the BSCs were recently recertified and passed certification, but they have not yet received the certifications from the certifying company. The Committee recommended that these newer BSC Certifications be provided to IBC Services when they become available.
3. An Institutional Representative noted that the BSCs are certified on an annual basis but agreed to verify this information.
4. The Committee recommended that 24/7 emergency contact information be posted on the study agent storage units.

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 3:13 pm Central Time.

15. Post-meeting notes: None.

Documents reviewed:
Agenda
Protocol, Amendment 7, dated 10-31-2025
Investigator's Brochure, Edition 7, dated 12-17-2025
Investigator's Brochure, Addendum 2 to Edition 7, dated 05-29-2026
Investigator's Brochure, Addendum 1 to Edition 7, dated 05-12-2026
Pharmacy Manual, Version 3.0, dated 03-05-2026
Intratumoral Injection Manual, Version 1.0, dated 01-20-2023
Post-injection Instructions, Version 2.0, dated 04-17-2024
Research Modification Evaluation, Protocol, Amendment 7
Research Modification Evaluation, Protocol, Amendment 6
Research Modification Evaluation, Protocol, Amendment 5
Research Modification Evaluation, Protocol, Amendment 4
Research Modification Evaluation, Investigator's Brochure, Edition 7
Research Modification Evaluation, Investigator's Brochure, Addendum 2 to Edition 7
Research Modification Evaluation, Investigator's Brochure, Addendum 1 to Edition 7
Research Modification Evaluation, Pharmacy Manual, Version 3.0
Biological Risk Assessment and Summary, updated 06-15-2026
Site Map, Germantown, dated 07-31-2025
Site Inspection Checklist, expires 10-04-2026, updated 07-08-2026
Photos, Germantown, dated 03-25-2026
Biohazard Sign, RP1 and RP2, dated 03-05-2025
Biological Safety Cabinet Certifications, dated 12-11-2025
SOP, Biosafety for RP1, and RP2, dated 03-11-2026
Training, Shipping Certification, expires 07-18-2027

CRRF, dated 04-02-2026
Prior Meeting Minutes, Continuing, dated 07-23-2025

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Wednesday, July 23, 2025**
Time:	3:00 pm Central Time
Location:	Zoom Teleconference
Institution:	The West Clinic, Germantown, TN
Principal Investigator:	**Axel F.K. Grothey, MD**
Protocol:	Replimune, Inc., **RP2-003**
NCT Number:	NCT05733598
Meeting Type:	Continuing Review of Protocol and Site
Title:	A Phase 2, Open-label, Multicenter Study Investigating RP2 Oncolytic Immunotherapy in Combination with Second-line Therapy in Patients with Locally Advanced Unresectable, Recurrent and/or Metastatic Hepatocellular Carcinoma

1. Call to order:

The Meeting was called to order at 2:58 pm Central 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 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 RP2 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 **3 months after the last subject's last dose of RP2 locall**y, 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 recommended that Biosafety SOP Section 5.2.4 be revised to indicate that the person is escorted to the closest plumbed eyewash station and the eye is rinsed for 15 minutes.
2. The Committee recommended that the Biohazard Sign be revised to indicate that the main phone number is available 24/7.

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 3:06 pm Central Time.

15. Post-meeting notes: None.

Documents reviewed:
Agenda
Protocol, Amendment 3, dated 06-19-2024
Investigator's Brochure, Edition 6, dated 04-01-2025
Pharmacy and Administration Manual, Version 2.0, dated 04-12-2024
Intratumoral Injection Manual, Version 1.0, dated 01-20-2023
Post-injection Instructions, Version 2.0, dated 04-17-2024
Research Modification Evaluation, Investigator's Brochure, Edition 6,
Biological Risk Assessment and Summary, updated 04-25-2025
Site Map, updated 07-24-2024
Site Inspection Checklist, expires 10-04-2026, updated 03-05-2025
Photos, dated 07-03-2025
Biohazard Sign, RP1 and RP2, dated 03-05-2025
Biological Safety Cabinet Certifications, dated 06-26-2025
SOP, Biosafety for RP1, and RP2, dated 03-05-2025
Training, Shipping Certification, expires 08-09-2025
CRRF, dated 04-07-2025
Prior Meeting Minutes, Initial, dated 07-31-2024