Meeting Minutes

Institution:	Rocky Mountain Cancer Centers, LLC - Lone Tree
Meeting Date:	November 13, 2025
Meeting Time	12:00 PM Mountain Time
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public
Members in Attendance:	**Member** **Voting** **Member Type** Noriea, Nicholas Yes Chair: Biosafety Expert/HGT Expert Ellis, Robert Yes Core Member: Biosafety Expert/HGT Expert Rastein, Daniel Yes Core Member: Biosafety Expert/HGT Expert Haltiwanger, Brett **(Left at 11:36am after the 1st review)** Yes Local Unaffiliated Member Greiman, Kevin Yes Local Unaffiliated Member Stensgard, Shelby No Site Contact
Invited Members Not in Attendance:	None
Guests:	None
Staff:	Payne, Kaylie

Call to Order: The IBC Chair called the meeting to order at 11:21 PM. A quorum was present as defined in the Sabai IBC Charter.

Conflicts of Interest: The IBC Chair reminded all members present to identify any conflicts of interest (COI). No COI was declared by any voting member of the IBC for any of the items on the agenda.

Public Comments: No public comments were made prior to or at the meeting.

Review of Prior Business: None

Previous Meeting Minutes: Previous meeting minutes from 12-16-24 were reviewed and approved with no changes requested.

New Business:

PI:	Cohn, Allen MD

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Sponsor:	BioNTech SE
Protocol:	BNT122-01 A multi-site, open-label, Phase II, randomized, controlled trial to compare the efficacy of RO7198457 versus watchful waiting in resected, Stage II (high risk) and Stage III colorectal cancer patients who are ctDNA positive following resection.
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: BNT122-01 is a Phase II clinical trial sponsored by BioNTech SE designed to assess the safety and potential efficacy of a recombinant personalized cancer vaccine for the treatment of participants with advanced colorectal cancer following surgical resection. The study agent RO7198457 (autogene cevumeran) consists of messenger RNA (mRNA) expressing personalized tumor antigens formulated as a liposome complex for delivery by intravenous injections

Biosafety Containment Level (BSL): [Because the study agent RO7198457 consists of synthetic mRNA incapable of replication and does not encode for known hazardous transgenes (e.g., toxins or oncogenes), BSL1 containment is considered the minimum biocontainment level. The administration of this agent by intravenous infusion in a clinical setting requires compliance with the OSHA Bloodborne Pathogen Standard.

Risk Assessment and Discussion:

- The Committee reviewed the clinical trial Sponsor's study documents and the Sabai-generated comprehensive study-specific Risk Assessment which collectively provided a thorough description of the recombinant or synthetic nucleic acid molecules (investigational product/s) and the proposed clinical research activities involving the IP.
    - In summary, the primary risks in this clinical trial include potential occupational exposure from accidental spills or splashes of the IP during preparation and/or administration

procedures and needlesticks due to the use of needles during preparation and/or administration. These potential risks are mitigated through a combination of relevant staff training, safe clinical practices including Standard Precautions and sharps safety and use of appropriate PPE (as prescribed in the Risk Assessment and documented in the IBC submission package).

- The Site confirmed that only study personnel who have been educated on the potential biohazards and the precautions to be taken when working with the IP will handle the IP or any materials contaminated by the IP.
- The Site confirmed that study personnel are sufficiently trained in the practices and techniques required to safely work with the IP.
- The Site confirmed that staff members receive Bloodborne Pathogens training.
- Occupational Health Recommendations: None
- The Committee had no additional significant comments or recommendations regarding the description of the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial, or the proposed mitigation strategies, as detailed in the Risk Assessment.

- The Committee reviewed the Site's facility details, relevant study-specific procedures and practices, the Annual Review Report and other applicable information provided by the Site for the purposes of the IBC review.
  - The Site verified that the information provided by the Chair was accurate.
  - The Site confirmed the portable eyewash bottles are checked regularly for expiration.
  - The Site confirmed that the Biohazardous Waste containers are not normally stacked on top of each other. The Site Map & Photos will be annotated to state that the photo showing the stacked container is not normal practice. The Committee recommended the Site ensure that waste containers are not stacked, alternately if containers must be stacked the site must ensure they are compliant with all applicable regulations for medical waste and that containers are only stacked in a manner secured against tipping or spillage of material. The Site had no concerns.

Motion: A motion of Full Approval for the study at BSL-1 plus Standard Precautions was passed by unanimous vote. There were no votes against and no abstentions.

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee: None

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New Business:

PI:	Jotte, Robert M. MD, PhD
Sponsor:	Genprex, Inc.
Protocol:	ONC-005 A Phase 1/2 Clinical Trial of Quaratusugene Ozeplasmid and Atezolizumab Maintenance Therapy in Patients with Extensive Stage Small Cell Lung Cancer (ES-SCLC)
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: ONC-005 (Acclaim-3 Trial) is a Phase I/II open-label trial sponsored by Genprex Inc. designed to identify the maximum tolerated dose (MTD) and/or recommended Phase 2 dose (RP2D), safety profile, and progression-free survival (PFS) of quaratusugene ozeplasmid (REQORSA®) in combination with atezolizumab in adults with extensive stage-small cell lung cancer (ES-SCLC). Quaratusugene ozeplasmid is a recombinant DNA plasmid expressing the TUSC2 tumor suppressor gene. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): The study agent quaratusugene ozeplasmid consists of a recombinant DNA plasmid incapable of replication and which encodes for a protein with no known toxic or tumorigenic properties, therefore, BSL-1 containment is the recommended biocontainment level. The administration of this agent in a clinical setting requires compliance with the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030).

Risk Assessment and Discussion:

- The Committee reviewed the clinical trial Sponsor's study documents and the Sabai-generated comprehensive study-specific Risk Assessment which collectively provided a thorough description of the recombinant or synthetic nucleic acid molecules (investigational product/s) and the proposed clinical research activities involving the IP.
    - In summary, the primary risks in this clinical trial include potential occupational exposure from accidental spills or splashes of the IP during preparation and/or administration procedures and needlesticks due to the use of needles during preparation and/or administration. These potential risks are mitigated through a combination of relevant staff training, safe clinical practices including Standard Precautions and sharps safety and use of appropriate PPE (as prescribed in the Risk Assessment and documented in the IBC submission package).

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- The Site confirmed that staff members receive Bloodborne Pathogens training.
- Occupational Health Recommendations: None
- The Committee had no additional significant comments or recommendations regarding the description of the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial, or the proposed mitigation strategies, as detailed in the Risk Assessment.

- The Committee reviewed the Site's facility details, relevant study-specific procedures and practices, the Annual Review Report and other applicable information provided by the Site for the purposes of the IBC review.
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Motion: A motion of Full Approval for the study at BSL-1 plus Standard Precautions was passed by unanimous vote. There were no votes against and no abstentions.

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee: None

Review of Incidents: Nothing to report.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 11:51 AM

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Post-Meeting Pre-Approval Note: None