

SAFETY Meeting Minutes
UAMS IBC

MEETING TIME RECORDS

Meeting start time: 9/4/2026 12:01 PM

Meeting end time: 9/4/2026 12:20 PM

Meeting type: Virtual

Name of Regular/Alternate Member	Status (Member or Alternate)	Present by Teleconference?
Ha-Neui Kim	Member	Yes
Matthew Jorgenson	Member	Yes
Robert Hunter	Member	No
Kimberly Murphy	Member	No
Lindsey Clark	Member	Yes
James Douglas	Member	Yes
James Bishop	Member	No
Youssef Aachoui	Member	Yes
Jia Liu	Member	Yes
Yuet-Kin Leung	Member	Yes
Melaney Gee	Member	Yes
Mark Manzano	Member	Yes
Antino Allen	Member	Yes
KyoungHyun Kim	Member	No
James Townsend	Member	Yes
Shengyu Mu	Member	Yes
Kikumi Ono-Moore	Ex Officio	No
Zhiqiang Qin	Member	Yes
Lawson Birmingham	Member	Yes
Andre Ewell	Member	Yes

QUORUM INFORMATION

Number of SAFETY members on the roster: 19

Number required for quorum: 10

Quorum: Yes

All members present via teleconference received all pertinent material before the meeting and were able to actively and equally participate in all discussions.

ATTENDANCE STATUS AND VOTING KEY	
ABSTAIN:	Present for the vote but not voting “For” or “Against.”
ABSENT:	Absent for discussion and voting for reasons other than a conflict of interest.
RECUSED:	Absent from the meeting during discussion and voting because of a conflict of interest.
SUBSTITUTION:	When regular members and their alternate(s) are listed in the ATTENDANCE table above and an alternate member serves as a substitute for the regular member this identifies the name of the alternate to indicate which individual is serving as the voting member for this vote. May be deleted if there are no substitutions.

GUEST NAMES
Lauren Grogan
Dr. David Neale

Previous Meeting minutes approved: Yes

REVIEW OF SUBMISSIONS

The review and discussion of the protocols listed below included the following elements: the agents involved and their characteristics; types of manipulations planned; the source(s) and nature of the nucleic acid sequences; the host organism(s) and vector(s) to be utilized; whether expression of a foreign gene is intended and, if so, the specific protein(s) to be produced; the containment conditions to be applied, including biosafety level and any special provisions; and the relevant sections of the NIH Guidelines.

All IBC members present were reminded to identify any conflicts of interest as each registration was reviewed.

For each protocol reviewed, it was confirmed that the Principal Investigator (PI) and laboratory personnel have received appropriate training in the safe conduct of research.

Initial Protocol**1. Review of SPROTO202600000048**

Title:	PRGN-2009
Investigator:	Michael Birrer
Submission ID:	SPROTO202600000048
Description:	This is a Phase 2 study of PRGN-2009 in participants with recurrent or metastatic cervical cancer who are pembrolizumab resistant. This study will combine the HPV vaccine PRGN-2009 with the anti-PD-L1 immune checkpoint inhibitor pembrolizumab to demonstrate an improved treatment outcome for participants with recurrent or metastatic cervical cancer. The rationale for combining the PRGN-2009 vaccine with immune checkpoint inhibitor is based on preclinical data and clinical data demonstrating that combination therapy of cancer vaccines and immune checkpoint inhibitors can trigger intensified immunogenicity leading to increased antitumor efficacy compared to either treatment alone. Eligible participants will receive PRGN-2009 (5×10^{11} PU, subcutaneous injection) every 3 weeks for three administrations, thereafter every 6 weeks, plus pembrolizumab (400 mg IV) every 6 weeks and will be monitored for safety, tolerability, and treatment response. Tissue will be collected for eligibility and optionally at the end of treatment. Blood samples will be collected at defined time points for standard clinical laboratory evaluations and exploratory biomarker analyses, including cytokine and immunogenicity assessments. After interim analysis, nasal swabs, skin swabs, blood, urine, and fecal samples along with the bandage that was used to cover the site of PRGN-2009 injection may be collected at specified time points and evaluated for presence of adenoviral vector. Results from this study will contribute to understanding the safety profile and effectiveness of PRGN-2009 combined with pembrolizumab in treating recurrent or metastatic cervical cancer that is pembrolizumab resistant.
Agent Containment:	Biological Containment Levels: • Nasal Secretions: BSL-2

	• Skin Swab: BSL-2 • Fecal pellets: BSL-2 • Human Tumor Tissue: BSL-2 • Urine: BSL-2 • Human Blood: BSL-2
Applicable NIH Guidelines:	• Section III-C • Section III-C-1

a. **Determination:** Modifications Required

b. **Required modifications:**

Please review and respond to comments throughout the protocol. Contact BSOs Lindsey Clark (LClark4@uams.edu) or J.C. Douglas (JDouglas@uams.edu) with any questions. Thank you!

c. **Votes:**

For:	15
Against:	0
Recused:	0
Absent:	4
Abstained:	0

Initial Protocol

2. Review of SPROTO202600000054

Title:	PiNACLE-H2H
Investigator:	Cesar Gentile Sanchez
Submission ID:	SPROTO202600000054
Description:	PiNACLE-H2H is a Phase 3 randomized controlled trial comparing the efficacy and safety of rondecabtagene autoleucel (ronde-cel, formerly known as LYL314) against the currently approved cluster of differentiation (CD)19 chimeric antigen receptor (CAR) T-cell therapies (axicabtagene ciloleucel [axi-cel] or lisocabtagene maraleucel [liso-cel]), in patients with aggressive large B-cell lymphoma (LBCL) that has relapsed or is refractory to first-line anti-CD20 antibody and anthracycline-containing chemotherapy. Patients will be randomized (1:1) before leukapheresis to receive either: Ronde-cel; or Investigator's choice of axi-cel or liso-cel. Most patients who receive currently approved CD19-directed CAR T-cell therapies, including axi-cel and liso-cel, still experience progressive disease, often due to mechanisms such

	as CD19 antigen loss or T-cell exhaustion. Ronde-cel is a novel, autologous, dual-targeting CD19/CD20 CAR T-cell product candidate enriched for CD62L-positive naïve and central memory T cells, which are associated with enhanced proliferation capacity and persistence. Ronde-cel is an "OR"-gated CAR construct that can fully activate upon recognition of either CD19 or CD20, aiming to improve durability of response despite antigen heterogeneity. The primary endpoint of the study is to compare the efficacy of ronde-cel to the CD19 CAR T-cell therapies (axi-cel or liso-cel) based on event-free survival (EFS), defined as the time from randomization to death from any cause, disease progression, failure to achieve a response (partial response or complete response) by the Day 84 visit after CAR T-cell therapy administration, or start of new anti-lymphoma therapy without documented progression, whichever comes first. Response and disease progression on positron emission tomography/computed tomography (PET/CT) imaging per Lugano Criteria 2014 will be assessed by a blinded Independent Review Committee (IRC) for all patients. Approximately 400 participants will be enrolled. CAR T-cell therapy in both arms will be administered as a single intravenous infusion following fludarabine and cyclophosphamide lymphodepletion. Participants will be followed for 3 years for safety and efficacy, with long-term follow-up extending to 15 years.
Agent Containment:	Biological Containment Levels: • Human Blood: BSL-2 • Human Bone Marrow: BSL-2 • Urine: BSL-2 • Human Tumor Tissue: BSL-2
Applicable NIH Guidelines:	• Section III-C • Section III-C-1

a. **Determination:** Modifications Required

b. **Required modifications:**

Please review and respond to comments throughout the protocol. Contact BSOs Lindsey Clark (LClark4@uams.edu) or J.C. Douglas (JDouglas@uams.edu) with any questions. Thank you!

c. **Votes:**

For: 15

Against: 0

Recused: 0

Absent: 4
Abstained: 0

REVIEW OF OTHER AGENDA ITEMS

No other items reviewed.