

Meeting Minutes

Institution:	Academic Urology & Urogynecology of Arizona - Peoria		
Meeting Date:	March 04, 2026		
Meeting Time	2:30 PM Arizona 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
	Rastein, Daniel (left at 3:00 PM AZ)	Yes	Core Member: Biosafety Expert/HGT Expert
	Campbell, Mark	Yes	Core Member: Biosafety Expert/HGT Expert
	Hockley, Sepideh	Yes	Local Unaffiliated Member
	Venable, Rachel	Yes	Local Unaffiliated Member
	Hill, Jennifer	No	Site Contact
Invited Members Not in Attendance:	None		
Guests:	Montoya, Dawn; Gray, Morgan (joined at 3:07 PM AZ)		
Staff:	Smith, Jennifer; Sreedharan, Aswathy		

Call to Order: The IBC Chair called the meeting to order at 2:31 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: None

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New Business:

PI:	Kundavaram, Chandan
Sponsor:	Candel Therapeutics, Inc.
Protocol:	PrTK05 A Biomarker Study in Men with Localized, Favorable, Intermediate-risk Prostate Cancer Treated with Aglatimagene Besadenovec
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: PrTK05 is an open-label, single-group Phase IIa study sponsored by Candel Therapeutics, Inc. to evaluate changes in biomarkers of participants with intermediate-risk prostate cancer after administration of aglatimagene besadenovec (CAN-2409). Aglatimagene besadenovec is a non-replicating adenoviral vector engineered to express thymidine kinase from Herpes Simplex Virus (HSV) to direct anti-HSV drugs to tumor cells. The investigational product (IP) is administered by intratumoral injection.

Biosafety Containment Level (BSL): The study agent aglatimagene besadenovec consists of a Risk Group 2 adenovirus containing more than two-thirds of the native genome, therefore BSL-2 containment is the recommended minimal containment level under the NIH Guidelines.

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.

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- 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 PI's credentials, 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.
 - Sabai staff noted that the CTR Form was received during the IBC meeting and will be available for the Committee to review at future meetings. The Committee had no concerns with the PI.
 - The Site confirmed the names they use for the study agent activities.
 - The Site confirmed that biohazardous waste containers are brought into any room when study agent is being handled.
 - The Site confirmed that they do not currently have an ultra-low freezer and plan to use the refrigerator in the photo. The Committee stipulated that the Site affix a biohazard symbol to the storage unit and send Sabai an updated photo by 4/4/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
 - The Committee discussed the removal of safety seals from eyewash bottles and the best practice of leaving the safety seals on. The Site confirmed they regularly check eyewash bottles for expiration dates and check for security seals and damage. The Site had no concerns and noted they are planning to buy additional eyewash bottles.
 - The Committee stipulated that the Site secure all sharps containers present in rooms when study agent is being handled and send Sabai an updated photo by 4/4/26. The Committee noted the containers must be secured such that they do not tip over and to place it at eye level or lower, such that all staff members can clearly see into the

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disposal port. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

- The Committee noted the close proximity of the sink to the preparation area. The Committee recommended that the Site not run the sink during preparation or install a Plexi-glass shield between the sink and preparation areas to reduce splashes.
- The Committee reminded the Site to ensure all furniture is easily cleanable in the rooms where study activities are occurring. The Site had no concerns and confirmed any absorbent furniture would be mitigated prior to agent handling.
- The Site confirmed that the biohazardous waste bags will be tied securely before the vendor picks them up. The Site noted they believe waste may be consolidated in a larger container for vendor pickup. The Committee stipulated that the Site get clarification on the biohazardous waste process and send Sabai an updated photo of the larger biohazard waste container, with a biohazard sticker affixed, by 4/4/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

Motion: A motion of Approval with Stipulations for the study at BSL-2 was passed by unanimous vote. There were no votes against and no abstentions.

- Contingencies stated by the Committee: None
- Stipulations stated by the Committee:
 - The Committee stipulated that the Site affix a biohazard symbol to the storage unit and send Sabai an updated photo by 4/4/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
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Review of Incidents: Nothing to report.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 3:48 PM.

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Post-Meeting Pre-Approval Note: None