

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: **Wednesday, November 19, 2025**
Time: 1:00 pm Eastern Time
Location: Zoom Teleconference
Institution: Carolina Urologic Research Center, Myrtle Beach, SC
Principal Investigator: **Neal Shore, MD**
Protocol: Ferring Pharmaceuticals A/S, **000434 (ABLE-22)**
NCT Number: NCT06545955
Meeting Type: Continuing Review of Protocol and Site
Title:

1. Call to order:

The Meeting was called to order at 1:25 pm Eastern 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 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 ADSTILADRIN (nadofaragene firadenovec), since it consists of a recombinant replication-defective adenoviral vector 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 ADSTILADRIN (nadofaragene firadenovec) 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

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

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 the formatting/section numbering error starting on page 3 of the Biosafety SOP be fixed.
2. The Committee discussed the amount of time an affected eye should be flushed after an exposure and recommended that "For Eye Contamination" section in the Biosafety SOP be revised to indicate that "(up to 15 minutes)" should be added after the word "thoroughly" since this section is written primarily for a biological agent exposure.
3. The Committee noted that bleach will be used to decontaminate the voided contents of the bladder and that this is a corrosive agent. The Committee recommended that "For Eye Contamination" section in the Biosafety SOP be revised to add "Note: In the event of an eye exposure to bleach, the affected eye should be rinsed for at least 15 minutes in compliance with OSHA standards."
4. The Committee noted that the addition of bleach to the toilet prior to voiding the contents of the bladder could result in a splash of the bleach on skin, and recommended that Biosafety SOP Section 3.5.1 be revised to add bleach only after voiding contents of the bladder into the toilet.
5. An Institutional Representative confirmed that the urinal has a lid, as confirmed in the updated photo provided to IBC Services.
6. An Institutional Representative noted that the darker area on the biohazardous waste box in a photo is just a shadow, and not a leak.

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 1:29 pm Eastern Time.