INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Monday, August 17, 2026**
Time:	2:00 pm Eastern Time
Location:	Zoom Teleconference
Institution:	Cincinnati Eye Institute, Cincinnati, OH
Principal Investigator:	**Robert Sisk, MD**
Protocol:	Astellas Institute for Regenerative Medicine, **2020-CL-0101**
NCT Number:	N/A
Meeting Type:	Initial Review of Protocol and Site
Title:	A Phase 1b, Open-label, Multicenter Dose-escalation Study to Evaluate the Safety, Tolerability, and Preliminary Efficacy of a Single Subretinal Dose of ASP2020 in Participants with Macular Dystrophies with a Stargardt-type Clinical Presentation

1. Call to order:

The Meeting was called to order at 2:00 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 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 ASP2020, since it consists of allogeneic retinal pigment epithelial (RPE) cells derived from genetically modified human induced pluripotent stem cells (iPSCs) administered via subretinal injection.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of ASP2020 locally**, provided all 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: 5 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 recommended that Biosafety SOP Section 3.5 be revised to indicate that the absorbent material will be disposed of as biohazardous waste.
2. The Committee recommended that Biosafety SOP Section 5.1.4 be revised to include how the water bath will be decontaminated in the event of a spill.
3. The Institutional Representative stated that the biological safety cabinet (BSC) is labelled with a biohazard symbol and that an updated photo of this will be submitted to IBC Services.
4. The Institutional Representative stated that larger eyewash bottles are available onsite and a photo of these will be provided to IBC Services.
5. The Institutional Representative stated that the cardboard biohazardous waste container, as shown in site photos, does not have a lid but does have foldable flaps and that only closed sharps containers or sealed bags go into that container. The Committee found this to be acceptable.
6. The Committee recommended that a biohazard symbol be placed at the entrance to the biohazardous waste storage area and that a photo of this be provided to IBC Services.
7. The Institutional Representative confirmed that both sharps and biohazardous waste containers are available in the dosing rooms and that photos of these will be provided to IBC Services.

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 2:12 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:
Agenda
Protocol, Amendment 1, dated 05-22-2026
Investigator's Brochure, Edition 2.0, dated 05-27-2026
Pharmacy Manual, Version 2.0, dated 05-27-2026
Surgical Manual, Version 1.0, dated 05-27-2026
Biological Risk Assessment and Summary, dated 06-01-2026
Site Map, dated 08-06-2026
Site Inspection Checklist, expires 10-29-2026, updated 08-06-2026
Photos, dated 08-06-2026
Biohazard Sign, all studies, dated 07-08-2026
Biological Safety Cabinet Certification, expires 11-2026
SOP, Biosafety for ASP2020, dated 07-08-2026
Training, Shipping Certification, expires 10-21-2026
CV, Sisk, R., signed 10-26-2023