

Document Register and Version Control

Site	_____ · Site # _____
Binder issued	19 August 2026
Protocol	Sterling IRB #16201 v1.4 — observational, minimal risk
Issued by	Sai Chavala, MD · Principal Investigator · schavala@gmail.com

The one rule

Consent only on the version in this binder.

If you believe a newer consent form exists — someone mentions it, emails it, or you see one elsewhere — **stop and call before consenting anyone.** A newer version is only in force once it has been issued into this binder through the procedure below.

This matters because an amendment is currently pending with the IRB. **Pending is not approved.** Until a replacement is issued to you in writing, the version in Section 06 is the only one that may be used.

Register — what is in force today

§	Document	Version	Status
00	Binder cover and contents	19 Aug 2026	Current
00b	This register	19 Aug 2026	Current
01	Site Operations Manual	19 Aug 2026	Work from this daily
02	Topcon Maestro Imaging Protocol	—	Current
03	SOP-003 — OCT Export and Imaging Data Handling	v1.0	Current. Where anything disagrees with it, SOP-003 governs
04	Patient Research Information (English · Spanish)	—	Draft — pending IRB approval. Not for patient distribution.
05	Retinal Imaging Modalities	—	Reference
06	IRB-approved materials	See below	Approved versions only

Section 06 — the approved set

Document	Status
16201.FINAL_IRB_PROTOCOL_v1.4.pdf	Approved protocol. The study you are participating in
16201.ICF.TEMPLATE.APPROVED	The consent form in force. Use this one.
16201.Study Material(s) - APPROVED.pdf	Approved participant-facing materials
Medical_Release_Form_v3 red line (1).APPROVED.pdf	Approved medical release

An amendment is pending — Spanish-language support, consent administration by clinical technicians under supervision, and additional data sources. **None of it is in force yet.** When it is approved you will receive a replacement pack.

Replacement procedure — how a new version reaches this binder

- 1. SpectOcular issues it.** Replacement pages come from the Principal Investigator, with a dated cover note saying what is being replaced.
- 2. Remove and destroy the superseded copy,** or mark it clearly and file it outside the working binder. A superseded consent form left in a binder will eventually be used.
- 3. File the replacement** in the same section.

4. Sign the acknowledgement below and return a copy to SpectOcular.
5. Nothing is consented on a version that did not arrive this way — not an emailed draft, not a printout from another source.

Why the paperwork: for every participant, the study must be able to state which consent version was in force on the date they signed. That record is built from this register and these acknowledgements. Without it, the enrollment cannot be evidenced later — no matter how correctly it was actually done.

Acknowledgement of receipt

Sign on issue, and again on each replacement.

Issue / replacement	Date issued	Received by (print)	Signature	Date signed
Initial binder — 19 Aug 2026				

If something goes wrong

Stop and call — do not improvise. Sai Chavala, MD · schavala@gmail.com · 214-233-6170

Call before proceeding if: a signature or date is missing · the patient has questions about risks, research use, or withdrawal · imaging would be done only for research · the wrong patient or eye may have been selected · an export contains another patient's information · you are unsure which consent version to use.

Nothing is lost by pausing an enrolment. A great deal is lost by an enrolment that cannot be evidenced.