

SpectOcular Site Binder

Site	
Site number	01
Protocol	Sterling IRB #16201 v1.4 — observational, minimal risk
Issued	19 August 2026
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The three rules everything else follows

- 1. Participation never changes routine care.** No imaging is performed solely for research. Only images acquired as part of routine care are included.
- 2. Written research consent and HIPAA authorization are signed before research inclusion.** No exceptions, no retrospective consent.
- 3. A patient is enrolled once.** A follow-up visit is not a new enrollment — see below.

What is in this binder

	Document	Use it for
01	Site Operations Manual	Start here. This is the document you work from every day — both service lines, research, imaging, export, troubleshooting, and the checklist for the day research opens
02	Topcon Maestro Imaging Protocol	Acquisition standards — dilation, minimum image set, quality
03	SOP-003 — OCT Export and Imaging Data Handling	The controlled export procedure. 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	Explaining the imaging to a patient who asks
06	Approved IRB materials — ICF template, medical release	Consent packets. Approved version only
07	Site Staff Workflow Quick Guide — SUPERSEDED	Reference only. Written before the current system was built; it describes folders and an ID register that do not exist. Do not train from it

What is live, and what is not

	From 20 August
SpectOcular Patient Services	LIVE
Retina IQ consults	LIVE
Research enrollment	NOT LIVE. Do not consent anyone for research until you receive written confirmation that IRB approval has been granted — expected the week of 24 August

Manual **Part 13** is the checklist for the day that confirmation arrives. Work through it before enrolling anyone.

A follow-up visit is not a new enrollment

This is the single easiest thing to get wrong, and the hardest to undo.

A patient keeps **one Subject ID for the life of the study**. When they come back in three months, you do not fill in the enrollment form again and you do not generate a new Subject ID.

If a returning patient is enrolled a second time they get a second Subject ID and a second folder, and their follow-up scan can no longer be connected to their first one. The study exists to measure *change over time*, so that connection is the whole point. It cannot be repaired later without going back through identifiable records to work out that the two were the same person.

For a repeat visit: look the patient up, use their existing Subject ID, and file the new imaging under it.

What this site's imaging is

Topcon **color fundus photography and structural OCT**. This site does not have OCT-A.

That is a complete submission for this site. Nobody should be chasing OCT-A images here, and no one from SpectOcular should query their absence. If that ever happens, say so and it will be corrected at our end.

What the site never does

- Never perform imaging solely for research
 - Never de-identify anything — SpectOcular does that centrally
 - Never copy or synchronise the live Topcon database
 - Never alter files inside an exported package
 - Never put a patient name, MRN or date of birth in a folder or file name
 - Never route imaging to Retina IQ unless the enrollment record says the patient consented to it
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If something goes wrong

Situation	What to do
The form errors or will not save	Stop. Do not keep re-submitting — that can create duplicate subject records. Call Sai
You think a patient may already be enrolled	Use the existing Subject ID. Never create a second
The export produces nothing, or looks wrong	Do not upload it. Write down what happened — the exam can be re-exported later
A patient asks a research question you cannot answer	Route it to the investigator or coordinator. Please do not improvise an answer
Anything concerning a patient's safety	Normal clinical pathway, immediately. The study never comes before care

Questions are always welcome, including after the fact. A question asked late is much cheaper than a record corrected late.