

SpectOcular Site Operations Manual

Site	Site # ____ — _____
Version	1.0 — 19 August 2026
Supersedes	Site Staff Workflow Quick Guide (retained for reference; where they disagree, this manual governs)
Protocol	Sterling IRB #16201 — observational, minimal risk
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Read this first

This manual is written to be used without anyone from SpectOcular present. Training happens once, on 20 August. After that, this document is your reference — including for research enrollment, which you will start on your own once IRB approval arrives.

If something here does not match what you see on screen, **stop and ask**. Do not improvise a workaround. A question costs a phone call; a workaround costs a record that has to be unpicked later.

PART 0 — WHAT IS LIVE, AND WHAT IS NOT

Service	Status from 20 Aug	Governed by
SpectOcular Patient Services	LIVE	Practice Patient Services consent + BAA
Retina IQ consults	LIVE	Patient Services consent + the patient's separate Retina IQ permission
Research enrollment	NOT LIVE — do not consent anyone for research	Sterling IRB #16201, pending approval

Research enrollment is expected to open the week of 24 August. You will be told in writing. Until that message arrives:

- Do not sign anyone onto the research consent
- Do not use the research enrollment form except for practice with made-up data
- Do not export imaging into the research folders

Everything else in this manual is live and in use from day one. **Part 13** is the checklist you work through on the day approval arrives.

PART 1 — THE THREE PERMISSIONS

The most common source of error at a new site is treating these as one thing. They are three, and a patient can agree to any combination.

	What it permits	Required for
1. Practice Patient Services consent	SpectOcular holds the patient's record and supports their care	Everything. Nothing happens without this
2. Retina IQ	The patient's images are sent for a specialist consult to their optometrist	Retina IQ only
3. Research consent + HIPAA authorization	The patient's coded data supports the research study	Research enrollment only

Three rules that never bend:

1. **Participation never changes routine care.** No imaging is ever performed solely for research or for Retina IQ. Only images acquired as part of the patient's routine care are used.
2. **Signatures come before inclusion.** Every consent is signed and dated *before* the thing it permits happens. There is no retrospective consent.
3. **Retina IQ is a consult to the doctor, not a report to the patient.** It supports the supervising eyecare professional's decision. It is not a diagnosis delivered to the patient, and results are not given to the patient directly by SpectOcular.

PART 2 — IDENTIFIERS — READ THIS TWICE

Three different numbers travel with a patient. Confusing them is the single most damaging mistake available in this system.

Identifier	Looks like	Who assigns it	Contains a name?
Clinic patient ID / MRN	Whatever your practice uses	Your practice	Yes, in your system
SpectOcular Patient Number	01-0001 — sequential, four digits	The system, automatically	No
Research Subject ID	01-K7M2Q — random, five characters	The system, automatically	No

The Subject ID is random on purpose. It is not sequential, and it encodes nothing — not diagnosis, not sex, not the order people enrolled. The approved consent form tells patients exactly this. The characters I, L, O, 0 and 1 are never used, so there is no ambiguity when a code is written by hand.

⚠ One patient, one number, for the life of the study

A follow-up visit is never a new enrollment.

When a patient returns in three months, you do not fill in the enrollment form again and you do not generate a new Subject ID. You look up the one they already have.

If a returning patient is enrolled a second time they receive a second Subject ID and a second folder, and their follow-up imaging can no longer be connected to their first visit. The entire point of the study is measuring *change over time*, so that link is the asset. Once broken it cannot be repaired without going back into identifiable records to prove the two records were the same person.

The system now checks for this and will hand back the existing ID rather than creating a new one. **Do not rely on it.** Look the patient up first — the check is a safety net, not the procedure.

PART 3 — SPECTOCULAR PATIENT SERVICES • LIVE

Follow this for every patient joining SpectOcular Patient Services.

Before the patient arrives

4. Confirm the imaging planned is **clinically indicated as routine care**.
5. Have the Practice Patient Services consent and the intake worksheet ready.

With the patient

6. Give the patient time and privacy to read. Route clinical questions to the supervising eyecare professional.
7. Obtain the **Practice Patient Services consent** — every signature, every date.
8. Ask about **Retina IQ** and record the answer. Yes or no, it gets recorded.
9. Collect intake: demographics and preferred contact method; PCP name, clinic, address, phone and fax; preferred pharmacy; relevant specialists; diagnoses, medications, allergies, smoking history; cardiovascular, diabetes, kidney and neurologic history; eye history including surgery, laser, injections and prior imaging.

Registering the patient

10. Open the SpectOcular site and register the patient. The system assigns the next **SpectOcular Patient Number** (01-0002, 01-0003, ...) and creates their folder.
11. **Before the patient leaves:** re-check every signature and date, confirm PCP and pharmacy details are usable, and confirm the history is legible.

Returning patients: search first. If they already have a SpectOcular Patient Number, use it. Do not register them again.

PART 4 — RETINA IQ • LIVE

Retina IQ is a specialist consult on the patient's imaging, delivered to the supervising eyecare professional.

Only for patients who have agreed to it. The recorded answer governs — not anyone's recollection of the conversation. If the record says No, the imaging supports their care and nothing else, however interesting the scan.

To submit a request you will need:

- The patient's SpectOcular Patient Number and clinic patient ID
- Date of the scan and which modalities were acquired
- The requesting professional and their contact details
- PCP details
- Relevant medical and ocular history
- **The clinical question.** The most useful field on the form — "rule out macular oedema" produces a better consult than "please review"

What happens next: the request and its imaging go to the interpreting physician; the report returns to the practice and is filed against the patient. Turnaround and billing follow the executed agreement.

What Retina IQ is not: it is not an emergency pathway. Anything requiring urgent attention goes down your normal clinical route immediately, and does not wait on a consult.

PART 5 — RESEARCH ENROLLMENT • NOT LIVE UNTIL IRB APPROVAL

Do not begin any part of this section until you receive written confirmation that IRB approval has been granted. Practising with invented patient details is encouraged. Consenting a real patient is not.

What the study is: an observational, minimal-risk study. It collects information and images that are already being generated by routine care. It changes nothing about how a patient is examined or treated.

Consent, in order

12. Confirm the patient already has the Practice Patient Services consent.
13. Give them the **Patient Research Information** sheet (English or Spanish) and time to read it.
14. Obtain the **research consent and HIPAA authorization** — the current approved version only. If you are unsure which version is current, ask before signing anyone.
15. Route every research question to the investigator. Please do not answer research questions from your own knowledge, however reasonable the answer seems.

Enrolling

16. Open the research enrollment form and complete it with the patient's details.
17. The form generates the **Subject ID. Write it on the consent packet** — this is the only durable link between the paper and the record.
18. Complete the medical-history and covariate fields.

"Don't know" is a real answer. Three of the history questions offer *Don't know*. Use it when that is the truth. Never record *No* to mean *we did not ask* — leaving it blank is correct when unknown. A false *No* is worse than a blank, because a blank is honest about being unknown and a *No* is not.

19. Confirm the record saved before the patient leaves.

Enrollment is once. See Part 2. For a returning subject you use their existing Subject ID.

PART 6 — IMAGING

This site: Topcon Maestro — colour fundus photography and structural OCT. This site does not have OCT-A.

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

Acquisition standard (full detail in the Topcon Maestro Imaging Protocol, document 02):

- Imaging after standard-of-care dilation unless contraindicated, declined, or not clinically appropriate. Target pupil ≥ 4.0 mm where achievable; document if smaller
- Minimum set per eye: macula-centred fundus photo, disc-centred fundus photo, macular OCT cube, optic nerve / RNFL OCT cube
- Same device and software version wherever possible
- Retain poor-quality and ungradable scans **with their labels** — do not silently delete and repeat. A known-ungradable image is data; a missing image is a hole

And again, because it is the rule that gets broken: nothing is acquired solely for research or for Retina IQ.

PART 7 — EXPORT AND UPLOAD

Controlled procedure: **SOP-003** (document 03). This is a summary — SOP-003 governs.

Confirm first: the Topcon is running the **research installation**. A clinical installation produces exports at the wrong regulatory tier which cannot be used, and the error is silent until someone checks. If you are not certain which is installed, ask before exporting.

Export

```
DicomOctExport.exe "<path>\<exam>.fda" "<output_dir>" -allDcm -json -debug
```

then a second pass for the layer-thickness files, which are the study's primary measurement:

```
DicomOctExport.exe "<path>\<exam>.fda" "<output_dir>" -thicknessMap -debug
```

In the GUI, tick **New Folder for Each FDA File**. Without it, a batch writes everything into one directory and the exams cannot be separated afterwards.

Name the output folder with the Subject ID and the exam date, and nothing else:

03-HN7JZ_2026-08-18

Never put a patient name, MRN or date of birth in a research folder or file name. Folder names travel into backups, sync logs and screenshots, none of which carry the protections the contents get.

Upload to that subject's own imaging folder:

01_Sites / <Site folder> / Subjects / <SubjectID> / 05_Retinal_Imaging_ZIP

Then confirm the upload was recorded. An export sitting in Drive with no custody record is not considered filed (SOP-003 §6.4). If you do not see it recorded, say so — do not upload it a second time.

Let each export finish completely before moving or zipping it. Never copy or synchronise the live Topcon database, and never alter files inside an exported package.

PART 8 — FOLDER NAMES: WHY TWO RULES THAT LOOK CONTRADICTIONARY ARE BOTH RIGHT

You will notice something that looks like an inconsistency, and it is worth understanding rather than working around.

	Folder name	Why
Patient Services	Lastname_Firstname_MMDDYYYY — name and date of birth	Identified record, held under the BAA. It is their chart; it is supposed to be findable by name
Research imaging	03-HN7JZ_2026-08-18 — Subject ID and date only	Coded record. The whole point is that it carries no identity

Both are correct. The rule is not "never write a name anywhere" — it is "**never write a name in the research side.**" If you are working in Subjects, no names. If you are working in SpectOcular_Patient_Services, names are how the folder is found.

Research subject folders are created for you: 01_Intake, 02_Signed_Consents, 03_Medical_Records, 04_Labs, 05_Retinal_Imaging_ZIP, 06_Retina_IQ_Reports, 07_Invoices, 08_Audit_Log. Do not create your own alongside them.

PART 9 — WHAT THE SITE NEVER DOES

- Never perform imaging solely for research or for Retina IQ
- Never de-identify anything — SpectOcular does that centrally. You have no second command to run
- Never copy or synchronise the live Topcon database
- Never alter files inside an exported package
- Never put a name, MRN or date of birth in a research folder or file name
- Never route imaging to Retina IQ unless the record says the patient agreed
- Never re-enroll a returning patient

- Never answer a research question on SpectOcular's behalf — route it

PART 10 — TROUBLESHOOTING WITHOUT AN EXPERT PRESENT

What you see	What to do
The form errors, or will not save	Stop. Do not keep re-submitting — repeated attempts can create duplicate records. Note the time and any message, and call
You think the patient may already be registered	Search first. Use the existing number. Never create a second
A Subject ID was generated but the patient was already enrolled	Use the original ID. Report the duplicate so it can be cleaned up before data accumulates against it
The export produced nothing, or far fewer files than usual	Do not upload it. Note what happened. The exam can be re-exported later — nothing is lost
The export ran but you are unsure of the tier	Do not upload. Ask. An export at the wrong tier is unusable and better caught now
The upload does not appear as recorded	Do not upload again. Report it — a duplicate is harder to resolve than a missing record
Patient asks a research question you cannot answer	Route to the investigator. Do not improvise
Patient withdraws, or asks to be removed	Stop all further collection for them immediately, and report the same day
Anything concerning patient safety	Normal clinical pathway, immediately. The study never takes precedence over care

When in doubt, the safe action is always: stop, write down what you saw, and ask. Nothing in this study is urgent enough to justify a guess.

PART 11 — SUPPORT

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Central account	admin@spectocularhealth.com
Best for	Anything you are unsure about — including after the fact

Please report near-misses, not just errors. If something nearly went wrong, that is the cheapest possible signal that a step needs changing. Nobody is in trouble for reporting one.

PART 12 — SITE ACCESS

Site address	☐ _____ (to be completed at training)
Access code	SPECTIQ2026
Who may use it	Only staff on the delegation log in Appendix A

Do not share the access code outside the delegated staff, and do not save it where a patient could see it.

PART 13 — ACTIVATION: THE DAY IRB APPROVAL ARRIVES

Work through this in order. It should take under an hour.

- [] 1. Written confirmation received from SpectOcular that research enrollment is open. **Do not start on a verbal or an assumption.**
- [] 2. Confirm which ICF version is approved, and that the packets you hold match it. **If they do not match, stop — do not consent anyone on a superseded form**
- [] 3. Destroy or clearly mark any superseded consent packets so they cannot be picked up by mistake
- [] 4. Confirm every staff member who will consent or enroll is on the delegation log (Appendix A)
- [] 5. Run one enrollment with invented details end to end. Confirm the Subject ID appears and the record saves. Report the practice record so it can be removed
- [] 6. Confirm the Topcon research installation is the one in use
- [] 7. Enroll the first real subject, and **call the same day** to confirm the record arrived intact
- [] 8. For the first three subjects, check each one's record before the patient leaves

First week: reconcile the number of consent packets against the number of records. They must match. A mismatch found in week one is a conversation; found in month three it is an audit finding.

APPENDIX A — TRAINING RECORD AND DELEGATION LOG

Signed at training on 20 August 2026. Required by SOP-003 §11 — only staff listed here may perform these tasks.

Name	Role	Trained on	Signature	Date
		Patient Services · Retina IQ · Research · Imaging · Export		
		Patient Services · Retina IQ · Research · Imaging · Export		
		Patient Services · Retina IQ · Research · Imaging · Export		
		Patient Services · Retina IQ · Research · Imaging · Export		

Trainer

Name	_____
Signature	_____ Date _____

Confirmed at training — tick each once demonstrated, not merely described:

- ☐ Each person can state the three permissions and which one governs what
- ☐ Each person can explain why a follow-up visit is not a new enrollment
- ☐ Each person has registered a patient and seen the number assigned
- ☐ Each person has submitted a Retina IQ request
- ☐ Each person has run an export and named the folder correctly
- ☐ Each person knows the research gate is closed and what opens it
- ☐ Each person knows what to do when something fails — stop, record, call

Training was performed on invented data only. No real patient record was created for training purposes.

APPENDIX B — BENCH CARD

Print this page and keep it at the imaging station.

EVERY PATIENT

20. Imaging clinically indicated? → If no, stop
21. Practice Patient Services consent signed and dated

- 22. Retina IQ — asked, answered, recorded
- 23. Intake complete: PCP · pharmacy · contact · history
- 24. Register → SpectOcular Patient Number assigned
- 25. Re-check signatures and dates **before they leave**

RESEARCH — only after approval

- 26. Approved research consent + HIPAA signed
- 27. Enroll → Subject ID generated → **write it on the packet**
- 28. Returning subject? **Use their existing ID**

IMAGING

Dilate · macula fundus · disc fundus · macular OCT · disc OCT

No OCT-A at this site — expected, not missing

Nothing acquired solely for research

EXPORT

Research installation · -allDcm -json -debug · second pass -thicknessMap -debug

Folder name: SubjectID_YYYY-MM-DD — **no names, no MRN, no DOB**

Upload to that subject's 05_Retinal_Imaging_ZIP · confirm it was recorded

STOP AND CALL IF

Form errors · patient may be already enrolled · export empty or wrong tier · upload not recorded · patient withdraws · anything you are unsure about

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APPENDIX C — GLOSSARY

Term	Meaning
Coded	Identifiers replaced by a Subject ID, with the key held separately by SpectOcular. Still protected information
De-identified	Identifiers removed entirely. Done centrally by SpectOcular — never at the site
Subject ID	01-K7M2Q. Random. Research only
SpectOcular Patient Number	01-0001. Sequential. Patient Services
Linkage key	The restricted record connecting a Subject ID to a person. Access is limited and logged
DICOM	The standard imaging format the Topcon exports
.fda	Topcon's native file. The export tool reads it and produces DICOM
Regulatory tier	Which Topcon installation produced an export. This study requires the research tier
Gradable / ungradable	Whether an image can be assessed. Ungradable images are kept and labelled, never deleted