

Site Staff Workflow Quick Guide

Patient encounter → consent → routine imaging → registration → Topcon export → quality control

This one-piece reference distills the full pilot manuals into the everyday steps your site team follows for each participant. It is a quick guide, not a replacement for the approved protocol and controlled documents (SOM-001, WI-001, WI-002, RC-001).

The three rules behind everything below

Participation is **prospective, observational, and minimal risk** — it must never change routine care. **No imaging is performed solely for research**; only images acquired as part of routine care are included. **Written research consent and HIPAA authorization must be signed before research inclusion.**

The encounter, step by step

1 Before the patient arrives

- Confirm imaging is clinically indicated as part of routine care.
- Have the current research consent / HIPAA authorization, the SpectOcular Practice Patient Services Consent, and the Patient Intake Worksheet ready.

2 Consent — before any research inclusion

- Give the patient privacy and time to review. Route research questions to the investigator or coordinator.
- Confirm every required signature and date on **both** consents. The Practice Patient Services Consent is separate from research consent.

3 Collect source information & history

- Demographics and preferred contact method; PCP (name, clinic, address, phone, fax); preferred pharmacy; relevant specialists.
- Diagnoses, medications, allergies, smoking history; cardiovascular, diabetes, kidney, and neurologic history; eye diagnoses, surgery, laser, injections, and prior imaging.

4 Acquire routine-care retinal imaging (Topcon Maestro 3D)

- Color fundus photography · Structural OCT · OCT-A if clinically available.
- Do **not** perform any additional imaging solely for research.

5 Before the patient leaves

- Re-check every signature and date; confirm PCP and pharmacy details are usable; confirm history is legible and complete.
- Place the packet in the controlled research handoff folder.

6 Coordinator: register the participant & assign the randomized ID

- Verify consent/HIPAA signatures and the Practice consent; confirm imaging was routine-care only.
- Create the Subjects record, assign the next randomized participant ID from the protected Randomization Register, and record the identity-to-ID mapping in the Linkage Key.
- Create the subject folder set: 01_CONSENTS, 02_INTAKE, 03_MEDICAL_RECORDS, 04_RETINA_IQ, 05_REPORTS, 06_CORRESPONDENCE, 99_ARCHIVE.

⚠ "Randomization" means ID assignment only

Assigning a randomized participant ID is **not** assigning a treatment arm. Do not allocate any intervention — the observational protocol does not authorize it. The ID must not encode diagnosis, sex, race, treatment, or a predictable sequence.

7 Export imaging: Topcon → restricted Google Shared Drive

- Select the correct patient and visit in Topcon. Export original/raw data — DICOM when available, otherwise the most complete vendor-supported raw export. Include fundus, OCT, and OCT-A when available.
- Export to the approved local staging folder (C:\SpectOcular_Export_Staging). Let the export finish fully before moving or zipping. Never copy or synchronize the live Topcon database, and never alter files inside the package.
- Name the package with Subject ID, date, modality, device, and eye. Move it to the Shared Drive upload inbox (04_RAW_IMAGING_RESTRICTED / [SiteID] / 00_UPLOAD_INBOX).

8 Verify, file, and close out

- Wait for the Drive sync icon to complete; verify at drive.google.com and compare file size.
- Move to the final subject folder and update the Imaging sheet. Delete the local staging copy **only after** verification — leave the original Topcon study intact.

Stop and ask for help when...

- A signature or date is missing.
- The patient has questions about risks, research use, or withdrawal.
- Imaging would be performed only for research.
- The wrong patient or eye may have been selected.
- An export contains another patient's information.
- The Topcon export fails or appears incomplete.

End-of-encounter standard

No patient leaves until the paper packet is checked. No export is complete until the coordinator verifies it in Google Drive. All outputs are investigational, do not guide care, and are not communicated to participants.

SpectOcular — The Retinal Intelligence Platform

Quick guide derived from SOM-001, WI-001, WI-002, RC-001. Where this guide conflicts with an IRB-approved document, the approved protocol and consents control.

Controlled reference

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