

**OPHTHALMOLOGY CLINICAL RESEARCH UNIT FEE STRUCTURE – 2025-2026:
UT SOUTHWESTERN**

Responsible Department: Ophthalmology
 Clinical Research Unit, Aston Building, 6th Floor
 5303 Harry Hines Blvd., Dallas, TX 75390-8863
 Effective Dates: September 1, 2025
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 Version: 2.0

This document outlines the costs related to Ophthalmology’s involvement but are not billable through EPIC. According to the protocol, the rates listed below may apply. **Please check the study-specific Ophthalmology estimate and PS approval letter for details.**

PROCEDURE COST

All procedures will be billed according to the protocol and clinical trials coverall analysis (CTCA) following Velos research rates. Any CPYs requiring additional research-specific modalities will incur Clinical Research Coordinator (CRC) effort charges, as applicable.

ADMINISTRATIVE FEE LEVEL 1 – OPTHALMOLOGY CRU

(CRC and photographer fee, if applicable. Refer to the Appendix for additional information.)

Description	Unit	Non-Industry Funded Studies	Industry Sponsored Studies
Departmental Start-up Fee (Non-refundable)	One-time	\$106.00	\$160.00
Study Amendment Fee ⁱ	Per Occurrence	\$50.00	\$75.00
Ophthalmology CRU CRC Fee ⁱⁱ	Per Hour	\$55.00	\$75.00
Ophthalmology CRU Photographer Fee ⁱⁱⁱ	Per Hour	\$65.00	\$85.00

ADMINISTRATIVE FEE LEVEL 2 – OPHTHALMOLOGY CRU

(Co-I, CRC and photographer fee, if applicable. Refer to the Appendix for additional information.)

Description	Unit	Non-Industry Funded Studies	Industry Sponsored Studies
Departmental Start-up Fee (Non-refundable)	One-time	\$252.00	\$490.00
Study Amendment Fee ⁱ	Per Occurrence	\$75.00	\$125.00
Co-Investigator (Co-I) Fee	Per Hour	\$125.00	\$175.00
Ophthalmology CRU CRC Fee ⁱⁱ	Per Hour	\$70.00	\$90.00
Ophthalmology CRU Photographer Fee ⁱⁱⁱ	Per Hour	\$100.00	\$130.00

OTHER SERVICES (Applies to Level I and Level II; invoiced if applicable)

Other Ophtha CRU Fees	Unit	Cost
Room/staff/device certification*, ^{iv}	Per CRC time	Invoiceable, as applicable
Data Entry/Source documentation*	Per CRC time	Invoiceable, as applicable
Monitoring visit*	Per CRC time	Invoiceable, as applicable

**Please confirm with your sponsor if this applies to your study.*

APPENDIX

Departmental Start-up Fee Tasks – Level 1

Routine eye exam follows institution's standard of care for eye examination; with standard results reported in EMR. CRC and/or/Photographer fees will be set based on ancillary review and study team discretion.

- Includes reviewing the protocol, ensuring accurate CPT coverage for protocol-required procedures on CTCA, and assessing study feasibility for ophthalmology assessments at Ophthalmology clinic, as applicable.
- Review and communicate study details with the ophthalmology clinic team to ensure awareness of the study, clarify visit requirements, and confirm feasibility for study participation.
- Upload protocol-specific ophthalmology research service fees to Velos for PS approval.
- No additional efforts are required from Ophthalmology clinic or clinical ophthalmic technologists.
- Not necessarily be conducted on same equipment for research study.
- Review and address billing issues as they arise, including ongoing correspondence with the research billing team, Ophthalmology billing team, and the respective study team.

Departmental Start-up Fee Tasks – Level 2

Specialized eye exams, including non-routine assessments, protocol specific assessment gradings, treatment or management plans as required by the protocol, along with any additional source documentation, necessary certifications, and CO-I delegation.

- Includes reviewing the protocol, ensuring accurate CPT coverage for protocol-required procedures on CTCA, and assessing study feasibility for ophthalmology assessments at Ophthalmology CRU, as applicable.
- Review protocol to ensure CRU Ophthalmology procedures are excluded from CTCA, resources are available, and related correspondence.
- Upload detailed protocol-specific Ophthalmology-related budget, service estimates, and performance site (PS)-ancillary approval.
- Ophthalmology CRU-assisted process, correspondence with the sponsor and staff staff, as applicable.
- In-service training for the study team.
- Assist with iLab setup, scheduling requests, and accurate billing processes.
- Troubleshoot iLab billing issues or concerns as they arise.
- Regulatory requirements (as applicable).

i. Study Amendment Fee Tasks (includes protocol amendments that necessitate updates to Ophthalmology assessments in the protocol or imaging manual, determined based on the criteria below):

- Major Changes – Amendments that result in corresponding revisions to the Ophthalmology Fee Budget and may require CRC and/or Photographer re-training or re-certification may incur additional charges. Such amendments include, but are not limited to:
 1. Amendments that introduce substantial changes, such as the addition of ophthalmic procedures or assessments, require re-review of Ophthalmology ancillary services.
 2. Changes to study criteria from Level I to Level 2.
- Minor Changes – Amendments involving minor modifications (e.g., schedule adjustments or administrative updates) will not incur additional charges.

ii. Ophthalmology CRC Tasks

Note: Level 1 – N/A (may vary if Ophthalmology CRU is engaged at the study team’s discretion).	Level I	Level II
Scheduling/Rescheduling via Clinic, no CRC involvement	Yes	N/A, no CRC involvement
Scheduling/Rescheduling via CRU. Priority level scheduling	N/A, no CRC involvement	Yes
CRU scheduling correspondence with the study team	N/A, no CRC involvement	Yes
Documentation – EPIC, per Soc, no additional documentation	N/A, no CRC involvement	Yes
Research-related procedures	N/A, no CRC involvement	Yes
Protocol review synopsis to provider at each visit	N/A, no CRC involvement	Yes
Correspondence with sponsor & study team	N/A, no CRC involvement	Yes
Pre- & post-visit correspondence	N/A, no CRC involvement	Yes
Post-visit physician diagnosis documentation via email	N/A, no CRC involvement	Yes
eCRF documentation	N/A, no CRC involvement	Yes

Departmental Notes – Level 1

- All study-related activities will be managed by the clinic, including but not limited to scheduling, performing research procedures, and Epic documentation.
- Scheduling requests and protocol-specific information, including required provider specialties, shall be communicated by the study team directly to the clinic scheduling team, unless the Ophthalmology CRU is engaged at the discretion of the study team.

Departmental Notes – Level 2

- CRU assistance with priority-based scheduling and re-scheduling.
- Manages appointment correspondence with the research team.
- Maintain documentation in Epic and via email required based on the protocol and study team.
- Conducts research-related procedures as per protocol.
- Provides protocol review synopsis to the provider at each visit.
- Maintains correspondence with the sponsor and study team as needed.
- Facilitate pre- and post-visit correspondence with the study team.
- Provides correspondence on post-visit physician diagnosis to the investigator and study team.
- eCRF documentation, when applicable.
- CRC effort to be billed on a pro-rated basis for tasks outside standard CPT.
- Ophthalmology CO-I fee may be requested when work exceeds standard CPT procedures, including studies with primary ocular endpoints, even if PI is non-Ophthalmology; significant CO-I oversight (care management, imaging review, protocol-driven decisions); sponsor or imaging center interactions (calls, meetings, troubleshooting); review of protocol amendments affecting Ophthalmology assessments, including CRC/staff re-training, CO-I-required trainings, device/room re-certification, and listing on DOA to perform study assessments. CO-I effort already included as % effort on a grant will not incur this fee.

ii. Photographer Tasks (as required by the protocol, beyond tasks covered under the CPT code)

- Reviews the protocol and imaging manual, as applicable.
- Performs research-specific imaging modalities as outlined in the imaging manual and/or protocol.
- Manages correspondence with the sponsor and study team as per protocol.
- Uploads images to the imaging center and addresses queries, if applicable, as required by the sponsor.

iii. Room/Staff/Device certification

Invoicing will be determined by the sponsor's requirements and will reflect the CRC's time and effort for each certification session.

INVOICING AND BILLING

Ophthalmology CRU billing will be processed through iLab. This includes both administrative activities and procedures conducted at the ophthalmology CRU (UTSW Ophthalmology CRU-iLab).

CONTACT INFORMATION

For all communications regarding PSR Ancillary, CRU Fees, Study Procedures, Review & Approvals, and Appointment Requests, please contact:

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For scheduling requests/questions, please email OphthaResearch@utsouthwestern.edu.