

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

Responsible Department: Ophthalmology
 Clinical Research Unit, Aston Building, 6th Floor
 5303 Harry Hines Blvd., Dallas, TX 75390-8863
 Effective Dates: September 1, 2025 – August 31, 2026
 Last Updated:
 Version: 1.0

The costs outlined herein reflect the Ophthalmology clinical research unit’s (CRU) review and feasibility approval for pediatric ophthalmology assessments conducted at the CMC or UTSW Ophthalmology clinics per protocol and are not billable through EPIC. Refer to the study-specific Ophthalmology CRU estimate and PS approval letter in Velos for details.

PROCEDURE COST

All procedures will be billed in accordance with the protocol and the Clinical Trials Coverage Analysis (CTCA), based on Velos research rates. Any CPT codes requiring additional research-specific modalities will be subject to Clinical Research Coordinator (CRC) effort charges, as applicable.

ADMINISTRATIVE FEE LEVEL 1 – OPTHALMOLOGY CRU

(Applies only if CMC [≤ 18 yrs age] is the performance site; refer to the Appendix for additional information.)

Description	Unit	Non-Industry Sponsored Studies <i>Includes IIT’s Internal-Departmental Funded, National Consortium, Federally Funded</i>	Industry Sponsored Studies <i>Includes Private-for-profit</i>
Departmental Start-up Fee (Non-refundable)	One-time	\$106.00	\$160.00
Study Maintenance Fee ⁱ	Per Occurrence	\$50.00	\$75.00

ADMINISTRATIVE FEE LEVEL 2 – OPTHALMOLOGY CRU

(Applies only if CMC [≤ 18 yrs age] is the performance site)

Description	Unit	Non-Industry Sponsored Studies <i>(Includes IIT’s Internal-Departmental Funded, National Consortium, Federally Funded)</i>	Industry Sponsored Studies <i>(Includes Private-for-profit)</i>
Departmental Start-up Fee (Non-refundable)	One-time	\$252.00	\$490.00
Study Maintenance Fee ⁱ	Per Occurrence	\$75.00	\$125.00
Co-Investigator (Co-I) Fee (if applicable. Refer to Appendix for additional information).	Per Hour	\$125.00	\$175.00

ADMINISTRATIVE FEE LEVEL 1 – OPHTHALMOLOGY CRU (Applies only if CMC and UTSW [≥ 18 yrs age] is the performance site. Patients over 12 years may be seen in the Aston Clinic/Ophthalmology CRU with prior approval. Patients 18 years and older will be seen at CMC or UTSW clinics, based on the ophthalmologist’s preference and prior approval. Refer to Appendix for additional information.

Description	Unit	Non-Industry Studies <i>Includes: IIT’s, Internal-Departmental Funded, National Consortium, Federally Funded</i>	Industry Sponsored Studies <i>Includes: Private-for-profit</i>
Departmental Start-up Fee (Non-refundable)	One-time	\$106.00	\$160.00
Study Maintenance fee ⁱ	Per Occurrence	\$50.00	\$75.00
CRC Fee ⁱⁱ	N/A	N/A	N/A
Photographer Fee ⁱⁱⁱ	N/A	N/A	N/A

ADMINISTRATIVE FEE LEVEL 2 – OPHTHALMOLOGY CRU (Applies only if CMC and UTSW [≥ 18 yrs age] is the performance site. Patients over 12 years may be seen in the Aston Clinic/Ophthalmology CRU with prior approval. Patients 18 years and older will be seen at CMC or UTSW clinics, based on the ophthalmologist’s preference and prior approval. Refer to Appendix for additional information.

Description	Unit	Non-Industry Studies <i>Includes: IIT’s, Internal-Departmental Funded, National Consortium, Federally Funded</i>	Industry Sponsored Studies <i>Includes: Private-for-profit</i>
Departmental Start-up Fee (Non-refundable)	One-time	\$252.00	\$490.00
Study Maintenance fee ⁱ	Per Occurrence	\$75.00	\$125.00
Co-Investigator (Co-I) Fee (if applicable. Refer to Appendix for additional information).	Per Hour	\$125.00	\$175.00
Ophtha CRU CRC Fee ⁱⁱ	Per Hour	\$70.00	\$90.00
Ophtha CRU Photographer Fee ⁱⁱⁱ	Per Hour	\$100.00	\$130.00

OTHER SERVICES (will be invoiced only 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.

- Includes reviewing the protocol, ensuring accurate CPT coverage for protocol-required procedures on CTCA and SOA, and assessing study feasibility for ophthalmology assessments at CMC and/or UTSW, as applicable.
- Review and communicate study details with the ophthalmology 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 CRU or CMC 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 SOA, and assessing study feasibility for ophthalmology assessments at CMC and/or UTSW, as applicable.
- Review and communicate study details with the ophthalmology 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.
- Also includes studies where patient care may transfer to UTSW and may or may not involve the Ophthalmology CRU in research visits.
- Review and address billing issues as they arise, including ongoing correspondence with the research billing team, Ophthalmology billing team, and the respective study team.

i. Study Maintenance Fee

- Includes ongoing regulatory support such as protocol amendments, personnel updates, CTCA amendments, and submission of other regulatory documents, as needed.
- Major Protocol Amendments: Amendments that introduce substantial changes (e.g., addition of procedures or assessments) and require re-review of ophthalmology ancillary services may incur additional charges.
- Minor Changes: Amendments involving minor modifications (e.g., schedule adjustments or administrative updates) will not incur any charges.
- Charges may be invoiced, as applicable, if requested by a sponsor or external funding source (e.g., private agency).

ii. Ophthalmology UTSW CRU CRC Tasks

Applicable when CMC research patients are evaluated at the UTSW Ophthalmology CRU, at the discretion of the ophthalmologist.	Level I	Level II
Scheduling/Rescheduling via CRU. Priority level scheduling	N/A, no CRU involvement	Yes
CRU scheduling correspondence with study team	N/A, no CRU involvement	Yes
Documentation – EPIC, per SoC, no additional documentation	N/A, no CRU involvement	Yes
Research-related procedures	N/A, no CRU involvement	Yes
Protocol review synopsis to provider at each visit	N/A, no CRU involvement	Yes
Correspondence with sponsor & study team	N/A, no CRU involvement	Yes
Pre- & post- visit correspondence	N/A, no CRU involvement	Yes
Post-visit physician diagnosis documentation via email	N/A, no CRU involvement	Yes
eCRF documentation	N/A, no CRU involvement	Yes

CRU CRC Level 1 (Applies only if UTSW \geq 18 yrs age] is the performance site)

- All study-related activities will be managed by the clinic, including but not limited to scheduling, performing research procedures, and Epic documentation.

CRU CRC Level 2 (UTSW Ophthalmology CRU will be included in all scheduling correspondence.)

- Ophthalmology CRU assistance with priority-based scheduling and re-scheduling for research billable visits.
- 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.

iii. Ophthalmology CRU Photographer Tasks (as required by the protocol, beyond CPT-covered tasks. Note that this is applicable when CMC research patients are evaluated at the UTSW Ophthalmology CRU at the discretion of the ophthalmologist.)

- 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 address queries, if applicable, as required by the sponsor.

iv. Room/Staff/Device certification

- Invoicing shall be determined in accordance with the sponsor's and study team's requirements and shall reflect the CRC's time and effort associated with each certification session.

INVOICING AND BILLING

Ophthalmology CRU billing will be processed through iLab. This includes both administrative activities and procedures billable to research conducted at CMC or UTSW Ophthalmology CRU/Clinic.

CONTACT INFORMATION FOR STUDY FEASIBILITY, CRU FEES, AND APPOINTMENT REQUESTS

For all communications regarding study feasibility, Ophthalmology CRU fees, and appointment scheduling, please contact:

Asha Varghese, Clinical Research Manager, Asha.Varghese@UTSouthwestern.edu, phone: 214-654-8037

Satish Veerla, Project Manager of Clinical Research, Satish.Veerla@UTSouthwestern.edu, phone: 214-645-9199

Note: All emails regarding these matters should include both contacts above to ensure proper tracking and response.