

Regulatory Fees (FY 2027)

| Institutional Research¹ <i>(research sponsored by UCCCC investigator and conducted at a <u>single site</u> and those sponsored by other academic sites)</i> | | | | |
|--|---|------------------------|--|--|
| | | Start-up/Year 1 | Annual Maintenance | |
| Interventional Trials | | \$3,200 | \$1,280 | |
| Observational or Ancillary/Correlative Research | | \$500 | \$500 | |
| Chart Review or Other Research (Registries, Tissue Bank, etc.) | | \$500 | \$500 | |
| Multi-Site Institutional Research¹ <i>(multi-site research sponsored by UCCCC investigator and/or coordinated by the UCCCC CTSO)</i> | | | | |
| | | Start-up/Year 1 | Annual Maintenance | |
| Interventional Trials | | \$5,000 | \$2,000 | |
| Observational or Ancillary/Correlative Research | | \$1,500 | \$500 | |
| Chart Review or Other Research (Registries, Tissue Bank, etc.) | | \$500 | \$500 | |
| Non Commercial Research¹ <i>(research sponsored by philanthropic organizations)</i> | | | | |
| | | Start-up/Year 1 | Annual Maintenance | |
| Interventional Trials | | \$5,000 | \$2,000 | |
| Observational or Ancillary/Correlative Research | | \$1,500 | \$500 | |
| Chart Review or Other Research (Registries, Tissue Bank, etc.) | | \$500 | \$500 | |
| Industrial Research <i>(research sponsored by pharmaceutical, medical device company, or other for profit organizations)</i> | | | | |
| Interventional Trials | | | | |
| | Start-up | \$15,000 | Standard Close-out | \$2,000 |
| | Start-up Master Protocol ² | \$15,000 | Amendment ³ | \$2,500 |
| | Start-up Master Protocol per Additional Cohort ⁴ | \$2,500 | Post Termination Reconciliation ⁵ | \$2,000 |
| | Year 1/Annual Maintenance | \$8,000 | IBC Fee ⁶ | \$3,000 |
| | Year 1/Annual Maintenance Master Protocol ² | \$8,000 | IND Safety Report Fee | \$50 |
| | Annual Maintenance Master Protocol per Additional Cohort | \$2,500 | Early Withdrawal or Termination ⁷ | Initial Consent: \$1,500 PRMC: \$3,000 PRMC+IRB: \$6,000 IRB Pre-review: \$10,500 IRB+Essential Docs: \$14,250 IRB Approved: \$15,000 |



AT THE FOREFRONT

UChicago Medicine

Comprehensive Cancer Center



A Cancer Center Designated by the National Cancer Institute

| Observational or Ancillary/Correlative Research | | | |
|--|----------|---------------------------------------|----------|
| Start-up | \$7,500 | Amendment | \$2,500 |
| Year 1/Annual Maintenance | \$2,200 | Close-out | \$2,000 |
| Chart Review or Other Research (Registries, Tissue Bank, etc.) | | | |
| Start-up | \$3,500 | Close-out | \$1,500 |
| Year 1/Annual Maintenance | \$1,500 | | |
| Non-Interventional Multi-Site Trials⁸ | | | |
| Multi-Site Coordination (1-10 Trials) | \$14,500 | Multi-Site Coordination (1-40 Trials) | \$58,000 |
| Multi-Site Coordination (1-20 Trials) | \$29,000 | Multi-Site Coordination (1-50 Trials) | \$72,500 |
| Multi-Site Coordination (1-30 Trials) | \$43,500 | | |
| Legend | | | |
| <ol style="list-style-type: none"> 1. Cancer Center subsidies are for a maximum of \$3,200 for Start-up / Year 1 and \$1,280 for Annual Maintenance. The PI/MDT/Program is responsible for paying the balance of the charge if applicable. 2. Invoiceable fee charged for clinical trials designed to evaluate more than one intervention and/or more than one cancer type within the same clinical trial. This fee includes the first two cohorts, with each additional cohort charged \$2,500 thereafter. 3. Sponsor-initiated protocol amendments will be billed an amendment fee. This includes submission and review of ancillary protocol documents that change the conduct of the study at our center (e.g. protocol clarification memos, dose modification guidance documents, etc.). 4. Invoiceable fee per cohort, after the included initial two cohorts, on Industry-sponsored Master Protocol trials. 5. Invoiceable fee charged for close-out visits that require re-monitoring and reconciliation of site investigator file, collection of previously provided historical documents for sponsor master file, and/or other requests that are outside of the normal trial close-out activities (e.g. submission of historical documents to IRB). 6. Invoiceable fee charged during initial review and any time IBC re-review is required. 7. Invoiceable fee charged any time a sponsor terminates or withdraws a study early. Fee structure is based on invoiceable effort timepoints on the respective trial 8. Invoiceable fee charged for projects where the CTSO Regulatory team is asked to act as the internal clinical research organization for large multi-site projects and which do not utilize the monitoring services of the CTSO Quality Unit. | | | |