AT THE FOREFRONT
UChicagoMedicine
Comprehensive Cancer Center

NCI Comprehensive Cancer Center
A Cancer Center Designated by the National Cancer Institute

CTSO Regulatory Fees - FY2024
Effective Date: July 1, 2023

Institutional Research[1] *(research sponsored by UCCCC investigator and conducted at a single site and those sponsored by other academic sites)*		
	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 Research[1] *(multi-site research sponsored by UCCCC investigator and/or coordinated by the UCCCC CTSO)*		
	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 Research[1] *(research sponsored by philanthropic organizations)*		
	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 *(research sponsored by pharmaceutical, medical device company, or other for profit organizations)*			
Interventional Trials			
Start-up/Year 1	$15,000	Standard Close-out	$2,000
Annual Maintenance	$8,000	Complex Close-out[3]	$8,000
Complex Amendment[2]	$5,000	Post Termination Reconciliation[4]	$2,000
IBC Fee	$3,000		
Observational or Ancillary/Correlative Research			
Start-up/Year 1	$7,500	Close-out	$2,000
Annual Maintenance	$2,200	Complex Amendment[2]	$5,000
Chart Review or Other Research (Registries, Tissue Bank, etc.)			
Start-up/Year 1	$3,500	Close-out	$1,500
Annual Maintenance	$1,500		

Legend

1. *Cancer Center subsidies are for a maximum of $3200 for Start-up / Year 1 and $1280 for Annual Maintenance. The PI/program is responsible for paying the balance of the charge if applicable.*
2. *Sponsor-initiated amendments that involve a redesign of trial, addition of study arms, etc and which*

require PRMC (scientific) re-review prior to implementation.

3. *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visits that require re-monitoring and reconciliation of site investigator file, collection of previously provided historical documents for sponsor master file, and/or other requests that are outside of the normal trial close-out activities (e.g. submission of historical documents to IRB).*
4. *Invoiceable fee charged for requests for additional documents or information more than 180 calendar days after trial close-out visit.*

Definitions

Industrial	Research funded, sponsored, and coordinated by a pharmaceutical, medical device and/or biotechnology company or other for-profit organization. This includes consortium research that are industry-initiated but being negotiated through the consortium master clinical trial agreements.
Other Institutional	Research sponsored by an investigator at another academic organization or hospital/clinical practice in which the UCCCC is participating. This includes consortium trials that are initiated by an investigator at another site and being negotiated through the consortium master clinical trial agreements (e.g. TBCRC, PCCTC) and which are not industry-initiated. This includes research funded by federal or other grants if another academic organization is the regulatory sponsor/coordinating center.
Non Commercial	Research sponsored by philanthropic charities, foundations, or other public-private partnerships.
PI Sponsored	Research sponsored by UCCCC investigator. This includes research funded by federal or other grants if UCCCC is the regulatory sponsor/coordinating center.
Multi-site/ UC Coordinating Center	Multi-site research sponsored by an investigator at the UCCCC or studies from another academic organization or hospital/clinical practice in which the UCCCC is acting as the coordinating center for regulatory oversight. This includes consortium research that is initiated by an investigator at the UCCCC and being negotiated through the consortium master clinical trial agreements (e.g. TBCRC, PCCTC).
Interventional	Clinical Trial in which participants are prospectively assigned to receive a specific intervention (e.g. diagnostic, drug, device, behavioral, or other interventions).
Non-Interventional	Research with no required prospective interventions (i.e. sample collection, survey/questionnaire, observational, prospective data collection only studies).
Expanded Access	Treatment protocols whose only purpose is to provide access to experimental agent(s) or device(s) outside of a clinical trial. May also be referred to as rollover treatment or compassionate use. Protocols which include a research objective/aim will be charged at the interventional rate.

Other	All other human subjects research which does not fall into category above.
Complex Amendment	Sponsor-initiated amendments that required re-review by PRMC including addition of new study arms/cohorts, additional of new drug/device/other intervention, removal or addition of randomization procedures, addition of minor subjects.

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Subsidy FAQ

Question	Answer
How are subsidies determined?	Subsidies are determined based on the score given to the protocol by the PRMC at initial review or continuing (annual) review. The PRMC score is based on the Committee's determination of the innovativeness, overall scientific merit and importance of the trial and, at the time of continuing review, by the Committee's assessment of study progress, particularly in terms of accrual.
How do I request a subsidy?	You do not have to do anything. All subsidy eligible trials will be automatically reviewed and scored by the PRMC. It is the PI's responsibility to ensure that the submission documentation submitted for initial PRMC review has the appropriate study type and classification noted. Studies that are not scored due to errors in the submission documentation will NOT be scored retrospectively. In these cases the PI is responsible for all applicable CTSO Regulatory costs as noted in this document.
How will I know if I was awarded a subsidy?	Your PRMC initial approval or PRMC Continuing Review notification will indicate the study's score and what that means in terms of a subsidy. A score of 1 indicates that a subsidy has been awarded based on the merit of the protocol. A score 2 indicates that a subsidy was not awarded.
What happens if I am not awarded a subsidy?	If you are not awarded a subsidy either at time of Initial or annual PRMC review you will be charged based on our current fee structure.
If I did not get a subsidy at the intial PRMC review, can I still get one for annual fees?	No - subsidies are based on scientific merit. A study that did not qualify at initial review will not be eligible for annual subsidies. However, if new scientific data have emerged that strengthen the study rationale, you can provide these data at the time you are billed and they will be reviewed by PRMS Executive Committee to determine if a subsidy is appropriate.
What if I only want to move forward with the trial if I am awarded a subsidy?	If you do NOT want to be liable for the CTSO Regulatory fee if you do not receive a subsidy, you must inform your assigned regulatory contact at the time of the initial PRMC submission. The assigned regulatory contact will then pause all other start-up activities until the PRMC has made its determination.

Can I dispute the PRMC's decision about a subsidy?	No. You should provide all relevant information at the time of submission, throughout the life of the study (e.g. ensuring CTMS is up to date), and/or at the time you are queried by PRMC as part of the continuing review process . These decisions are made by Committees with wide representation. You should feel free to volunteer to sit on the PRMC if you would like to be more involved.