CCTO Fee Structure
Revised: May 2020
Effective Date: July 1, 2020

Study Type	Study Classification	Charge to PI/Program		Eligible for Subsidy^
		Start-up/ Year 1	Annual Maintenance	
Industrial	Therapeutic/Interventional	$8000	$3200	No
	Non Interventional	$4000	$1600	No
	Expanded Access OR Retrospective Data Collection	$1500	$500	No
Institutional OR Externally Peer Reviewed	Therapeutic/Interventional	$3200	$1280	Yes
	Non Interventional OR Expanded Access OR Retrospective Data Collection	$500	$0	Yes
Non Commercial OR Multi-site/ UC Coordinating Center	Therapeutic/Interventional	$5000	$2000	Yes
	Non Interventional	$1500	$500	Yes
	Expanded Access OR Retrospective Data Collection	$500	$0	Yes

^ 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.

Definitions:

Industrial	Trials funded, sponsored, and coordinated by a pharmaceutical, medical device and/or biotechnology company or other for-profit organization. This includes consortium trials that are industry-initiated but being negotiated through the consortium master clinical trial agreements.
Institutional	Single-center trials sponsored by an investigator at the UCCCC or studies from 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.
Externally Peer-Reviewed	Trials funded and reviewed as part of peer-review funding agencies. Eligible organizations are those listed in the CCSG data table guide (https://cancercenters.cancer.gov/GrantsFunding/DataGuide#dt4)
Non Commercial	Trials sponsored by philanthropic charities, foundations, or other public-private partnerships. All such organizations must be reviewed and approved by UCCCC leadership. Trials sponsored by organizations not approved by UCCCC will be charged the industrial rate unless they meet the definition of an institutional, externally peer-reviewed, or national trial. The list of currently approved organizations are posted on the UCCCC website. If your study is sponsored by an organization not on this approved list, a request should be sent to the CRAC administrator, Amber Burnett, prior to CTRC submission. A rationale for why this sponsor meets the above-definition should be included. The request will be reviewed by the UCCCC leadership and a determination made as to whether or not the sponsor organization qualifies as eligible for subsidy.
Multi-site/ UC Coordinating Center	Multi-site trials 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 trials that are initiated by an investigator at the UCCCC and being negotiated through the consortium master clinical trial agreements (e.g. TBCRC, PCCTC).
Interventional	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.
Retrospective Data Collection	Human subjects research using existing records and which does not require patient consent.

FAQ

1. **How are subsidies determined?** Subsidies are determined based on the score given to the protocol by the CTRC at initial review or by the SAM at annual review. The CTRC score is based on the Committee's determination of the innovativeness, overall scientific merit and importance of the trial and, at the time of annual SAM review, by the Committee's assessment of study progress, particularly in terms of accrual.

2. **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 CTRC and/or SAM.

   It is the PI's responsibility to ensure that the submission documentation submitted for initial CTRC 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 CCTO costs as noted above.

3. **How will I know if I was awarded a subsidy?** Your CTRC approval or SAM follow-up email 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.

4. **What happens if I am not awarded a subsidy**? If you are not awarded a subsidy either at time of CTRC or SAM review you will be charged based on our current fee structure.

5. **If I did not get a subsidy at the CTRC, can I still get one for annual fees (SAM)?** 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 CRAC to determine if a subsidy is appropriate.

6. **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 CCTO fee if you do not receive a subsidy, you must inform your Regulatory Manager at the time of CTRC submission. The Regulatory Manager will then hold the protocol (not submit to the IRB) until the CTRC has made its determination.

7. **Can I dispute the CTRC or SAM's decision about a subsidy?** No. You should provide all relevant information at the time of submission, or at the time you are queried by SAM. These decisions are made by Committees with wide representation. You should feel free to volunteer to sit on the CTRC or SAM if you would like to be more involved.