Stanford MEDICINE | Cancer Clinical Trials Office
Stanford Cancer Institute

# Stanford Cancer Clinical Trials Office
# Industry Fee Descriptions

## Administrative Fees

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| **Cancer Clinical Trials Office (CCTO) Administrative Study Start-up** | A one-time, non-refundable, non-negotiable administrative start-up fee is charged for all industry-sponsored trials. This fee includes but is not limited to the following items:<br>• Pre-study document preparations, completion of critical study documents and sponsor correspondence<br>• Protocol review by principal investigator and research personnel<br>• Informed consent form review, revision and negotiation<br>• Preparation and submission of regulatory documents for sponsor and site files; preparation of submission of study to the Institutional Review Board, and associated correspondence<br>• Preparation and submission of protocol to Stanford Committees for review, including but not limited to, Scientific Review Committee, Radiation Safety Committee, Biosafety Committee, and Clinical Translational Research Unit<br>• Budget preparation and negotiation by investigator and research personnel<br>• Administrative Fees including protocol review, site selection visit, site initiation visit and other training, budget preparation and negotiation<br>• Study information technology set-up in Stanford clinical trial management system and posting of study on Stanford website<br>• Time and resources to host the pre-study site qualification visit and the site initiation visit |
| **SHC Coverage Analysis Fee** | Fee to cover the formal review of study documentation and Medicare billing rules to determine which items and services performed as a part of a clinical research study may be billed to the research participant's insurance, and which items must be paid for by the study sponsor. This fee is charged by the Stanford Hospital for this service performed. |
| **Cancer Cell Therapy (CCT)** | Applicable to studies including apheresis.<br><br>Fee for services related to management of apheresis study procedures. This fee is charged at each visit that apheresis is performed. |
| **Cell Therapy Facility (CTF) fee** | Applicable to studies including cell therapy. |

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| | Fee for services related to management of cell therapy product management carried out by Stanford Cell Therapy Facility, Cell Pharmacy for both Stanford Health Care and Lucile Packard Children's Hospital, including the following activities:<br>.<br>• All Cellular Products that leave or enter the facility to support clinical trials under an investigational new drug (IND) application are required to pass through the Cell Pharmacy team.<br>• The Cell Pharmacy is responsible for making sure that the outgoing products are collected from the correct donor and shipped to the correct external site for processing.<br>• Once processing has been completed, the Cell Pharmacy team receives the incoming product, stores the product in a controlled environment, performs any processing that is required prior to infusion (e.g. thaw) and then ensures the product is delivered bedside for infusion to the correct patient.<br>• CTF processing may include but not limited to thawing, washing, dilution, addition of other reagents to the bag of cells.<br>• Additional hours – This is provided for one technician per hour to cover additional work over and above what is originally requested e.g. create reports, attend extra meetings, etc. This rate allows CTF to charge for "Out of Scope Activities"<br><br>Fees associated with services provided by CTF are NON-NEGOTIABLE. |
| **Lucile Packard Children's Hospital (LPCH) Investigational Drug Service (IDS) Research Pharmacy set-up fee** | The Lucile Packard Children's Hospital (LPCH) Investigational Drug Service (IDS) charges a one-time, non-negotiable startup fee for all clinical trials sponsored by industry.<br><br>The fee is charged to reimburse LPCH Department of Pharmacy for the following activities:<br><br>• Participation in the site initiation visit<br>• Protocol review<br>• Protocol validation<br>• Protocol entry into electronic drug accountability software<br>• Formulating IND product information sheets for the Oncology pharmacists training and attestations<br>• Setting up the IND binder (includes product information sheet, IRB approval letter, enrolled patient list, paper DARF when necessary, packaging receipts, correspondences, enrollments and consents)<br>• Procuring the agent<br>• Drug Receipt (which includes documenting the receipt on database system, labelling the IND product, setting up storage space/totes for the product) |

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| | • Acknowledgment/documentation of the receipt of the agent on sponsor site<br>• Coordinating to generate a drug record number, Intravenous (IV) agent labels and/or Outpatient Pharmacy Rx labels for (oral agents)<br>• Roadmap formulation and/or review for the Clinical Research Associate (CRA)<br><br>This fee is based on an estimate of the time and costs (over and above preparation and dispensing a prescription) required to set-up and service an investigational protocol.<br><br>These fees are not part of the investigator's compensation and are transferred from the investigator's study account directly to the Department of Pharmacy accounts. |
| **LPCH Investigational Drug Service (IDS) Research Pharmacy annual fee** | For studies that require LPCH IDS, an annual, non-negotiable administration fee is charged based on nearest calendar quarter end date. This fee, which is charged regardless of protocol activity and drug inventory, continues until pharmacy closeout visit occurs and post drug destruction or return is completed. This fee includes (but not limited to) the following:<br><br>• Monthly inventory of the agent<br>• Re-ordering of inventory<br>• Monthly review / audit of drug accountability records for appropriateness of dispensation and administration<br>• Quarantine agent when expiration date approaches<br>• Correspondences with sponsor for drug destruction<br>• Temperature monitoring (calibration certificates, follow-up on temperature deviations with engineering and the sponsor)<br>• Local destruction<br>• Coordinate drug returns<br>• Annual training of pharmacists for IDS dispensation function<br>• Updating IDS information sheets to capture all of the protocol amendment requirements.<br>• Management of monitor visits<br><br>The time commitment can vary based on the number of years the study will be active, the number of monitor visits, number of patients to be enrolled at site, along with other factors. The costs can vary based on supplies that must be provided by the pharmacy for preparation of drug, the costs of maintenance of a refrigerator or freezer, and the cost of drug destruction. These fees are not part of the investigator's compensation and are transferred from the |

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| | investigator's study account directly to the Department of Pharmacy accounts. |
| **Stanford Health Care (SHC) Investigational Drug Service (IDS) Research Pharmacy set-up fee** | The Stanford Health Care (SHC) Investigational Drug Service (IDS) charges a one-time, non-negotiable startup fee for all clinical trials sponsored by industry.<br><br>The fee is charged to reimburse the SHC Department of Pharmacy for the following activities:<br><br>• Review of study materials for research pharmacy requirements<br>• Participation in Site Qualification Visit and Site Initiation Visit meetings with sponsor/investigator and staff to review protocol, storage, drug preparation, drug accountability, and labeling requirements.<br>• Preparation of the background information about the drug as well as the dispensing procedures for pharmacy staff<br>• Build study in inventory management database<br><br>This fee is based on an estimate of the time and costs (over and above preparation and dispensing a prescription) required to set-up and service an investigational protocol.<br><br>These fees are not part of the investigator's compensation and are transferred from the investigator's study account directly to the Department of Pharmacy accounts. |
| **SHC Investigational Drug Service (IDS) Research Pharmacy annual fee** | For studies that require Investigational Drug Service (IDS), an annual, non-negotiable administration fee is charged yearly based on first shipment receipt. This fee which is charged regardless of protocol activity and drug inventory continues until pharmacy closeout visit occurs, and includes the following:<br>• Inventory storage<br>• Facilitation of study monitor visits<br>• Study drug return or disposal<br>• Ordering, receiving, and properly storing drug supplies and patient returns<br>• Reconciliation of Drug Accountability Records<br><br>The time commitment can vary based on the number of years the study will be active, the number of monitor visits, number of patients to be enrolled at site, along with other factors. The costs can vary based on supplies that must be provided by the pharmacy for preparation of drug, the costs of maintenance of a refrigerator or freezer, and the cost of drug destruction. These fees are not part of the investigator's compensation and are transferred from the |

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| | investigator's study account directly to the Department of Pharmacy accounts. |
| **Archiving/Document storage/per site, one-time** | This one-time fee covers the long-term storage of research records in accordance with federal, local and study contract requirements. |
| **Food and Drug Administration (FDA) or Sponsor audit (not for cause) per day, per staff member** | Fee for activities performed to support a site FDA inspection include (but not limited to) the following:<br>• Participate in entrance and exit meetings with FDA inspector by applicable parties including the Principal Investigator, IRB representative, University Legal representative, leadership from Cancer Clinical Trials Office and others, as appropriate<br>• Facilitate all activities of the inspection proceedings by meeting requests of the inspector for source data on site, in storage, from the study sponsor or from other sources. This may include navigation of the electronic medical record for the inspector. Provide all copies of source as requested by the inspector either in paper or electronic. The lead study coordinator and a scribe are dedicated to the inspection and is either with the inspector or proximal to the inspector for the duration of the inspection and for all hours that the inspector is on site to ensure all inquiries are responded to in a timely manner. Other staff members support the 2 dedicated staff members, as appropriate.<br>• Conduct regular meetings with the Principal Investigator and FDA inspector, typically daily, to respond to any questions arising from the inspection.<br>• Provide regular reports on the proceedings of the inspection to the study sponsor, typically daily but may be more frequent.<br>• Inspections typically last 4 -5 business days.<br>• This is a non-negotiable fee. |
| **Informed Consent Translation (ICF) fee** | Fee for written translation of the study-specific informed consent form into another language. |
| **Interpretation fee** | Fee for interpreter services for non-English-speaking or non-verbal research subjects. This service is provided by the hospitals.<br>• Minimum charge is two hours per service. |
| **Institutional Review Board (IRB) Initial Review Fee** | This initial review is a one-time, non-refundable fee due upon initial Stanford IRB approval. Fee also applies to studies using a single IRB (sIRB).<br>• Confirmation of the fees associated with the conduct of Industry sponsored Clinical Trials at Stanford University. |

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| | • These fees are only applicable to industry sponsored clinical trials, including those reviewed by an sIRB (the IRB of another institution, organization, or an independent IRB).<br>• Stanford's IRB bears responsibility for the local conduct of sIRB studies, managing reliance agreements, handling study specific issues, managing noncompliance and unanticipated problems, ensuring training, and study monitoring. |
| **IRB Protocol Renewal (yearly) Fee** | Continuing Review fee for each annual Stanford IRB review<br>• Fee for preparation, submission and management of IRB continuing review of the study.<br>• Fee also applies to studies using a central IRB. |
| **IRB Protocol Renewal Document Preparation fee** | Applicable should the protocol be amended /revised and therefore requiring a submission to the IRB for review and approval. This is an administrative fee. |
| **IRB Modification/ Revision Document Preparation fee (Non-Complex)** | Administrative fee charged for preparation and management of the IRB submission and review related to a **non-complex** study modification or revision. |
| **IRB Modification/Revision Document Preparation fee (Complex)** | Administrative fee charged for preparation and management of the IRB submission and review related to a **complex** study modification or revision.<br>• Complex modification is defined as requiring **2 or more** additional study arms or cohorts. |
| **Clinical Trial Budget Revision fee / Required by contract amendment (Non-Complex)** | Administrative fee charged for preparation and negotiation of **non-complex** protocol amendment budget revisions. |
| **Clinical Trial Budget Revision fee / Required by contract amendment (Complex)** | Administrative fee charged for preparation and negotiation of **complex** protocol amendment budget revisions.<br>• Complex modification is defined as requiring **2 or more** additional study arms or cohorts. |
| **Clinical and Translational Research Unit (CTRU) General Study Set up and Maintenance** | The Clinical and Translational Research Unit (CTRU) provides clinical and lab services for Stanford School of Medicine.<br><br>Additional detailed information related to the CTRU is provided below. CTRU charges all industry studies an administrative fee. This fee covers administrative review costs associated with processing new studies. This is a one-time charge inclusive of applicable overhead. |
| **IND Safety Report Processing and/or Submission to IRB (includes retention),** | Fee for effort of the Principal Investigator, Study Coordinator and Clinical Trials Office staff for the following activities:<br>• Review of report<br>• Processing and documentation of report<br>• Retention and storage of report |

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| **initial and follow-up report fee** | • IRB submission, as appropriate<br><br>All submission forms of the IND Safety Reports (e.g.: hard copy, CDs, web-based portal) are charged the same fee. |
| **Pre-Screening Logs, yearly fee** | Yearly fee for sponsor-required submission of screening and pre-screening logs/information on a regular basis. This fee is invoiced based on study open date. |
| **Study closeout fee** | Fee for closeout of the study at Stanford including the following activities:<br>• Final review of consent forms and remaining clinical research data including outstanding completion of all data queries<br>• Confirm IRB closure and documentation of study completion within local institution<br>• Documentation of end of study for participants in progress note<br>• Discussion of SAE tracking post study and ongoing safety communication<br>• Discuss retention of study records and storage plan. Verify records will be available to audit according to sponsor requirements<br>• Verify destruction / return of study agents and materials and completion of drug accountability logs.<br><br>Study close out includes participation of Protocol Director and Study Coordinator, and may require 4-6 hours for completion at in-person visit from sponsor. Additional time may be required by clinical trials office regulatory staff for internal trial closure. |
| **Subject Re-consenting Fee** | Fee related to the re-consenting process when study team obtains and documents the subject's decision about continuation on the study based on new information. The re-consenting process is time intensive and is not built into the per-patient fee. |
| **Serious Adverse Event (SAE) fee – per occurrence** | Fee covers the effort of the principal investigator and research staff to collect all relevant source information, document, review, and report the SAE to the study sponsor and to the Stanford Cancer Institute Data and Safety Monitoring Committee. Substantial effort is required to ensure accurate and complete information is provided for the event reporting that is above and beyond the standard effort for the study conduct. |
| **Monitoring Visit, per day per Monitor** | Fee covers the effort of research staff members to adequately prepare for and support a monitoring visit.<br>• Study personnel ensures current log and submissions of safety reports, updated regulatory binders and current patient data entered on Case Report Form (CRFs) in database. |

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| | • Research staff is also expected to be present during the monitoring visit.<br>This effort is not covered by the Sponsor in the per-patient budget. |
| **Change in Sponsor Monitor Personnel** | Fee covers the extensive time effort of research staff members to support changes in industry study monitors including the following orientation to our site:<br>• Stanford policies and procedures.<br>• Study chart organization<br>• Process for scheduling of monitoring visits including research pharmacy<br>• Logistics of facilities and equipment available to monitors<br>• Subject-specific information and prior monitoring |
| **Change in Contract Research Organization (CRO) Fee** | Fee covers extensive time effort required of research staff members to facilitate changes in the contract research organization during the conduct of the study. Change in CRO during the conduct of the study requires extensive effort that is above and beyond the normal course of study conduct with examples of effort related to re-monitoring, extensive query generation, budget/contract modification, along with orientation all relevant CRO staff members according to the "change in sponsor monitor personnel" category noted above. |
| **Retrospective data entry for additional data field added to CRFs during conduct of the study, per data field** | Fee covers additional effort required to transcribe data for additional data fields added to the case report form (CRF) during the conduct of the study which requires retrospective review of the source documents to find these new data points that have been requested by the sponsor and enter them on the CRF. |
| **Study Specific Tumor Measurements** | Fee covers the radiologist effort to perform the following activities related to study-specific tumor measures:<br>• Quantitative measurements on target lesions<br>• Reporting on non-target lesions<br>• Comparing results with the prior response assessment<br>• Filling out a lesion tracking sheet to serve as the source document for the study<br><br>Fee for study-specific tumor measures (e.g., RECIST) is NOT part of the Principal Investigator's (PI) compensation. |
| **Copy of Imaging, per time point, per patient** | Fee charged to obtain copy of the scans and coordinator effort to retrieve and submit the scans to the study sponsor. |

## Stanford Clinical and Translational Research Unit (CTRU)

The CTRU is a primary backbone for accelerating the translation of bedside diagnostics and treatments and advancing research technologies into clinical applications. The center is at the frontier of precision health efforts across the research community. On average, the center is supporting over 350 clinical research studies annually across more than 200 faculty members. The studies stretch across multiple medical disciplines and many are first-in-human trials, with novel therapies that have been discovered and developed at Stanford. The CTRU clinical team consists of highly-specialized research nurses and other medical professionals to support these advanced human subject trials. The laboratory personnel are set up to handle high-volume, longitudinal studies and disease registries that require advanced isolation and distribution of various biofluid and tissue specimens.

Please visit http://med.stanford.edu/ctru.html for additional information.

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| **Clinical and Translational Research Unit (CTRU) 0.5-hour adverse reaction management** | Fee for management of adverse reactions including registered nurse (RN) care, medication administration emergency supplies (for IV, oxygen, etc.), lab draws, electrocardiogram (ECG), frequent vital signs, assessment and documentation of participant's status throughout the event.<br>• Fee applies, regardless of participant's condition, for the duration that additional emergency management orders are being implemented.<br>• Fee is billed in 30 minute increments. |
| **CTRU Hour ancillary labor fee - Clinical** | Fee charged for clinical services performed under Registered Nursing (RN) care / supervision. Fee applies to study-specific requests that are not defined in the current CTRU catalog. Fee is charged on an hourly basis for labor only. |
| **CTRU off hours processing add-on fee** | Fee charged for sample processing on weekdays on or after 5:30PM, or on weekends. Fee is charged on an hourly basis for labor only. |
| **CTRU Ad-hoc Processing (Late notice)** | Fee charged for sample processing on weekdays without a 48 hour advance notice or on the weekends without 2-week advance notice.<br>• Fee is add on to the normal sample processing fee.<br>• Fee is billed on an hourly basis for labor only. |
| **CTRU Reagent Storage Annual Fee** | Fee for storing study reagents. This annual fee is charged for each reagent stored. |

## Patient-Related Fees

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| **Screening Failure** | Fee for screening patients who are deemed not eligible for participation in the study, representing the effort and procedure charges required to assess eligibility.<br>• Billed at the rate of the negotiated screening visit fee plus applicable invoiceable items. |
| **Unscheduled Visit** | Fee for patient visit outside the scheduled study visits in the protocol schedule of events (e.g., adverse event assessment). |

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| **Procedures and Tests completed by hospitals** | The rates being budgeted at this time are set by the hospitals. The requested payments for these services are not part of the Principal Investigator's compensation.<br>All prices for lab / procedures completed at the hospitals are NON-NEGOTIABLE. |
| **Patient Travel** | Reimbursement of travel and lodging to cover applicable expenses related to study visits and assessments.<br>• Lodging (per night)<br>• Meals (by receipt)<br>• Parking (per day)<br>• Bridge/freeway tolls<br>• Personal auto usage (per mile)<br>• Other transportation costs |

Last Updated: June 2019