CHRISTUS INSTITUTE FOR INNOVATION & ADVANCED CLINICAL CARE
ADMINISTRATIVE CHARGE MASTER

Effective Date: July 1, 2019

Institutional Review Board Fees

TYPE OF REVIEW/SERVICE	DESCRIPTION IMPORTANT: The following fees may be applicable in the event that a study and/or study documents are retracted (by client) prior to a scheduled or unscheduled meeting/review, if the IRB members have completed pre-review of the study document(s).	FEES for CHRISTUS STUDIES	FEES for AFFILIATED STUDIES
Initial Review (Full Board)	Review of New Study Application to include as applicable, protocol and amendment(s), Investigator Brochure, package insert, investigator CV, training, and qualifications, subject recruitment materials, informed consent form(s) to ensure inclusion of institutional Catholic Directive language, use & disclosure of PHI, and applicable local context issues, etc. This fee covers the preparatory work as well as initial review by the CHRISTUS Health IRB office, Chair and IRB panel at a convened meeting. It also includes reviews for regulatory compliance, privacy provisions, and information management.	$2,500	N/A
Initial Review (Expedited/Exempt)	Review of research projects determined to be exempt from IRB oversight or allowed for expedited approval. Review New Study Application to include as applicable, protocol and amendment(s), Investigator Brochure, package insert, investigator CV, training, and qualifications, subject recruitment materials, informed consent form(s) to ensure inclusion of institutional Catholic Directive language, use & disclosure of PHI, and applicable local context issues, etc. This fee covers the preparatory work as well as initial review by the CHRISTUS Health IRB office, Chair and IRB panel. It also includes reviews for regulatory compliance, privacy provisions, and information management.	$1,250	N/A
Priority Review (Full Board)	Full-board review specially requested by study sponsor at times other than regularly scheduled meetings, including the initial review of a new study, continuing review, protocol amendment, etc.	$500 (add-on)	N/A
Continuing Review (As Needed)	Review of Continuing Review Application to include as applicable, protocol and amendments, informed consent form(s), Investigator Brochure, package insert, Investigator CV, training, and qualifications, adverse events, site visits, and significant protocol deviations not previously reviewed. This fee is as needed and at least Annually.	$1,000	N/A
Major Amendment Review	Full Board Review requiring convened meeting	$750	N/A
Minor Amendment Review	Expedited review not requiring convened meeting	$250	N/A

Institutional Review Board Fees (cont'd)

TYPE OF REVIEW/SERVICE	DESCRIPTION IMPORTANT: The following fees may be applicable in the event that a study and/or study documents are retracted (by client) prior to a scheduled or unscheduled meeting/review, if the IRB members have completed pre-review of the study document(s).	FEES for CHRISTUS STUDIES	FEES for AFFILIATED STUDIES
Facilitated Review	Secondary review for studies previously approved by an external IRB of Record. This fee includes review and acknowledgement of the Initial Study Application and approval documents from the external IRB of Record. The essential documents to be reviewed from the Initial Study Application includes but are not limited to the following: Feasibility application, Protocol amendments, Investigators Brochure, review of Informed Consent Form(s) to ensure inclusion of institutional Catholic Directive language, use & disclosure of PHI, and applicable local context issues, etc. Moreover, acknowledgements will be performed on an ongoing basis during the conduct of the research study to include continuing reviews, protocol violations, protocol deviations, patient complaints, any 483s, etc.	N/A	$1,000
Translation Services and Interpretation Services	Translation services of study documents to non-English language. Rush requests will result in an additional charge. Interpretation services of oral rendition of spoken or signed communication from one language to another language.	Pass Through	Pass Through
Compliance Auditing Fee	A for-cause audit service may be required for sponsored studies in the event of a serious non-compliance, continuous non-compliance, research misconduct, notice of sponsor/IRB audit, FDA 483, regulatory agency site visit, major research litigation, etc. This process involves a targeted or complete review of research records, writing an audit report, re-education and corrective or preventive action plan (CAPA) including follow-up. This service entails time expended by Research Compliance Auditor including necessary travel to site(s) resulting in expenses such as hotel accommodation and car rental. For-cause audit service may not apply to Investigator Initiated Studies (IIS) or a majority of minimal risk studies.	$150/hour	$150/hour

Other Administrative Fees

TYPE OF SERVICE	DESCRIPTION	FEES for CHRISTUS STUDIES	FEES for AFFILIATED STUDIES
Start-up Fees			
Research Administration Fee	This fee is assessed on all studies to defray the costs associated with legal review of the contract, fiscal analysis, as well as determination of fixed administrative costs related to setting up the study fund. It is also assessed to defray the cost for the automation of study management, invoicing and collections including iRIS, eProposal, CTMS, ClinCard, and other technical services throughout the lifecycle of the project. **IMPORTANT**: A 25% ($875) fee will be assessed when a study and/or study documents are retracted (by client) prior to contract execution or a scheduled or unscheduled IRB meeting/review, if the Office of Sponsored Programs members have completed pre-review of the study document(s).	$3,500	$1,750
Protocol Preparation Fee	This fee covers the time and effort that the principal investigator and study staff expend in reviewing the protocol, undergoing site qualification process, feasibility analysis, regulatory paperwork, training of staff for quality and patient safety, laying the groundwork for operational conduct of the study, and preparing the application for submission to CHRISTUS IRB.	$3,000	$1,250
Research Coverage Analysis Fee	To ensure compliant clinical research billing, all new studies involving medical procedures are required to undergo the process of 'Research Coverage Analysis' to decipher the standard-of-care services (non-billable to study sponsor) from the research-only services (billable to study sponsor) before study activities begin. This requirement stands even if the study may not have any items or services that are or may be invoiced to Medicare.	$750	$750
Pharmacy Administrative Fee	This fee covers the investigational product related receipt, storage, labeling, management, randomization, accountability, shipment, and disposal.		
	• Initial Fee	$1,500	$1,500
	• Annual Fee	$1,000	$1,000
	• Closeout Fee	$500	$500
Sponsor Visit Fee	This fee covers costs associated with the research coordinator, research nurse, ancillary staff, and investigator time during Sponsor's site initiation visits (SIV), interim monitoring visits (IMV), and closeout visits (COV).	$400/visit	$400/visit

Other Administrative Fees (cont'd)

TYPE OF SERVICE	DESCRIPTION	FEES for CHRISTUS STUDIES	FEES for AFFILIATED STUDIES
Clinical Research Coordinator Fee	Hourly Rate	$75/hour	$75/hour
Investigator Fee	Hourly Rate	$200/hour	$200/hour
Regulatory Closeout Fee	This fee covers costs associated with time for the regulatory coordinator, investigator, and research coordinator to prepare for study closeout through the local IRB, and conclude other regulatory documentation, including final data submission.	$1,800	N/A
Storage Fee	This fee covers long-term document storage. In order to comply with HIPAA regulations regarding storage of records, our Institution has contracted with an outside vendor to provide long-term storage of study materials. Our policy states that closed studies will be stored for a period of 10 years or longer if required by the sponsor. In the event that the sponsor requires written notification of destruction of documents, the standard fees will be adjusted accordingly.	$500	$500
Indirect Cost Rate	Assessed at 30% on all research services and expenses	30%	30%