



Name of Document:
Teletrial Fees and Charges Guideline – A recommendation
for Commercially Sponsored Studies

The original version of this document is housed with TrialHub; however, this is intended to be used as a guideline to be downloaded and adapted for local requirements.

If you have any specific questions or queries as to how to implement, please contact TrialHub on TrialHub@alfred.org.au

Authors /Contributors

This work is a result of significant consultation with metro and regional health service clinical trial units and commercial sponsors, in particular IQVIA and Cancer Trials Australia.

Amendment History

Version	Date	Amended by	Amendment Details
Original	SEP 2023	TrialHub	

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Primary Site Fees				
Item	Description	Payment Terms	Payable to	Fee
Primary Site Study Start-up Fee (including HREC/RGO submission preparation)	Study start-up fee includes but not limited to feasibility, assessment and site selection processes with PI/SC's, Protocol review, study training for study team including PI/SI/SC/DM/Lab staff, setup of study essential documentation including protocol proformas, pharmacy scripts, pathology and radiology forms, set up and certification/review of essential equipment, education and training of RN's for administration of study drug.	Payable at SIV	Payable to Primary Site	As per site pricing
Primary Site HREC and/or RGO Review Fees		Payable upon receipt of invoice	Payable to HREC/RGO as applicable	Pass through costs; as per HREC/RGO website
Primary Site Annual Administration Fee	Annual Administration fee includes but is not limited to: routine communication with CRA between interim monitoring visits (IMVs); maintaining the investigator site file; managing inventory of study supplies; attendance by site staff during IMVs and study teleconferences; managing and reconciliation of study payments; follow-up of outstanding site issues after IMVs; submission of SUSAR line listings and annual/progress reports; general administrative tasks (printing, photocopying, scanning, faxing, etc.	Payable at SIV and annual thereafter	Payable to Primary Site	As per site pricing

Primary Site Fees (continued)				
Item	Description	Payment Terms	Payable to	Fee
Primary Site Set-up of Satellite Site (Primary Site)	Work performed by Primary Site for the set-up of each Satellite Site. Fee includes but not limited to feasibility assessment and review of protocol, drafting and development of supervision plan, discussions with Satellite Site regarding supervision plan, Primary Site and legal review of subcontracting agreement, budget, staff training, logistical set up. Set up of study essential documentation including protocol proformas, pharmacy scripts, pathology and radiology forms, set up and certification/review of essential equipment, education and training of RN's for administration of study drug.	Payable at SIV	Payable to Primary Site, applies per Satellite Site	\$2,500 for 1 st Satellite Site; \$2,000 per additional Satellite Site
Primary Site Annual Satellite Site Coordination Fee	Annual Teletrial coordination fee includes but not limited to: regular meetings coordinated by Primary Site with Satellite Site, optimising recruitment, mentorship and support as set out in supervision plan.	Payable at SIV and annually thereafter	Payable to Primary Site, applies per Satellite Site	\$1,500- \$2,000 per Satellite Site
Primary Site Close Out Fee	Covers all close out activities incurred by the Primary Site	Payable at site closure	Payable to Primary Site	Standard site fees
Primary Site Archiving Fees	Covers the costs associated with archiving study records for a period of 15-25 years	Payable at site closure	Payable to Primary Site	Pricing may be higher than Primary Site standard pricing if Primary Site is responsible for archiving study documents on behalf of Satellite Site. Please refer to supervision plan for details

Primary Site Fees (continued)				
Item	Description	Payment Terms	Payable to	Fee
Primary Site Amendment Submission Fees	Preparation and submission of amendment submissions – major, minor and administrative	Per occurrence	Payable to Primary Site	As per standard site fees
Primary Site Other ad-hoc site fees	Other site fees that may be required for conduct of study (i.e. medical records, remote monitoring, EMR/IT set up fees, sponsor audits as examples)	Payable at SIV or as required	Payable to Primary Site	As per Primary Site pricing
Primary Site Departmental Set-up and Annual Fees	Other site fees that may be required for the conduct of the study	Payable at SIV or as required	Payable to Primary Site	As per Primary Site Pricing

Satellite Site Fees				
Item	Description	Payment Terms	Payable to	Fee
Satellite Site Study Start-up fee (including preparation of RGO submission)	Covers activities incurred by the satellite site to set up the study including but not limited to preparation of submission to RGO, finalisation of supervision plans, negotiation of budget and legal subcontracting agreements, staff training liaison with Primary Site	Payable at SIV	Payable to Satellite Site, applies per Satellite Site	\$4,500 per Satellite Site
Satellite Site RGO Review Fees (initial and subsequent reviews)		Payable upon receipt of invoice	Payable to RGO as applicable	Pass through costs; standard fees as per Satellite Site pricing or RGO website
Satellite Site Annual Administration Fee	Satellite Site Annual administrative fee includes but not limited to: communication with Primary Site; sharing source documents with Primary Site for site file; managing inventory of study supplies; managing and reconciliation of study payments; follow-up of outstanding site issues after IMVs; submission of SUSAR line listings, DILs and annual/progress report to RGO; general administrative tasks; may include monitoring visits	Payable at SIV and annually thereafter	Payable to Satellite Site; applies per Satellite Site	\$2,000 per Satellite Site
Satellite Site Close Out Fee	Covers all close out activities incurred by the Satellite Site	Payable at site closure	Payable to Satellite Site; applies per Satellite Site	\$750
Satellite Site Archiving Fees (if archiving occurs at Satellite Site)	Covers the costs associated with archiving study records for a period of 15 – 25 years	Payable at site closure	Payable to Satellite Site; applies per Satellite Site	Only required if Satellite Site is to archive independently at site. Please refer to supervision plan for further details
Satellite Site Amendment Submission Fees	Preparation and submission of amendment submissions – major, minor and administrative	Per occurrence	Payable to Satellite site; applies per Satellite Site	As per Satellite Site pricing

Satellite Site Fees (continued)				
Item	Description	Payment Terms	Payable to	Fee
Satellite Site Other Ad-hoc site fees	Other site fees that may be required for conduct of study (i.e. medical records, remote monitoring, EMR/IT set up fees, sponsor audits as examples)	Payable at SIV as required	Payable to Satellite Site; applies per Satellite Site	As per Satellite Site pricing
Satellite Site Departmental set-up and annual fees	This includes all departmental fees required to conduct the study as per the supervision plan	Payable at SIV or as required	Payable to Satellite Site; applies per Satellite Site	As per Satellite Site pricing
Courier Costs	Covers the kits, equipment, Investigational Product, Records, Notes and Samples	As required	Payable to Primary Site or Satellite Site as required	Pass through costs
Per patient payments	<p>The primary site is responsible for making payments to the satellite site (this includes all site fees and per patient payments).</p> <p>Per patient costs are negotiated between the PS and Satellite site during start up, and activity based as per outlined in the supervision plan.</p> <p>SS payment frequency should align with the head agreement (CTRA between sponsor and PS) as stated in the CTRA and subcontracting agreement.</p>	Payable on invoice	Payable to Primary site and passed through to SS as per CTRA subcontract	As per CTRA subcontract

Teletrial subcontract Schedule 2 example:

SCHEDULE 2 – PAYMENTS AND INVOICING

All payments will be made by Institution in Australian Dollars, including any GST payable.
The Institution agrees to pay the Subcontractor the following amounts (all amounts stated ex GST) for teletrial related activities.

Item	Payment Terms	Fee
Subcontractor Study Start-up fee	Payable at SIV	\$4,500
Subcontractor RGO Review Fees: Initial Subcontractor RGO Review Fees: amendments	Payable upon receipt of invoice	As per Subcontractor pricing
Subcontractor Annual Administration Fee	Payable at SIV and annually thereafter	\$2,000
Subcontractor Close Out Fee	Payable at site closure	\$750
Subcontractor Archiving Fees (if archiving occurs at Subcontractor)	Payable at site closure	Only required if Subcontractor is to archive independently at site.
Subcontractor Amendment Submission Fees	Per occurrence	As per Subcontractor pricing
Subcontractor Other Ad-hoc site fees	Payable at SIV as required	As per Subcontractor pricing
Subcontractor Departmental set-up and annual fees	Payable at SIV or as required	As per Subcontractor pricing
Courier Costs	As required	Pass through costs
Per patient payments	Payable on invoice	As per CTRA subcontract