



Site Management Organisation

CTRA Instructions and Standard Fee Schedule:

INITIAL BUDGET	Send to lyn.mursalo@paratusclinical.com
DRAFT CTRA	Send to lyn.mursalo@paratusclinical.com
DRAFT MA Indemnity documents	Send to Jane.Stein@paratusclinical.com
Two-Way CTRA: Legal Entity	Paratus Clinical Pty Ltd Level 17, 40 Mount Street, North Sydney NSW 2060 AUSTRALIA ABN: 83 161 500 778
SIGNATORY FOR CTRA and INDEMNITY on behalf of PARATUS CLINICAL PTY LTD	Jeff Wall Managing Director Send to jeff.wall@paratusclinical.com
STANDARD INVOICING TERMS	Invoice or RCTI to be raised on a monthly basis based on Completed CRFs for visit performed during the invoiced period.
STANDARD PAYMENT TERMS	30 days from date of Invoice
PAYEE Bank Account Details	Paratus Clinical Pty Ltd Commonwealth Bank Ltd BSB: 062-948 ACCOUNT: 1292 8839 SWIFT CODE: CTBAAU2S



STANDARD SMO FEES:

Item	Staff performing task	Standard Cost (AUD)
Site protocol Review	All	Included in Establishment Fee
Practice Overhead	Practice management	25% of per patient fee
Establishment/set-up Fees (Includes time to attend Qualification visits; general site set-up administration; contract negotiation; signatures of all associated paperwork; online training for PI and one SC)	Site Activation Staff (Site specific) Pharmacy/IP set up Pathology (if used) Radiation (if used)	\$2,500 per clinical trial site \$1,500 per pharmacy \$450 per pathology collection center \$600 per Radiation practice
Project Management Fee Includes oversight from Operational Management, Recruitment activities, regular internal project meetings, single escalation point at Senior Management level, third party vendor management)	Per Clinical Trial Site	\$1,000 per clinical trial site per month (after SIV)
Protocol specific training (Additional to initial online training and IM or SIV training)	All relevant Staff	\$250 per clinical trial per staff member
On-Call fees – Pharmacy	Pharmacy Staff	\$400 per call back
Site Selection including feasibility assessment	Site Activation Staff	Included in Site Activation Fee
Preparation and submission of HREC application (Includes reviewing/customizing PICF documents, entering submission to HREC, responding to queries, general admin associated with HREC submission)	Site Activation Staff	\$2,750 per application
Lead Site Fee (In addition to all other fees)	Site Activation Staff	\$600 per annum (additional to Preparation and submission of HREC application fee)
Preparation and submission of HREC Major Amendment	Site Activation staff	\$1000 per application
Preparation and submission of HREC Minor Amendment	Site Activation staff	\$500 per application

HREC Review	Bellberry Ltd (Pass-through Cost)	See table below Bellberry reserves the right to alter these fees.
Investigator Meeting	Site Staff	<u>International Meeting:</u> \$1200 per Clinical Trials Coordinator/Nurse \$3500 per Investigator <u>Local meeting:</u> \$375 per Clinical Trials Coordinator/Nurse \$850 per Investigator
Staff Training (Study Specific) Any training required outside of the initial online, IM or SIV	Site Staff	\$650 per Clinical Trials Coordinator/Nurse \$450 per Investigator
Site Start-up Meeting (SIV)	Site Staff	\$2000 per start-up meeting
Pre-screening activity (includes time taken but the SC in mining databases, liaising with referral point, advertising and general promotion. Review of patient records for eligibility and liaison with the PI)	Site Staff (per site)	\$3000-4000 per clinical trial
Recruitment Activity	Site Staff (per site)	\$1,500 per study
Additional Monitoring Visit	We allow for one person on site monitoring every 8 weeks. Any visits additional to this will be charged per site per visit	\$900 per site per visit
Study Close-out activity	Site Staff (per site)	\$750 per site per clinical trial protocol
Off-site Archiving	Archive provider (RECALL)	\$500 per box for the duration of the required archive period

Note:

1. The charges above are in addition to any agreed Per Patient fee.
2. Pass through costs are subject to change.



HREC Pass through:

Bellberry Ltd Fees:

Please refer to Bellberry website for updated fees (www.bellberry.com.au)

	Ex GST	<u>Inc GST</u>
Funded or Sponsored Studies		
New HREC Review Application (per site)	\$5,500	\$6,050
New Phase 1 HREC Review Application (per site)	\$7,500	\$8,250
Extension Study (per site)	\$2,750	\$3,025
Amendments (per site)	\$550	\$605
Investigator Brochure Updates (per submission)	\$550	\$605
Investigator-Initiated/Unfunded Studies		
New HREC Review Application (per site)	\$2,750	\$3,025
Extension Study (per site)	\$1,375	\$1,512.50
Amendments (per amendment, per site)	\$275	\$302.50
Multi-Centre Study Discount		
Site #1	\$5,500	\$6,050
Sites #2-5 (each)	\$3,300	\$3,630
Sites #6+ (each)	\$2,300	\$2,530