

## HEALTH SCIENCES RESEARCH ETHICS COMMITTEE

### REVIEW FEE STRUCTURE

- **No Pro-Forma Invoices will be generated. Invoices will be generated after submission**
- **Purchase Order numbers (where applicable) must be provided with the application**
- **Please quote invoice number on electronic payments**
- **Application documents must clearly indicate VAT numbers and to whom the invoice must be made out**

HSREC REVIEW FEE STRUCTURE		
INDUSTRY-SPONSORED CLINICAL TRIALS		
Item	Description	HSREC Review Fee (incl. VAT)
New application	Pharmaceutical / Industry driven company sponsors an investigator to conduct a new research project	R10000
Extension / Roll-over study / Sub-study	Project is extended; study rolls over to open label; re-evaluation of protocol	R7500
Annual re-certification / Progress	Annual evaluation of research progress report for re-certification	R900
Protocol amendment - Major	Relaxation of inclusion criteria; relaxation of exclusion criteria; change in objectives / rationale of study; change in the study design and number of participants; relaxation of standards for data analysis; any change to the protocol that requires full committee approval	R2000
Protocol amendment - Minor	Tightening of inclusion criteria; tightening of exclusion criteria; changes in the Investigator's Brochure; changes in the background information; extension of study period; budget change or change to the contract; minor technical amendments; other changes that do not affect study design or analysis / results	R1250
Informed consent / Information Leaflet amendment	Any change to the content of the original informed consent form / information leaflet	R1 000
Participant / Recruitment material	This includes all material to be handed out to participants, all forms of advertising and blanket approvals.	R1 000
Additional investigator	Any additional investigator (per investigator)	R500
Administrative changes	Name changes; additional sites; typographical changes; other administrative changes	R500
External Administrative Charge	General Admin required by HSREC e.g. copying of lost trial documentation, protocols etc.	R450
Expedited / Urgent review of documentation		R450

\*Administrative Fees for the process of SAE's / Progress Reports / Safety Reports / Investigators Notifications are incorporated in the pricing structure

INTERNATIONAL GRANT FUNDED RESEARCH		
Item	Description	HSREC Review Fee (incl. VAT)
New application	International grant funded research (Total project budget > R1m)	R7500
New application	International grant funded research (Total project budget R500 000 to R1m )	R3500
New application	International grant funded research (Total project budget R100 000 to R500 000)	R2000
New application	International grant funded research (Total project budget < R100 000)	R900
Extension / Roll-over study / Sub-study	Project is extended; study rolls over to open label; re-evaluation of protocol for continuation; sub-study	R900
Annual re-certification / Progress	Annual evaluation of research progress report for re-certification	R750
Protocol amendment - Major	Relaxation of inclusion criteria; relaxation of exclusion criteria; change in objectives / rationale of study; change in the study design and number of participants; relaxation of standards for data analysis; any change to the protocol that requires full committee approval	R900
Protocol amendment - Minor	Tightening of inclusion criteria; tightening of exclusion criteria; changes in the Investigator's Brochure; changes in the background information; extension of study period; budget change or change to the contract; minor technical amendments; other changes that do not affect study design or analysis / results	R600
Informed consent amendment	Any change to the content of the original informed consent form	R600
Participant / Recruitment material	This includes all material to be handed out to participants, all forms of advertising and blanket approvals.	R600
Additional investigator	Any additional investigator (per investigator)	R400

\*Administrative Fees for the process of SAE's / Progress Reports / Safety Reports / Investigators Notifications are incorporated in the pricing structure

#### GENERAL INFORMATION:

- HSREC has a graded administrative fee structure in place, which is revised annually.
- Student projects for degree purposes, self-funded projects and projects funded solely from a University of the Free State Departmental budget are exempt from fees.
- **IMPORTANT NOTE:** HSREC reserves the right to not review a research application, or to withhold an HSREC letter if invoicing details have not been submitted to HSREC Administration **with** the application.