



HEALTH SCIENCES RESEARCH ETHICS COMMITTEE

REVIEW FEE 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.
- <u>IMPORTANT NOTE</u>: 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.

HSREC REVIEW FEE STRUCTURE INDUSTRY-SPONSORED CLINICAL TRIALS		
New application	Pharmaceutical / Industry driven company sponsors an investigator to conduct a new research project	R11 096.49
Extension / Roll-over study / Sub-study	Project is extended; study rolls over to open label; re-evaluation of protocol	R8 322.37
Annual re-certification / Progress	Annual evaluation of research progress report for re-certification	R998.68
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	R2 219.30
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	R1 387.06
Informed consent / Information Leaflet amendment	Any change to the content of the original informed consent form / information leaflet	R1 109.65
Participant / Recruitment material	This includes all material to be handed out to participants, all forms of advertising and blanket approvals.	R1 109.65
Additional investigator	Any additional investigator (per investigator)	R554.82
Administrative changes	Name changes; additional sites; typographical changes; other administrative changes	R554.82
External Administrative Charge	General Admin required by HSREC e.g. copying of lost trial documentation, protocols etc.	R554.82
Expedited / Urgent review of documentation		R554.82

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



INTERNATIONAL GRANT FUNDED RESEARCH			
ltem	Description	HSREC Review Fee (incl. VAT)	
New application	International grant funded research (Total project budget > R1m)	R8 322.37	
New application	International grant funded research (Total project budget R500 000 to R1m)	R3 883.77	
New application	International grant funded research (Total project budget R100 000 to R500 000)	R2 219.30	
New application	International grant funded research (Total project budget < R100 000)	R998.68	
Extension / Roll-over study / Sub-study	Project is extended; study rolls over to open label; re-evaluation of protocol for continuation; sub-study	R998.68	
Annual re-certification / Progress	Annual evaluation of research progress report for re-certification	R832.44	
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	R998.68	
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	R665.79	
Informed consent amendment	Any change to the content of the original informed consent form	R665.79	
Participant / Recruitment material	This includes all material to be handed out to participants, all forms of advertising and blanket approvals.	R665.79	
Additional investigator	Any additional investigator (per investigator)	R443.86	

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NOTES:

- The amounts may appear unusual, as they have been adjusted with the 15% VAT increase, but not rounded.
- 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 <u>invoice number</u> on electronic payments, and **send proof of payment to** <u>ethicsfhs@ufs.ac.za</u>
- Application documents must clearly indicate VAT numbers and to whom the invoice must be made
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