

## Health Sciences Research Ethics Committee Review Fee Structure Effective date: January 2025

### GENERAL INFORMATION:

- HSREC has a graded administrative fee structure that is revised annually.
- **Self-funded projects of UFS staff and students 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.

INDUSTRY-SPONSORED CLINICAL TRIALS		
Item	Description	HSREC Review Fee (Excl. VAT)
New application	Pharmaceutical/Industry sponsors an investigator to conduct a new clinical research project.	R20 000
Annual re-certification / Progress report	Annual evaluation of research progress report for re-certification: Re-evaluation of protocol for annual continuation.	R 5 000
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: Major or substantive changes require a change(s) to the study methodology or procedure that may result in an alteration of the risk-benefit profile of the study.	R6 000
Protocol amendment - Minor	Tightening of inclusion criteria; tightening of exclusion criteria; changes in the Investigator's Brochure; changes in the background information; extension of the study period; budget change or change to the contract; minor technical amendments; other changes that do not affect study design or analysis/results: does not change the risk-benefit profile of the study in any way; neither materially increases risk nor materially decreases benefit when considered in light of any changes proposed to mitigate risk and improve benefit; does not materially decrease scientific merit; and does not adversely affect the assessment of the research with respect to the criteria for approval.	R2 000
External Administrative Charge	General Admin required by HSREC, e.g. copying of lost trial documentation, protocols, etc.	R2 000
Time-sensitive document review	This includes reporting of SAEs, protocol deviations, safety reports, investigator notifications and DSMB reports	R2 000

INTERNATIONAL GRANT FUNDED RESEARCH		
Item	Description	HSREC Review Fee
		(Excl . VAT)
New application	International grant-funded research (Total project budget > R1 000 000)	R15 000
New application	International grant-funded research (Total project budget R500 000 to R1 000 000)	R10 000
New application	International grant-funded research (Total project budget R100 000 to R500 000)	R5 000
New application	International grant-funded research (Total project budget < R100 000)	Exempt
Annual re-certification / Progress report	Annual evaluation of research progress report for re-certification, Re-evaluation of protocol for annual continuation	Project budget > 1 million: R 4 500
		Project budget 500 000 – 1 million: R3000
		Project budget 100 000 - 500 000: R1500
		Project budget < R100 000: exempt
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: Major or substantive changes require a change(s) to the study methodology or procedure that may result in an alteration of the risk-benefit profile of the study.	R1 500
		Project budget < R100 000: exempt
Protocol amendment - Minor	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: Major or substantive changes require a change(s) to the study methodology or procedure that may result in an alteration of the risk-benefit profile of the study.	R1 000
		Project budget < R100 000: exempt
Time-sensitive document review	This includes reporting of SAEs, protocol deviations, safety reports, investigator notifications and DSMB reports.	R1 000

EXTERNAL RESEARCHERS (non-UFS/CUT who are neither industry-sponsored nor international grant-funded)		
Item	Description	HSREC Review Fee (Excl. VAT)
New application		R2 500
Annual re-certification / Progress report	Annual evaluation of research progress report for re-certification, Re-evaluation of protocol for continuation	R1 000
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: Major or substantive changes require a change(s) to the study methodology or procedure that may result in an alteration of the risk-benefit profile of the study.	R500
Protocol amendment - Minor	Tightening of inclusion criteria; tightening of exclusion criteria; changes in the Investigator's Brochure; changes in the background information; extension of the study period; budget change or change to the contract; minor technical amendments; other changes that do not affect study design or analysis/results: does not change the risk-benefit profile of the study in any way; neither materially increases risk nor materially decreases benefit when considered in light of any changes proposed to mitigate risk and improve benefit; does not materially decrease scientific merit; and does not adversely affect the assessment of the research with respect to the criteria for approval.	R250
Time-sensitive document review	This includes reporting of SAEs, protocol deviations, safety reports, investigator notifications and DSMB reports.	R500

**NOTES:**

- 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, and **send proof of payment to [ethicsfhs@ufs.ac.za](mailto:ethicsfhs@ufs.ac.za)**
- Application documents must clearly indicate VAT numbers and to whom the invoice must be made out