UNIVERISTY OF CAPE TOWN

HEALTH RESEARCH ETHICS COMMITTEE

Contact Information

Room: E52.24
Old Main Building, GSH
Tel: 021 406 6492
Fax: 021 406 6411
Website link: http://www.health.uct.ac.za/fhs/research/humanethics/forms

The function of any health research ethics committee is to ensure protection of and respect the rights, safety and wellbeing of participants involved in a trial as well as to provide public assurance of that protection by reviewing, approving and providing comments on clinical trial protocols, investigators, facilities and procedures.

Fees:

Follow the link below:
http://www.health.uct.ac.za/fhs/research/humanethics/fees

Meeting Dates 2016:

http://www.health.uct.ac.za/fhs/research/humanethics/dates

Initial Submission:

Complete the FHS013: New protocol application form
Please pack **3** copies for full committee review study. For scanning purposes please refrain from binding the documents. Please use binder clips, paper clips and staples.
NB! Protocols, ICFs, Participant Information, Participant materials, Recruitment materials MUSR be version and date controlled (i.e. V1.0 dated DD/MMM/YYYY)

Submission checklist:

- ☐ Completed Protocol Application Form
- ☐ Cover letter listing all submitted docs with version numbers and version dates
- ☐ PI Generated Synopsis (see FHS014) (Required)
- ☐ Sponsor's Synopsis (if applicable)
- ☐ Research Protocol (see FHS015hlp)
- ☐ Appendices (as applicable)
- ☐ Consent and assent forms (English versions)
- ☐ Sponsor's Protocol
- ☐ NIH or other US federal grant application (if PI is primary awardee)
- ☐ If an application has been submitted to the MCC, a copy of Section 13 (Ethical Issues) extracted from the CTF1 application form
- ☐ Surveys, questionnaires, interview schedules
- ☐ Recruitment materials: advertisements, flyers, posters
- ☐ Materials for participants: diaries, patient identification cards
- ☐ Letters of authorisation from institutions such as hospitals, clinics and schools
- ☐ Post-trial care/Care after research justification

- ☐ A summary of Phase III efficacy and safety data if this is an application for an open label or extension study
- ☐ Budget summary
- ☐ MCC letter of approval, if available
- ☐ Investigator's brochure and package inserts
- ☐ In the case of clinical trials, PI's declaration, CVs and GCP certificates for PI and co-investigators
- ☐ If Minors are involved, please attach FORM A found on the website
- ☐ Other relevant documentation

Please click on the UCT HREC link for more information concerning the application/submission of Undergraduate research, databases/registries/repositories and expedited review.

Active Protocols:

Amendment of Protocol:

Complete FHs006 form

All **major** amendments must include a local PI Synopsis justifying the changes for the amendment. Please include track changed and clean copies of the amendment and all documents affected by the amendment for review

Amendment of Staff:

Complete FHs007 form

Additional staff members to participate in the trial

Have you requested approval or acknowledgment from the MCC? *(see MCC page and CTF3)*

Internal Adverse Events or unanticipated problem:

Complete FHS008 form

Reporting Form for Safety Information

Complete FHS009 form

This will include Investigator Brochure, Safety Information, DSMB Report, Hold on Study Activity

Study Deviations:

Complete FHS011 form

Continuing Review/ Annual Progress report:

Complete FHS016 form

AS stipulated on your initial cover approval letter please ensure that an annual progress report is submitted within 2 months of expiry date for ongoing approval.

Please refer to the UCT HREC website concerning continuing review for Record Reviews/Audits/Collection of Biological Specimens/Repositories/Databases/Registries

Study Closure /End of study Report:

Complete FHS010 form