**Form FHS013hlp: New protocol application and post-submission instructions for researchers**

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| Instructions |

New Protocol Application

Researchers submitting a new application to conduct human research must complete a New Protocol Application Form (FHS013). (Always download the current form from the website)

<http://www.health.uct.ac.za/fhs/research/humanethics/forms>

Forms needed:

* Section A: New Protocol Application Form: (complete FHS013 Form)
* Section B: Preparing a PI Generated Synopsis: (see Pointers for Researchers FHS014)
* Section C: Research Protocol: Preparing the Research Protocol (see Pointers for Researchers FHS015)
* Eligibility for Expedited Review of US Federally-funded Research — see Pointers for Researchers

Please send **New Applications** to [hrec-submissions@uct.ac.za](mailto:hrec-submissions@uct.ac.za)

* Email subject lines must be clearly titled as follows:
  + New protocol application – Full Committee review and PI name OR

#### New protocol application – Expedited review and PI name

Please send all **forms and queries** you may have to [hrec-enquiries@uct.ac.za](mailto:hrec-enquiries@uct.ac.za)

* Email subject lines for forms must be clearly titled as follows, HREC REF [insert reference number] – [type of form] and PI name
* Email queries must be clearly titled as follows: query and reference number where applicable

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| Human Research Ethics Committee,  E 53 Room 46, Old Main Building, Groote Schuur Hospital, Observatory  Telephone: 27 21 404 7682  Contacts for Administrators: [hrec-enquiries@uct.ac.za](mailto:hrec-enquiries@uct.ac.za)  For any invoicing enquiries please contact [hrec-payments@uct.ac.za](mailto:hrec-payments@uct.ac.za)  **Note:** **An** **electronic copy of your new submission should be emailed to** [**hrec-submissions@uct.ac.za**](mailto:hrec-submissions@uct.ac.za) |

**How to prepare your submission pack:**

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| **Please pack s for category 1 and for category 2 in the order specified below: Note: Submissions will be sent back when insufficient copies are provided.** | | |
| **For Full Committee Review**  **Category 1** |  | **For Expedited Review**  **Category 2** |
| 1. Completed Protocol Application Form |  | 1. Completed Protocol Application Form |
| 1. Cover letter listing all submitted docs with version numbers and version dates |  | 1. Cover letter listing all submitted docs with version numbers and version dates |
| 1. PI Generated Synopsis (see FHS014) (**Required**) 2. Debit Order   (**Required**) |  | 1. PI Generated Synopsis (see FHS014) (**Required**) 2. Debit Order   (**Required – When Applicable**) |
| 1. Sponsor’s Synopsis (if applicable) |  | 1. Motivation for Expedited Review |
| 1. Research Protocol (see FHS015hlp) |  | 1. Research Protocol (see FHS015hlp) |
| Appendices (as applicable) |  | Appendices (as applicable) |
| 1. Consent and assent forms (English versions) |  | 1. Consent and assent forms (English versions) |
| 1. Sponsor’s Protocol |  | 1. NIH or other US federal grant application  (if PI is primary awardee) |
| 1. NIH or other US federal grant application (if PI is primary awardee) |  | 1. Surveys, questionnaires, interview schedules |
| 1. If an application has been submitted to the SAHPRA, a copy of (Ethical Issues) extracted from the CTF1 application form |  | 1. Recruitment materials: advertisements, flyers, posters |
| 1. Surveys, questionnaires, interview schedules |  | 1. Materials for participants: diaries, patient identification cards |
| 1. Recruitment materials: advertisements, flyers, posters |  | 1. Letters of authorisation from institutions such as hospitals, clinics and schools |
| 1. Materials for participants: diaries, patient identification cards |  | 1. Insurance Certificate (where applicable) |
| 1. Letters of authorisation from institutions such as hospitals, clinics and schools |  | 1. Budget summary |
| 1. Post-trial care/Care after research justification |  | 1. Other relevant documentation |
| 1. A summary of Phase III efficacy and safety data if this is an application for an open label or extension study |  | 16. Post-trial care/Care after research justification |
| 1. Insurance Certificate |  | 17. If Minors are involved, please attach FORM A found on the website |
| 1. Budget summary |  | 18. SOP for governance and storage of samples; and MTA’s (where applicable) |
| 1. SAHPRA letter of approval, if available |  | 19. SOP for research-related activities during COVID-19 lockdown |
| 1. Investigator’s brochure and package inserts |  |  |
| 1. In the case of clinical trials, PI’s declaration, CVs and GCP certificates for PI and co-investigators |  |  |
| 1. If Minors are involved, please attach FORM A found on the website |  |  |
| 1. SOP for governance and storage of samples; and MTA’s (where applicable) |  |  |
| 1. Other relevant documentation |  |  |
| 1. SOP for research-related activities during COVID-19 lockdown |  |  |

**Note:**

* Clearly list all documents with version numbers and dates on the cover letter.
* Please submit the application form to [hrec-submissions@uct.ac.za](mailto:hrec-submissions@uct.ac.za)
* Documents under 35MB kindly send in one single PDF
* Large documents can you kindly send in a PDF portfolio via Dropbox

Post Submission Guidance

Responding to the Committee’s Feedback

* Copy or restate the question or concern and then provide a detailed and thoughtful response. Incomplete responses are likely to trigger a repeat query from the reviewer.
* Address all points and queries on a cover letter, using examples, references and hard data where necessary.
* If a reviewer’s feedback is unclear or ambiguous, contact the HREC staff and request clarification. If you disagree with a comment or recommended change, provide your rationale.
* If the response requires a change in study procedures or design, revise the protocol, recruitment materials and information sheets/ consent forms accordingly.
* If your response requires revisions to the protocol and consent documents, submit copies with changes highlighted in bold or italics on the paper copy so the reviewer can immediately determine where and what changes have been made.
* Proofread the final versions for grammatical, typographical and formatting errors.

**Note:** Email subject lines for PI Response must be clearly titled as follows: (HREC Reference Number + PI RESPONSE) and email directly to[**hrec-**submissions@uct.ac.za](mailto:hrec-submissions@uct.ac.za).

Annual Progress Reports (Continuing Review of Ongoing Research)

In line with international and national regulatory and ethical requirements, the HREC must review active research at least annually. The PI is responsible for submitting an annual progress report to the HREC in a timely manner before the approval period for the study expires. The HREC has the authority to suspend or terminate research which does not comply with annual reporting requirements. The following forms and guidance are available on the web page:

* Annual Progress Report (FHS016)
* Annual Progress Report ⎯ Pointers for Researchers (FHS016hlp)
* Annual Progress for Records Reviews, Audits, Collection of Biological Specimens, Repositories, Databases or Registries (FHS017)
* Study Closure Report (FHS010)
* Final Report for Record Reviews, Audits, Collection of Biological Specimens, Repositories, Databases or Registries (FHS019)

**Note:** Please send all **forms and queries** you may have to [hrec-enquiries@uct.ac.za](mailto:hrec-enquiries@uct.ac.za)

* Email subject lines for forms must be clearly titled as follows, HREC REF [insert reference number] – [type of form] and PI name

**Active Protocols**

All changes to research protocols, including for example information/consent documents, advertisements, and study instruments must have HREC approval prior to implementation except where necessary to eliminate immediate hazards to enrolled participants. The following forms and guidance are available on the web page:

* Amendment Form (FHS006)
* Amendment Form ⎯ Study Staff (FHS007)
* Amendment Form ⎯ Pointers for Researchers (FHS006hlp)
* Internal Adverse Events or Unanticipated Problems Reporting Form (FHS008)
* Preparing an Internal Adverse Events or Unanticipated Problem Reporting Form ⎯ Pointers for Researchers (FHS008hlp)
* Study Deviation Form (FHS011)
* Study Exception Form (FHS012)
* Study Exceptions and Study Deviations ⎯ Pointers for Researchers (FHS011hlp)
* Reporting Form for Safety Information: Investigator Brochure, Safety Information, DSMB Report, Hold on Study Activity (FHS009)

**Note:** Please send all **forms and queries** you may have to [hrec-enquiries@uct.ac.za](mailto:hrec-enquiries@uct.ac.za)

* Email subject lines for forms must be clearly titled as follows, HREC REF [insert reference number] – [type of form] and PI name

**Process for submission:**

[**http://www.health.uct.ac.za/sites/default/files/image\_tool/images/116/HREC%20-%20Electronic%20submission%20process\_11.10.2021.pdf**](http://www.health.uct.ac.za/sites/default/files/image_tool/images/116/HREC%20-%20Electronic%20submission%20process_11.10.2021.pdf)