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| **Checklist – FHS013 submissions** | | |
| **For Full Committee Review** |  | **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 Form   (**Required**) |  | 1. PI Generated Synopsis (see FHS014) (**Required**) 2. Debit Form   (**Required – When Applicable**) |
| 1. Sponsor’s Synopsis (if applicable) |  | 1. Motivation for Expedited Review |
| 1. Research Protocol (see FHS015hlp) |  | 1. Research Protocol (see FHS015hlp) |
| 1. Consent and assent forms (English versions/and translated into local language) |  | 1. Consent and assent forms (English versions/and translated into local language) |
| 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 |
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| 1. Letters of authorisation from institutions such as hospitals, clinics and schools |  | 1. Budget summary |
| 1. Post-trial care/Care after research justification |  | 1. Post-trial care/Care after research justification |
| 1. A summary of Phase III efficacy and safety data if this is an application for an open label or extension study |  | 16. If Minors are involved, please attach **FORM A** found on the HREC website |
| 1. No-Fault Insurance Certificate (If applicable) |  | 17. SOP for governance and storage of samples; and MTA’s (where applicable) |
| 1. Budget summary |  | 18. Other relevant documentation and appendices |
| 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 |  |  |
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| 1. SOP for governance and storage of samples; and MTA’s (where applicable) |  |  |
| 1. Other relevant documentation and appendices |  |  |
| 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