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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
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| 1. Cover letter listing all submitted docs with version numbers and version dates
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 |
| 1. PI Generated Synopsis (see FHS014) (**Required**)
2. Debit Form

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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)
 |
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 |  | 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
 |
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 |  | 1. Letters of authorisation from institutions such as hospitals, clinics and schools
 |
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 |  | 1. No- Fault 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. 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
 |  |  |
| 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 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
* Documents under 35MB kindly send in one single PDF
* Large documents can you kindly send in a PDF portfolio via Dropbox