

HREC Submission Guidelines

1. For full ethical review studies

HREC Application Form	1 original and signed documents + 19 copies for submission
Clinical Protocol	1 original and signed documents + 4 copies for submission
Investigator's Brochure	1 original + 4 copies for submission
Patient Information & Consent	1 original + 19 copies for submission
Study Tools	1 original + 19 copies for submission
Insurance Certificate	1 original
Form of Indemnity	2 Originals (1 x Sponsor, 1 x original per site)
Clinical Trial Agreement	2 Originals (1 x Sponsor, 1 x original per site)
CTN	1 x Site (1 original per site)
Other requirements: <ul style="list-style-type: none"> • Please <u>do not staple or bind</u> any of the papers included in your submission – each set of documents can be separated by a sheet of A4 coloured paper, clipped with a bulldog clip or held together with a rubber band. Please do not separate sections within the document. • <u>Hole-punched & double sided</u> copies • Email the HREC co-ordinator a copy of the following documents: <ul style="list-style-type: none"> ○ Copy of the Application Form e.g. NEAF or DHS Modules (Converted pdf or WORD format) ○ Copy of the Submission Letter (WORD format) 	

2. For Low Risk studies

Low Risk Application Form	1 original and signed documents + 6 copies for submission
Protocol	1 original + 6 copies for submission
Patient Information and Consent Document	1 original + 6 copies for submission
Other Documents	1 original + 6 copies for submission
Other requirements: <ul style="list-style-type: none"> • Please <u>do not staple or bind</u> any of the papers included in your submission – each set of documents can be separated by a sheet of A4 coloured paper, clipped with a bulldog clip or held together with a rubber band. Please do not separate sections within the document. • <u>Hole-punched & double sided</u> copies • Email the HREC co-ordinator a copy of the following documents: <ul style="list-style-type: none"> ○ Copy of the Low Risk Application Form (WORD format) ○ Copy of the Submission Letter (WORD format) 	

3. Amendments

- **Major Amendments** (If the amendments result in a change of protocol which directly affects the participants)
 - HREC Amendment Form
 - http://www.health.vic.gov.au/cchre/downloads/hrec_amendment_form.pdf
 - 1 original + 19 copies of amended documents for submission
 - Tracked and Clean copies of the amended documents to be submitted.
 - Cover letter outlining the amendments and including study title and number. Please ensure that the correct version numbers and dates are clearly stated on the amended documents and on the cover letter
- **Minor Amendments** (If the participants are not affected by the amendments i.e. typographical changes, additional researchers etc.)
 - 1 original + 1 copy of amended documents for submission
 - If the amendment relates to a change in personnel please include the relevant pages from Module One, indicating the new researchers.
 - Tracked and Clean copies of the amended documents to be submitted.
 - Cover letter outlining the amendments and including study title and number. Please ensure that the correct version numbers and dates are clearly stated on the amended documents and on the cover letter

4. SAE Reporting

- When there has been a recommendation to change the protocol as the result of an SAE or SUSAR, or when an SAE is determined to be **probably or definitely related** to the study, then these must be reported to the Committee **immediately** (1 copy only required for submission).
- Other SAE's may be also report to the HREC on a monthly basis and preferably in a tabulated format.
- All other SAE's may be reported to the Committee in the Annual Report.

5. Annual or Progress Reports

- A report **must** be submitted to the Committee on the progress of this study either on completion or on the expiration of each twelve months from the date of approval, whichever is earlier.
- A progress report **may** also be submitted at the End of the Financial Year to coincide with Epworth's annual report.
- Information regarding the number of participants and outcomes relating to general progress should be included in interim reports.
- The report template can be found on Epworth's webpage at the following link: <http://www.epworth.org.au/human-research-ethics-committee.aspx>