

Copies of Documents Required by HREC for New & Continuing Applications

- Include a covering letter outlining the request and/or attachments (original + copies required)
- **Paperwork must be collated** - (eg original letter, PICF, NEAF, Protocol clipped together, then copy of covering letter, PICF, NEAF, Protocol clipped together, etc). Single copy items are to be included in the originals bundle.

NEW APPLICATIONS (include version control numbers & dates on documents where appropriate)	
Application / Submission Form	1 Original
Covering Letter – listing items submitted	1 Original + 17 Copies
Resource Form (signed by PI and/or appropriate Department)	1 Copy
National Ethics Application Form (NEAF)	1 Original (signed) +17 Copies
Investigator's Brochure / Product Information Sheets	4 Copies
Study Documents (i.e. Questionnaires, Patient ID cards, Patient Diaries Etc)	1 Original + 17 Copies
Protocol	1 Original + 17 Copies
Participant Information and Consent Form	1 Original + 17 Copies
New Protocol Levy Memo – for fully sponsored Pharmaceutical Trials	1 Copy
CTN or CTX form (if applicable)	1 Original (Signed by sponsor and Principal Investigator)
Clinical Trial Agreement (CTA) (if applicable)	3 Originals (Signed by sponsor and Principal Investigator)
Indemnity Form (if applicable)	3 Originals (Signed by Sponsor)
Insurance Certificate (if applicable)	1 Copy

AMENDMENTS / MODIFICATIONS and ADVERSE EVENTS (with updated version control numbers & dates where appropriate)	
Covering Letter – listing items submitted	1 Original + 17 Copies
Participant Information Sheet and Consent Forms	1 Original Clean Copy + 17 Tracked Copies (Changes to be <u>highlighted</u> or <u>underlined</u>)
Protocol Amendments	1 Full Protocol + 16 'Summary of Changes'
Protocol Amendment Levy Memo – for fully sponsored Pharmaceutical Trials	1 Copy
External Adverse Events	1 Original letter with summary table 1 Copy of letter with summary table
Onsite Adverse Events	1 Original Letter 17 Copies of Letter
Updated Investigator's Brochure / Product Information Sheet	1 Copy of Investigator's Brochure 1 Copy of "Summary of Changes" (separate from IB)
Project Documents (ie Questionnaires, Patient ID cards, Patient Diaries, etc)	Minor amendments: 1 Original Major amendments: 1 Original + 17 copies with tracked changes
Updated Insurance Certificates	1 Copy
Data Safety Monitoring Board Letters	1 Copy