

Applicant Checklist for a Clinical Trial

Name of Committee: SJH/AMNCH Research and Ethics Committee
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All applications for review of clinical trials must be submitted in full in BOTH hard and electronic format and paid for in advance of review.

The fee for a clinical-trial is €1000 and €150 for each additional site. The details of fees and payment can be found under fees and payment instruction. Please note that fees for clinical trials are **legislated** for and are **non-negotiable**.

This checklist must be submitted in word format.

| Documentation | | |
|--|------------------------------|-------------|
| Documents | Type and Copies | Version No. |
| DoH Application Form | 1 electronic and 1 hard copy | |
| Site Specific Assessment Form (per site) | 1 electronic and 1 hard copy | |
| CV of Principal Investigator | 1 electronic and 1 hard copy | |
| Clinical Trial Protocol | 1 electronic and 1 hard copy | |
| Investigator Brochure | | |
| Patient Information Leaflet | 1 electronic and 1 hard copy | |
| Consent Form | 1 electronic and 1 hard copy | |
| Assent Form | 1 electronic and 1 hard copy | |
| GP Letter (if applicable) | 1 electronic and 1 hard copy | |
| Questionnaire (if applicable) | 1 electronic and 1 hard copy | |
| Telephone script (if applicable) | 1 electronic and 1 hard copy | |
| Other | 1 electronic and 1 hard copy | |
| Other | 1 electronic and 1 hard copy | |
| Other | 1 electronic and 1 hard copy | |
| Proof of payment | 1 electronic and 1 hard copy | |