

## Applicant Checklist for a Clinical Trial

Name of Committee: TUH/SJH Research and Ethics Committee  
Contact Person: Dr. Sadhbh O'Neill  
Position: REC Officer  
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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**.

Documentation		
Documents	Type and Copies	Version No.
CT 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	1 electronic and 1 hard copy	
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	