checklist: clinical trials of medicinal products only

committee contact details:

Name of Committee: Beaumont Hospital Ethics (Medical Research) Committee

Contact Person: Administrator

Address: Beaumont Hospital, Dublin 9

Tel: 00 353 1 809 2680

E-Mail: beaumontethics@rcsi.com

Website (if any): <https://beaumontethics.ie>

committee remit:

Reviews Clinical trials of medicinal products in the State of Ireland

Local requirements (if any):

Applicants conducting clinical trials in Beaumont Hospital are requested to adapt the Sample Draft Information Leaflets and Consent Forms available on <https://beaumontethics.ie> to their own studies.

THESE TEMPLATES ARE COMPULSORY FOR USE – commercial sponsors unable to use these templates are requested to contact the administrator

Applicants conducting clinical trials in Beaumont Hospital are requested to complete and submit the Template Data Protection Impact Assessment Statement available on <https://beaumontethics.ie>

Local restrictions (if any):

**NB -** 1 electronic copy (all documents) to be submitted to beaumontethics@rcsi.com

**Please aim to keep the file sizes as small as possible**

fees:

See <https://beaumontethics.ie/application/fees.htm>

An invoice will issue upon receipt of the application for ethical review.

documents required:

|  |  |  |  |
| --- | --- | --- | --- |
| **Documents Required:** | **No. of E Copies Required:** | **Yes / No / N/A** | **Document Version / Date** |
| Cover Letter (listing all documents for review, including Version number) | 1 |  |  |
| Department of Health and Children Application Form | 1 |  |  |
| CV of Chief Investigator, signed and dated (for file) | 1 |  |  |
| Site Specific Assessment Form (for each site) | 1 |  |  |
| CV of Principal Investigator at each site, signed and dated (for file) | 1 |  |  |
| Clinical Trial Protocol | 1 |  |  |
| Investigator’s Brochure (or SmPC) | 1 |  |  |
| Information Leaflet (s) – use templates 31.8.18 | 1 |  |  |
| Consent Form (s) – use templates 31.8.18 | 1 |  |  |
| Letter to Family Doctor | 1 |  |  |
| Recruitment Material | 1 |  |  |
| Questionnaire / Interview Prompts | 1 |  |  |
| Other |  |  |  |
| Other |  |  |  |
| Details of Independent Data Safety Monitoring Board | 1 |  |  |
| Draft Standard Clinical Trial Indemnity Form (for Beaumont Hospital) (Sponsored Studies only) – use template V3, 25.10.20 | 1 |  |  |
| Draft Clinical Trial Agreement / Investigator Agreement | 1 |  |  |
|  |  |  |  |
| Certificate of Insurance for Sponsor Company (Sponsored Studies only) | 1 |  |  |
| Proof of Current Insurance for each Investigator not covered by the Clinical Indemnity Scheme | 1 |  |  |
| Health Products Regulatory Authority (HPRA) approval (if in place) | 1 |  |  |
| Draft Data Protection Impact Assessment – use template May 2020 (or word template 01.21) | 1 |  |  |
| Section E2 31.8.18 | 1 |  |  |
| Radiation Declaration Form | 1 |  |  |
| Invoice Details Form(Invoice to follow) | 1 |  |  |