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.ie

Website (if any): www.beaumontethics.ie

committee remit:

Reviews applications to conduct research in: Clinical trials of medicinal products in the State of Ireland

Local requirements (if any):

Applicants are requested to adapt the Sample Draft Information Leaflets and Consent Forms available on [www.beaumontethics.ie](http://www.beaumontethics.ie) to their own studies.

Local restrictions (if any):

1 electronic copy (all documents) to be submitted via email by midnight on the date of the submission deadline to [beaumontethics@rcsi.ie](mailto:beaumontethics@rcsi.ie)

* Please make special efforts to keep the file size of each individual document as small as possible.
* Please ensure that to submit a cover letter listing each document being submitted review, including version number of each document. This cover letter should be submitted as a *Microsoft Word Document.*

1 paper copy (all documents) to be submitted via internal / external post or courier, or via hand-delivery to Main Hospital Reception Desk by midnight on day of the submission deadline to Ethics (Medical Research) Committee, Beaumont Hospital, Dublin 9, Ireland.

fees:

See <http://www.beaumontethics.ie/application/fees.htm>

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

documents required:

|  |  |  |  |
| --- | --- | --- | --- |
| **Documents Required:** | **No. of Paper 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) | 1 |  |  |
| Consent Form (s) | 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) | 1 |  |  |
| Draft Clinical Trial Agreement / Investigator Agreement | 1 |  |  |
| Draft Standard Clinical Trial Indemnity Form (for RCSI) (Sponsored Studies taking place in the RCSI Clinical Research Centre only) | 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 |  |  |
| Fee | Invoice to follow |  |  |