local committee checklist:

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 applications to conduct research in:

1. Beaumont Hospital, Dublin 9 (incorporating St. Joseph’s Hospital, Raheny, D5) and including Raheny Community Nursing Unit, Dublin 5 [part of Beaumont Hospital}
2. Royal College of Surgeons Clinical Research Centre, Beaumont Hospital, Dublin 9 [part of Royal College of Surgeons in Ireland]

Local requirements (if any):

It is a requirement to name an authorised healthcare professional who is employed by Beaumont Hospital as the principal investigator in all cases.

In case of multi-site studies, it is a requirement to name either: -

* an authorised healthcare professional who is employed by Beaumont Hospital as the chief investigator; or
* an authorised healthcare professional who is employed by / at another Delegated State Authority (DSA) in the Republic of Ireland as the chief investigator.

In case of uncertainty, please contact stateclaims@ntma.ie

Please ensure that the healthcare professional named as Principal Investigator will remain in the employment of Beaumont Hospital for the entire duration of the research study.

(For ‘clinical trials’ there is an additional requirement for the authorised healthcare professional to be a medical practitioner)

Where a research study involves Beaumont Hospital patients, their family members or informal caregivers and the named Principal Investigator is a Beaumont Hospital healthcare professional, but not a Beaumont Hospital consultant doctor, it is a requirement to list a Beaumont Hospital consultant doctor as a co-investigator in all cases – for the purposes of clinical governance -

* The Principal Investigator must sign the Signatory Page
* The Academic Supervisor (where applicable) must sign the Signatory Page

APPLICATIONS WHICH DO NOT FULFILL THE ABOVE LOCAL REQUIREMENTS WILL BE DEEMED INVALID.

Applicants submitting studies to this committee are requested to adapt the Template Information Leaflets and Consent Forms available on <https://beaumontethics.ie> to their own studies.

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

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

APPLICATIONS WHICH DO NOT FULFILL THE ABOVE LOCAL REQUIREMENTS WILL BE DEEMED INVALID.

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:** | **Number of E Copies** **Required** | **Yes / No / N/A** | **Document Version / Date** |
| Cover Letter (listing all documents for review, including Version number) | 1 |  |  |
| Signatory Page | 1 |  |  |
| 2 page CV of Chief Investigator, signed and dated (for file)  | 1 |  |  |
| 2 page CV of Principal Investigator, signed and dated (for file) for multi-site studies, this refers to the cv of the Principal Investigator in Beaumont Hospital only | 1 |  |  |
| Standard Application Form (RECSAF Version **5.6** last updated Beaumont 31.7.22**- Refer to the Instructions for Use** ADAPTED 31.8.18 **when completing the Application Form** | 1 |  |  |
| Research Proposal / Study Summary / Protocol / Clinical Investigational Plan (if one exists) | 1 |  |  |
| Information Leaflet(s) – use template 1.10.21  | 1 |  |  |
| Consent Form(s) – use templates 31.7.22 | 1  |  |  |
| Recruitment Material  | 1 |  |  |
| Questionnaire / Interview Prompts | 1 |  |  |
| Letter to Family Doctor as per your response to Question D9 | 1 |  |  |
| Draft Agreement / Contract (where applicable) | 1 |  |  |
|  |  |  |  |
| Draft Data Protection Impact Assessment – see template 9.5.22) | 1 |  |  |
|  |  |  |  |
| Radiation Declaration Form | 1 |  |  |
|  |  |  |  |
| Genomic Research with a Commercial Company Declaration Form | 1 |  |  |
| Other | 1  |  |  |
| Other | 1 |  |  |
|  |  |  |  |
| Invoice Details Form (Invoice will be sent after the submission has been received, and has been validated)(Fee waiver requests cannot be accommodated) | 1 |  |  |
| additional documents: insurance / indemnity (SECTION J) |
| **Documents Required:** | **Number of Paper Copies Required:** | **Yes / No / N/A** | **Document Version / Date** |
| Evidence of appropriate Insurance / Indemnity for each site as per J1 (for file)(does not apply if the site is Beaumont Hospital, any other public hospital or voluntary hospital) | 1 |  |  |
| Evidence of appropriate insurance / indemnity for each investigator as per J2 (for file)(does not apply for investigators employed by Beaumont Hospital, any other public hospital or voluntary hospital)(does apply to any investigators who are not employees) | 1 |  |  |
| Evidence of appropriate insurance / indemnity for the sponsor / legally responsible entity as per J3.1 (where applicable)(for file)(where the sponsor is RCSI, this refers to a letter from the RCSI sponsorship office) | 1 |  |  |
| Evidence of additional insurance / indemnity arrangements as per J3.3 (where applicable) (for file) | 1 |  |  |
| Draft Clinical Trial Indemnity Form (for Beaumont Hospital) as per J3.3 (where applicable) (for file) – use template V4, 18.8.21 | 1  |  |  |
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