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:

1. Reviews applications to conduct research in:
2. Beaumont Hospital, Dublin 9 (incorporating St. Joseph’s Hospital, Raheny, D5) and including Raheny Community Nursing Unit, Dublin 5 [part of Beaumont Hospital}
3. Royal College of Surgeons Clinical Research Centre, Beaumont Hospital, Dublin 9 [part of Royal College of Surgeons in Ireland]
4. Provides a single national opinion under S.I. No. 29 / 2023 for
* all sites in the Republic of Ireland

– studies involving exposure to medical ionising radiation only -

Local requirements (if any):

It is a requirement to name an employee of Beaumont Hospital as the principal investigator in all cases.

For most studies the principal investigator will be an authorised healthcare professional employed by Beaumont Hospital – for the purposes of indemnity.

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

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

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

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 –

**NCHDs on rotation in Beaumont Hospital should name the Beaumont Hospital consultant supervising the research study as the Principal Investigator when applying to the research ethics committee.**

**Rationale - the consultant supervisor will remain in the employment of Beaumont Hospital, and thus be available to address any queries arising in relation to the study after the NCHD has left.**

* 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 26.6.23**- 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 31.7.22 | 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 05.23) | 1 |  |  |
| Other | 1 |  |  |
| Radiation Declaration Form | 1 |  |  |
| Supplementary Questions when applying for a single national opinion – studies involving exposure to medical ionising radiation only | 1 |  |  |
| Genomic Research with a Commercial Company Declaration Form | 1 |  |  |
| Proof of engagement with RCSI Sponsorship Office / Contracts Office (studies being conducted in collaboration with RCSI only)-Green Light from RCSI required before submitting to an ethics committee | 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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