Beaumont Hospital

Ethics (Medical Research) Committee

FREQUENTLY ASKED QUESTIONS

1. I am planning an audit. Do I need research ethics approval?

No. Clinical Audit does not require REC approval. To register the audit, log on to the Beaumont Hospital staff INTRANET[1]

2. I am planning a chart review. Do I need research ethics approval?

It depends on the purpose for which the chart review is being conducted

- Chart review for service evaluation purposes does not require REC approval
- Chart review for the purposes of clinical audit does not require REC approval
- Chart review as part of usual practice does not require REC approval
- Chart review for research purposes requires REC approval

See definitions.[2]

To register a clinical audit or service evaluation, log on to the Beaumont Hospital staff INTRANET[3]

3. I am planning on surveying staff or patients. Do I need research ethics approval?

It depends on the purpose.

If the survey is being conducted for research purposes, then REC approval is required.

To register a survey for the purposes of clinical audit or service evaluation, log on to the Beaumont Hospital staff INTRANET[4]

4. I am planning a case study / report. Do I need research ethics approval?

No. Contact the journal in question, and obtain written informed consent of the patient. REC approval is not required.

5. I am planning a laboratory validation. Do I need research ethics approval?

No. Routine laboratory validation does not require REC approval. Liaise with the Quality Manager in the Laboratory Directorate.

6. I plan to work with patients, patient groups and members of the public to design a research study and develop a research proposal. Do I need research ethics approval?

No. This is called Patient and Public Involvement (PPI)[5]. PPI activities do not require REC approval. [6]

[1] http://my.beaumont.ie/Pages/Departments/Clinical%20Audit/Home.aspx or QPULSE

[2] https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/what-is-research/

[3] See footnote 1

[4] See footnote 1

[5] https://www.beaumontethics.ie/home/PPI.htm

[6] Although REC approval is not needed researchers still need to adhere to ethical standards during any engagement involving patients.

7. I plan to conduct a research study and need to assess how many patients meet the inclusion criteria to take part. Do I need research ethics approval?

No. This is called 'pre-screening' to assess for eligibility to take part in a study. REC Approval is not required provided that you are:

a) A healthcare practitioner *employed by* Beaumont Hospital
b) An *employee* of Beaumont Hospital who has access to healthcare records as part of your day-to-day duties;
c) A student in training to become a healthcare practitioner under the direction and control of Beaumont Hospital

There is no mechanism in place in Beaumont Hospital for other persons including 'authorised persons' to conduct pre-screening at this time. Only persons listed in 7 (a) (b) and (c) can conduct pre-screening.

8. I am planning on conducting a retrospective chart review for research purposes and collecting data from patient charts. Do I need research ethics approval?

Yes; and in addition,

I. an assessment of data protection risk must be conducted and the REC must be satisfied and state in writing that the assessment of the risk is low;
II. only those listed in 7 (a), (b) and (c) can be involved in data collection;
III. collected data cannot be shared;
IV. any findings that are published cannot identify a patient.

Where criteria I, II, III and IV are not met, explicit patient consent or an application to a national committee called the Health Research Consent Declaration Committee[7] will apply.

9. How do I apply for local research ethics committee approval?

Log on to the REC website.[8] Obtain the relevant documentation to include the application form and Data Protection Impact Assessment (DPIA) and complete. Design participant information leaflets and consent forms – see templates on the website.[9]

Attach supplementary documentation as per checklist e.g. signatory page, cvs, certificates of insurance, recruitment material, surveys etc. Submit to beaumontethics@rcsi.ie

10. Can the local research ethics committee in Beaumont Hospital approve all study types?

No. You will need to apply to a National Research Ethics Committee[10] to conduct a clinical trial of a medicine, a clinical investigation of a medical device, or a follow-up investigation of a medical device. More national research ethics committees will be set up over time.

[7] https://hrcdc.ie/
[8] https://www.beaumontethics.ie/application/index.htm
[9] https://www.beaumontethics.ie/application/templates.htm
[10] https://www.nrecoffice.ie/

11. Can I start the study once I have REC approval from a national research ethics committee?

No. You must follow the site sign off process[11] which is overseen by the Director of Quality and Patient Safety or the Cancer Clinical Trials and Research Unit.

The study cannot commence until the process is complete and all contracts have been executed.

12. Can I start the study once I have REC approval from the local research ethics committee in Beaumont Hospital?

It depends on the study.

Some studies require an application to a national committee called the Health Research Consent Declaration Committee (HRCDC)[12] after REC approval;

All studies require cover under the Clinical Indemnity Scheme (CIS) and some studies require confirmation of this cover from AON[13]/State Claims Agency[14]. [note: it is a requirement of cover under the CIS that the PI be a healthcare professional employed by a Delegated State Authority (DSA)/Beaumont Hospital]

Some studies need to be notified to the Radiation Safety Committee of the hospital (or organisation / undertaking) in which the medical exposures take place;[15]

Some studies require the employment of staff which will need to be arranged with the Hospital HR Department;

Some studies may require input of the HR Department in respect of Garda Vetting / Mandatory Training etc. for external researchers;

Some studies require lodgement of funds into hospital research accounts which will need to be arranged with the Hospital Finance Department;

Some studies require the hospital to enter into a contract which means that the site sign off process[16] overseen by the Director of Quality and Patient Safety or the Cancer Clinical Trials and Research Unit will apply. The study cannot commence until the process is complete and all contracts have been executed.

13. Can the REC in Beaumont Hospital approve studies which involve exposure to medical ionising radiation?

Yes. It is one of a number of committees which has been recognised under S.I. No. 29/2023. This means it can review studies which involve exposure to medical ionising radiation, and can also give a single national research ethics committee opinion in relation to these studies. St. Luke's Radiation Oncology (SLRON) REC is also recognised under S.I. No. 29/2023. HIQA Guidance on Dose Constraints in Medical Exposures to Ionising Radiation 2020[17] applies.

[11]https://www.beaumontethics.ie/home/sign_off.htm
[12] https://hrcdc.ie/
[13]https://www.aon.com/ireland/industryexpertise/healthcare.jsp
[14] https://stateclaims.ie/
[15]https://www.beaumontethics.ie/home/radiation_studies.htm
[16]https://www.beaumontethics.ie/home/sign_off.htm
[17] https://www.hiqa.ie/reports-and-publications/guide/guidance-dose-constraints-medical-exposures-ionising-radiation

14. Where can I go for advice or support?

	Queries related to:	Contact:
Beaumont Hospital Clinical Governance / Audit Department	Clinical audit and service evaluation	clinicalaudit@beaumont.ie
Beaumont Hospital Cancer Clinical Trials and Research Unit	Studies / trials taking place in conjunction with this unit	keithegan2@beaumont.ie
Beaumont Hospital Cardiology Unit	Studies / trials taking place in conjunction with this unit	davidfarrell2@beaumont.ie
Beaumont Hospital Clinical Risk Management	Insurance / Indemnity for studies / trials	lynneherbert@beaumont.ie
Beaumont Hospital Data Protection Office	Data Protection Impact Assessments for studies / trials	dpo@beaumont.ie
Beaumont Hospital Director of Quality and Patient Safety	Site sign off procedure	sharondwyer@beaumont.ie
Beaumont Hospital Finance Department	Finance / research accounts	dof@beaumont.ie
Beaumont Hospital Gastroenterology / Hepatology Unit	Studies / trials taking place in conjunction with this unit	nualagodwin@beaumont.ie; caroleschilling@beaumont.ie
Beaumont Hospital Human Resources	Employment contracts / research personnel	hrdirector@beaumont.ie
Beaumont Hospital Legal Services	Legal review of contracts / agreements for studies / trials	legalresearch@beaumont.ie
Beaumont Hospital Quality Manager - Laboratory Directorate	Laboratory validation	paulaconran@beaumont.ie
Beaumont Hospital Radiation Protection Safety Adviser	Exposure to medical ionising radiation in research / trials	thomasheary@beaumont.ie
Beaumont Hospital Research Ethics Office	- Applications for research ethics approval - studies / trials involving Beaumont Hospital patients or staff - Applications for a single national research ethics committee opinion (studies involving exposure to medical ionising radiation)	beaumontethics@rcsi.ie
St. Luke's Radiation Oncology Network (SLRON)[18] Research Ethics Committee	- Applications for research ethics approval - studies involving SLRON patients or staff - Applications for a single national research ethics committee opinion (studies involving exposure to medical ionising radiation)	valerie.owens@slh.ie

[18] Includes St. Luke's Radiation Oncology Unit, Beaumont Hospital

15. Where else can I go for advice or support?

Health Products Regulatory Authority	Applying for HPRA authorisation	https://www.hpra.ie/
Health Research Consent Declaration Committee	Applying for a HRCDC declaration	https://hrcdc.ie/
HSE National Office of Research and Development	HSE publications relevant to research	https://hseresearch.ie/
National Office for Research Ethics Committees	Applying for national research ethics approval	https://www.nrecoffice.ie/
RCSI Clinical Research Centre	Studies / trials taking place in this facility	crc@rcsi.ie
RCSI Contracts Office	Studies which propose to enter into contracts with RCSI etc. **Follow RCSI Sponsorship Office Process where applicable**[19]	researchcontracts@rcsi.ie
RCSI Data Protection Officer	Studies / trials where RCSI is the data controller / data processor	dataprotection@rcsi.ie
RCSI PPI Ignite	Patient and Public Involvement (PPI)	ppi@rcsi.ie
RCSI Research Ethics Committee	Applying for research ethics approval - studies / trials involving RCSI students or staff	recadmin@rcsi.ie
RCSI Sponsorship Office	Studies / trials sponsored by RCSI etc. **Follow RCSI Sponsorship Office process where applicable**[20]	sponsorship@rcsi.ie

[19] https://www.beaumontethics.ie/home/sponsorship_office.htm
[20] https://www.beaumontethics.ie/home/sponsorship_office.htm

16. Research Ethics Department Personnel:

Prof. Gerry McElvaney, Chairperson	The Research Ethics Office in Beaumont Hospital processes applications to conduct research received to this committee, and liaises with legal counsel in relation to these submissions.
Prof. Peter Branagan, Convenor	
Ms. Gillian Vale, Research Ethics Specialist / Administrator	
Post Vacant, Research Ethics Officer / Response Administrator	
Ms. Mary Kirwan, Legal Counsel	

17. Legal Counsel

Mary Kirwan is a Barrister and lecturer in Healthcare Law. Her particular area of specialisation is data protection law, health research regulation, research ethics governance. Aside from her interest in Data Protection Mary is a medical law lecturer at the Royal College of Surgeons at undergraduate, postgraduate and doctoral level. She lectures on the RCSI MSc Healthcare Ethics and Law programme and is legal lead for the Royal College of Physicians basic and higher specialist training programmes. She is also an invited lecturer in the Honourable Society of Kings Inns, Trinity College Dublin and is recipient of the Law Society of Ireland's Justice Media Award. She acts as legal advisor to a number of academic and hospital Research Ethics Committees and Clinical Ethics Committees. Mary provides advices on a broad range of health related projects. She acted as legal consultant to the EU Health Support Consortium tasked by the European Commission with examining and presenting EU Member State rules governing the processing of health data. She has advised Irish Association of Physicists in Medicine, the Irish Institute of Radiography and Radiation Therapy and the Faculty of Radiologists and has provided consultation to the Irish Pharmaceutical Society among others. Mary is a member of the Ethics Advisory Board to a number of H2020 projects.

18. Contact Us

Ms. Gillian Vale Research Ethics Specialist / Administrator 00 353 1 809 2680; beaumontethics@rcsi.ie (Mon, Tue and Friday)	Queries regarding the Research Ethics Committee Review Process - this includes general queries, first applications to this committee, and amendments and reports to studies previously approved by this committee.
Post Vacant Research Ethics Officer / Response Administrator 00 353 1 797 4711 (Weds, Thurs)	Responses to questions posed by the committee at meetings
Ethics (Medical Research) Committee, Beaumont Hospital, Dublin 9, Ireland https://www.beaumontethics.ie/	

GDPR and the Health Research Regulations

GDPR took effect on the 25 May 2018

GDPR required among the following -

- the identification of DATA CONTROLLERS and DATA PROCESSORS
- putting contracts / agreements in place between various organisations
- the identification of an article 6 legal basis, and an article 9 condition
- the provision of information outlined in article 13 and 14 to data subjects[21]
- the conduct of Data Protection Impact Assessments (DPIAs)
- safeguards be put in place when conducting scientific research (article 89)

The Health Research Regulations took effect on the 8th August 2018.

The HRRs specified the mandatory safeguards to be put in place when conducting health research in the Republic of Ireland.

The primary safeguards were 'explicit consent' from the data subject or a 'health research consent declaration'; and research ethics committee approval.

Amendments to the Health Research Regulations took effect on the 21st January 2021

They provided for some exemptions in respect of these safeguards.[22]

Is training in data protection law and practice mandatory for all persons engaged in health research?

Yes – this is a mandatory safeguard under the Health Research Regulations.

Beaumont Hospital provides an online data protection course which is mandatory for all Beaumont Hospital staff – see BORIS

The HSE provides an online data protection course which is mandatory for all HSE staff – see HSELAND

RCSI provides an online data protection course which is mandatory for all RCSI staff.

Links to a number of presentations relevant to data protection and scientific research are available on the ethics committee website.[23]

Is there a template Data Protection Impact Assessment (DPIA) for Research and Clinical Trials?

Yes. See the Beaumont Hospital and RCSI Template for Clinical Trials and Research on the committee website.[24]

[21]https://www.dataprotection.ie/en/individuals/know-your-rights/right-be-informed-transparency-article-13-14-gdpr

[22]https://www.beaumontethics.ie/docs/application/overview_GDPR_HRRs.pdf

[23]https://www.beaumontethics.ie/home/training_ghent.htm

[24] https://www.beaumontethics.ie/home/t_dpia.htm