Standard Operating Procedure for Research Projects to take place at Beaumont Hospital		
BEAUMONT HOSPITAL RCSI HOSPITALS OSPIDÉIL RCSI	**Author(s):**	Ciara O'Toole & Jennifer Brannigan
	Owner:	Helen Ryan, Interim Head of Quality & Patient Safety
	Version Number:	Version 10
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	Date for Review:	May 2027
	Approved by:	Executive Management Group
	SOP number:	PPCF-IQS-15

1.0 Purpose:

The process in order to conduct research in Beaumont Hospital

2.0 Scope:

This applies to all anyone wishing to undertake research in Beaumont Hospital

3.0 Definitions:

PI – Principal Investigator
DPO – Data Protection Officer
HPRA – Health Products Regulatory Authority
HRCDC – Health Research Consent Declaration Committee

4.0	Stages in the procedure:	Responsibility
4.1	**Ethics** All research must be approved by the relevant National Research Ethics Committee (NREC-CT, NREC-MD etc.), or by a research ethics committee recognised under S.I. No. 29/2023 - European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) (Amendment) Regulations 2023 - to give a single national opinion for studies which involve exposure to medical ionising radiation, or by Beaumont Hospital Ethics (Medical Research) Committee. Details of requirements for application to Beaumont Hospital Ethics (Medical Research) committee are available at https://www.beaumontethics.ie/application/index.htm Link to Radiation Safety Committee https://www.beaumontethics.ie/home/radiation_studies.htm	Principal Investigator/Delegated Person

4.2	**DPO** All health research conducted in Beaumont must have a Data Protection Impact Assessments (DPIA) form completed and submitted to the DPO researchdpo@beaumont.ie	Principal Investigator/Delegated Person
4.3	**Legal** All contract/agreements for review must be submitted to the legal services department for review, email legalresearch@beaumont.ie. The legal services department will issue comments for review by the PI who will be responsible for ensuring any recommendations from this review are acted upon.	Principal Investigator/Delegated Person
4.4	**Insurance** Beaumont Hospital's insurer's need to be satisfied that the appropriate insurance is in place prior to conducting research in Beaumont Hospital. This letter of insurance indemnity can be obtained via the Risk & Legal department by emailing crm@beaumont.ie and submitting the following documentation: • *Clinical Trial Indemnity Form (CTIF) if applicable,* • *Approved contract/agreement* • *Ethics Approval* • *Sponsor Insurance Cert (min value €6.5m) if applicable*	Principal Investigator/Delegated Person
4.5	**Finance** Beaumont Hospital must be satisfied that there are no financial implications for Beaumont Hospital while conducting research. In order to obtain financial approval for research the following documents must be submitted to financesecretary@beaumont.ie ➢ *Obtained ethics approval* ➢ *Evidence of insurance cover* ➢ *3rd party insurance cert (if applicable)* ➢ *Clinical Trial Agreement* ➢ *Memo/cover letter declaring that there is no financial implications to Beaumont Hospital and whether any drugs or equipment are being provided to the hospital.* Once finance review is completed, the Director of Finance will issue a memo to the Principal Investigator for the attention of the CEO (or delegated person) outlining any financial implications for the hospital.	Principal Investigator/Delegated Person

4.6	**QPS Department review / CEO Sign-off** Once all of the above sign-offs are obtained, **Ethics** / **DPO** / **Legal** / **Insurance** / **Finance** a hard copy of these documents should be submitted in a pack for CEO (or delegated person) sign-off to the Director of Quality & Patient Safety's office. **All** research packs should include: Fully completed **Appendix 1 Form** Ethics Approval DPO Approval Legal contract which is **partially executed** Insurance cert from **Beaumont's insurer's** (AON) Finance **memo** showing finance sign-off ***In addition to the above the pack may also require the below approvals but these are only (if applicable) to the study*** - HPRA approval (if applicable) - HRCDC declaration (if applicable) - Confirmation of notification to Radiation Safety Committee for studies which involve additional exposure to ionising radiation that take place on the Beaumont Hospital Campus (if applicable) Once the Quality & Patient Safety department have completed their review, the pack is submitted to the CEO's office for final sign-off. Once executed the researcher will be informed. ***Please note the PI or lead contact person must retain a copy of all original signed documents***	Principal Investigator/Delegated Person
5.0	**Monitoring & Evaluation:** SOP will be updated every 3 years or sooner if the need arises	
6.0	**References:** • Appendix 1 Request for signature Form Appendix 1 Request for Signatu	
7.0	**Appendices:** **N/A**	