Standard Operating Procedure
Final approval for Research Projects to take place at Beaumont Hospital following Ethics Committee approval

Author(s):	Sharon Dwyer
Job Title:	Director of Quality & Patient Safety
Version Number:	3
Issue date:	7th January 2021
Date for Review:	January 2024
Approved by:	Executive Management Group
SOP number:	PPCF-IQS-15

Actions	**Responsible**
Principal Investigators (PIs), Co-Principal Investigators (CPIs) or Programme Managers (PMs) must ensure that all relevant documentation is completed and reviewed as required prior to submission to the CEO (or delegated person) for approval to proceed with research at Beaumont Hospital. Prior to the process below, approval must have been given by a recognised Research Ethics Committee.	PI/CPI/PM
1. Data Protection Impact Assessments (DPIA) form part of submissions to the Beaumont Hospital Ethics (Medical Research) Committee. Where Research Ethics approval is from a Research Ethics Committee outside of Beaumont Hospital, the PI must carry out a Data Protection Impact Assessment (DPIA) and submit this to the Data Protection Officer (DPO)[1] for review. The PI will be responsible for ensuring full compliance with GDPR Regulations. A template DPIA is available at http://www.beaumontethics.ie/home/t_dpia.htm	PI/CPI/PM
2. Any contract, clinical trial agreement (CTA), data sharing agreement (DSA) or material transfer agreements (MTA) must be submitted for a review by Beaumont Hospitals Legal Advisor.[2] Note, this could require amendments and should be done early in the process.	PI/CPI/PM
3. Beaumont Hospital Legal Advisor will issue a document review form and the PI will be responsible for ensuring any recommendations from this review are acted upon.	PI/CPI/PM
4. Confirmation is required that appropriate insurance and / or clinical indemnity is in place by submitting the following documents to Beaumont Hospital Insurance Department:[3] - Sponsor Insurance Certificate (minimum value €6.5M) (if applicable) - Clinical Trial Indemnity Form	PI/CPI/PM
5. Confirmation is required that there are no financial implications for Beaumont Hospital by submitting the following documents to the Director of Finance[4]: - Ethics Committee approval letter - Sponsor Insurance Certificate (minimum value €6.5M) (if applicable) - Letter from AON Insurance confirming that the study is covered under the Clinical	PI/CPI/PM

[1] orlacarty@beaumont.ie
[2] crm@beaumont.ie / 01 809 2611
[3] Insurance Department – lynneherbert@beaumont.ie / 01 809 2611
[4] adamohare@beaumont.ie

Indemnity Scheme - CTA / research protocol as applicable - Study cover letter to declare whether there are any cost implications to Beaumont Hospital and whether any drugs or equipment are being provided to the hospital.	
6. The Director of Finance will issue a memo to the PI/CPI/PM for the attention of the CEO outlining any financial implications for the hospital.	Director of Finance
7. In order to proceed with contract execution the following documents must be made available to the Director of Quality and Patient Safety[5] (QPS) in **hard copy** and **marked as appropriate where signatures are required** - A completed "*Request for signature of research-related documents by Beaumont Hospital CEO*" (Appendix 1) - Site specific assessment form - Ethics Committee approval letter - HPRA approval (if applicable) - Sponsor Insurance Certificate (minimum value €6.5M) (if applicable) - HSE Clinical Trial Indemnity Form - Confirmation letter from AON Insurance that the study is covered under the Clinical Indemnity Scheme - Director of Finance Memo - Confirmation of approval by Radiation Safety Committee (for studies which involve exposure to ionising radiation only) - CTA (reviewed by Beaumont Hospital Legal Advisor) or research protocol as applicable - MTA and / or DTA (as applicable) – reviewed by Beaumont Hospital Legal Advisor - Beaumont Hospital Legal Advisor Document Review Form - Copy of DPIA (for studies approved by RECs outside of Beaumont Hospital)	PI/CPI/PM
8. Once satisfied that all appropriate approvals are in place the following documents will be submitted to the CEO (or delegated person) for approval as required: - Site specific assessment form - HSE Clinical Trial Indemnity Form - CTA / Research Protocol as applicable - MTA and / or DSA (if applicable).	Director QPS
9. Once signed the PI/CPI/PM will be contacted.	Director QPS
10. The PI/CPI/PM/lead contact person must: - retain a copy of all original signed documents - provide one copy of the "Request for signature of research-related documents by Beaumont Hospital CEO" form and a certified scanned copy of the final signed CTA / MTA /DSA to the **Ethics (Medical) Research office**[6] at Beaumont Hospital - provide copy of annual report in relation to status of the study to the Director of Quality& Patient Safety[7].	PI/CPI/PM
11. Hold copy of Request for signature of research-related documents by Beaumont Hospital CEO" form on file.	BH Research Ethics
12. Hold certified scanned copy of final signed CTA / MTA /DSA on file.	Insurance Department
1.0 **Monitoring & Evaluation:** Review every 3 years or more frequently if required	

[5] Director of QPS – 01 809 3921
[6] lynnmcglynn@beaumont.ie
[7] sharondwyer@beaumont.ie