Standard Operating Procedure
Hospital sign off of Research Projects requiring approvals

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Approved by:	Executive Management Group
SOP number:	

1.0 Purpose:

All research studies at Beaumont Hospital require approval from the Beaumont Hospital Ethics (Medical) Research Committee or a HSE recognised Research Ethics Committee (multi-site clinical trials of medicinal products only). The purpose of this procedure is to ensure appropriate approvals and documentation have been completed and/or sought by Principal Investigators (PIs), Co-Principal Investigators (CPIs) or Programme Managers (PMs) prior to commencement of a research study at Beaumont Hospital.

2.0 Scope:

Applies to research studies being undertaken at Beaumont Hospital.

The PI is responsible for ensuring this process is followed throughout the study, that there is full compliance with all regulations including but not limited to GDPR and informed consent and that Good Clinical Research Practice[1] is followed.

The PI is responsible for ensuring that all contracts, clinical trial agreements, material transfer agreements or data sharing agreements are compliant with and reflect research regulations in place at the time of application.

3.0 Actions	Responsible
3.1 The Cancer Clinical Trials & Research Unit co-ordinates this process for studies relating to cancer clinical trials. The relevant PI/CPI/PM/lead contact person should contact the Cancer Clinical Trials Research Unit Programme Manager for guidance.	PI/CPI/PM
For all other studies, once research ethics approval[2] has been confirmed the following approval process must be followed prior to commencement of the research study:	
3.2 Any contract, clinical trial agreement (CTA), data sharing agreement (DSA) or material transfer agreements (MTA) to be submitted for review by Beaumont Hospitals Legal Advisor.[3]	PI/CPI/PM
3.3 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
3.4 Seek confirmation that appropriate insurance and / or clinical indemnity is in place by submitting the following documents to Beaumont Hospital Insurance Department:[4] - Sponsor Insurance Certificate (minimum value €6.5M) (if applicable) - Clinical Trial Indemnity Form	PI/CPI/PM

[1] Handbook for Good Clinical Research Practice – Guidance for Implementation (WHO, 2002)
[2] Full details available at https://www.beaumontethics.ie/application/index.htm
[3] Legal Advisor 01 797 7330
[4] Insurance Department 01 8092611

3.5 Seek confirmation that there are no financial implications for Beaumont Hospital by submitting the following documents to the Director of Finance: - 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 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.	PI/CPI/PM
3.6 A memo will be issued to the PI/CPI/PM for the attention of the CEO outlining any financial implications for the hospital.	Director of Finance
3.7 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 - 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.	PI/CPI/PM
3.8 Once satisfied that all appropriate approvals are in place the following documents will be submitted to the CEO (or delegated person) for signature as required: - Site specific assessment form - HSE Clinical Trial Indemnity Form - CTA / Research Protocol as applicable - MTA and / or DSA (if applicable).	Director QPS
3.9 Once signed the PI/CPI/PM will be contacted.	Director QPS
3.10 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 at Beaumont Hospital.	PI/CPI/PM
3.11 Hold copy of Request for signature of research-related documents by Beaumont Hospital CEO" form on file. 3.12 Hold certified scanned copy of final signed CTA / MTA /DSA on file.	BH Research Ethics Insurance Department
3.0 **Monitoring & Evaluation:** Review every 3 years or more frequently if required	

[5] Director of QPS – 01 809 3921