


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

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	Job Title:	Director of Quality & Patient Safety
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	Approved by:	Executive Management Group
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Actions	Responsible
<p>Principal Investigators (PIs)¹, 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.</p> <p>1. All research must be approved by the relevant National Research Ethics Committee (Clinical Trials of Medicinal Products, Clinical Investigation of Medical Devices) or by a ‘recognised Research Ethics Committee’² or by Beaumont Hospital Ethics (Medical Research) Committee³. Details of requirements for application to Beaumont Hospital Ethics (Medical Research) committee are available at https://www.beaumontethics.ie/application/index.htm</p> <p>2. 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)⁴ 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</p> <p>3. 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.⁵ Note, this could require amendments and should be done early in the process. This should be done through the eform link available on the Beaumont’s homepage: http://eforms/administration/requestforclinicaltriallegalreview/lists/forms/newform.aspx?FlowId=1&IsDlg=1&src=http://my.beaumont.ie</p> <p>4. Beaumont Hospital Legal Advisor will issue a report and the PI will be responsible for</p>	<p>PI/CPI/PM</p> <p>PI/CPI/PM</p> <p>PI/CPI/PM</p> <p>PI/CPI/PM</p>

¹ Principal study investigator must be a Beaumont Hospital employed healthcare professional

² Applies to clinical trials of medicines approved under S.I.190 of 2004 approved by a recognised research before the 31st December 2021 only. From the 1st January 2022, only national research ethics committee may approve a clinical trial of a medicine.

³ Applies to studies which fall outside the remit of national research ethics committees only.

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⁵ legalservices@beaumont.ie / 01 797 7330

<p>ensuring any recommendations from this review are acted upon.</p>	
<p>5. Confirmation is required that appropriate insurance and / or clinical indemnity is in place by submitting the following documents to Beaumont Hospital Insurance Department:⁶ (this is not necessary if you already have confirmation letter from AON Risk Solutions confirming that the study is covered under the Clinical Trial Indemnity Scheme)</p> <ul style="list-style-type: none"> - Sponsor Insurance Certificate (minimum value €6.5M) (if applicable) - Clinical Trial Indemnity Form (a CTIF may not be necessary where a master agreement exists AND where the sponsor is covered directly by the Clinical Indemnity Scheme) 	<p>PI/CPI/PM</p>
<p>6. Confirmation is required that there are no financial implications for Beaumont Hospital by submitting the following documents to the Director of Finance⁷:</p> <ul style="list-style-type: none"> - 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. 	<p>PI/CPI/PM</p>
<p>7. The Director of Finance will issue a memo to the PI/CPI/PM for the attention of the CEO (or delegated person) outlining any financial implications for the hospital.</p>	<p>Director of Finance</p>
<p>8. In order to proceed with contract execution the following documents must be made available to the Director of Quality and Patient Safety⁸ (QPS) (or delegated person) in hard copy and marked as appropriate where signatures are required</p> <ul style="list-style-type: none"> - A completed “<i>Request for signature of research-related documents by Beaumont Hospital CEO or delegate</i>” (Appendix 1) - Ethics Committee approval letter - HPRA approval (if applicable) - HRCDC declaration (if applicable) - Sponsor Insurance Certificate (minimum value €6.5M) (if applicable) - HSE Clinical Trial Indemnity Form (a CTIF may not be necessary where a master agreement exists AND where the sponsor is covered directly by the Clinical Indemnity Scheme) - 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 additional exposure to ionising radiation - CTA (reviewed by Beaumont Hospital Legal Advisor), Master Agreement (copy) 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) 	<p>PI/CPI/PM</p>
<p>9. 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:</p> <ul style="list-style-type: none"> - HSE Clinical Trial Indemnity Form (if applicable) - CTA / Research Protocol as applicable - MTA and / or DSA (if applicable). 	<p>Director QPS</p>

⁶ Insurance Department – lynnherbert@beaumont.ie / 01 809 2611

⁷ adamohare@beaumont.ie

⁸ sharondwyer@beaumont.ie – 01 809 3921

10. Once signed the PI/CPI/PM will be contacted.	Director QPS
11. The PI/CPI/PM/lead contact person must: <ul style="list-style-type: none"> - retain a copy of all original signed documents - email 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 office⁹ at Beaumont Hospital (The Cancer Clinical Trials & Research Unit will retain copies of all relevant documents on behalf of Beaumont Hospital Ethics Committee) - provide copy of annual report in relation to status of the study to the Director of Quality & Patient Safety¹⁰ or Cancer Research Executive as appropriate. 	PI/CPI/PM
12. Hold copy of “Request for signature of research-related documents by Beaumont Hospital CEO” form on file.	BH Research Ethics
13. Hold 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	

⁹ lynnemcglynn@beaumont.ie - 01 797 4711

¹⁰ sharondwyer@beaumont.ie