

SOP for Investigators Conducting Research and Clinical Trials in Beaumont Hospital and applying to Beaumont Hospital Ethics (Medical Research) Committee (Phase 1)

From 1st September 2023, investigators conducting research studies and clinical trials in Beaumont Hospital and applying to Beaumont Hospital Ethics (Medical Research) Committee must:

Before applying to REC	
1. Contact the Royal College of Surgeons in Ireland (RCSI) Sponsorship Office - sponsorship@rcsi.ie See RCSI SOP - https://www.beaumontethics.ie/home/sponsorship_office.htm	RCSI requirement - applies to research studies in collaboration with RCSI only
2. Contact the RCSI DPO - dataprotection@rcsi.ie	RCSI requirement - applies to research studies where RCSI is the data controller / joint data controller only
3. All investigators conducting research studies and clinical trials in Beaumont Hospital in collaboration with RCSI must wait Green Light from RCSI to proceed to next step - <i>green light equals a signed Clinical Research Registration Form or Material Data Transfer Form</i> https://www.beaumontethics.ie/home/sponsorship_office.htm	RCSI requirement - applies to research studies in collaboration with RCSI only
Apply to REC	
4. Apply to Beaumont Hospital REC - https://www.beaumontethics.ie	
5. The Beaumont REC administrator will validate the submission.	
DPO Review	
6. The Beaumont REC administrator will forward the <i>DPIA and PILs and CFs to the Beaumont Hospital DPO for review</i> and forward DPO feedback and review comments to the investigator.	Beaumont Hospital requirement
7. The Beaumont REC administrator will coordinate communication between the DPO and the investigator until such time as the DPO feedback and review comments have been addressed to the satisfaction of the DPO.	Beaumont Hospital requirement
REC Review	

8. The submission will be scheduled for REC review.	
9. The REC administrator will forward feedback and review comments from the REC to the investigator.	
10. The REC administrator will schedule responses from the investigator for review.	
11. The REC administrator will communicate further feedback or final decision of the REC to the investigator.	
After REC approval	
12. Where full research ethics committee approval is granted, the investigator will commence the hospital site sign off process - https://www.beaumontethics.ie/home/sign_off.htm	Beaumont Hospital requirement - applies to research studies entering into contracts with the hospital
13. The outcome of the site sign off process is executed contracts.	