

Short SOP for Investigators Conducting Research and Clinical Trials in Beaumont Hospital and applying to Beaumont Hospital Ethics (Medical Research) Committee (Phase 2)

From 1st September 2024, 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. 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 Information Form or confirmation that neither applies</i> https://www.beaumontethics.ie/home/sponsorship_office.htm	RCSI requirement - applies to research studies in collaboration with RCSI only
Apply to REC	
3. Apply to Beaumont Hospital REC - https://www.beaumontethics.ie	
4. The Beaumont REC administrator will validate the submission.	
DPO Review	
5. The Beaumont REC administrator will send specific validated documents to the Hospital DPO.	Beaumont Hospital requirement
6. The DPO will review validated documents received.	Beaumont Hospital requirement
7. REC Review may not proceed until the DPO review is complete and all recommendations from the DPO have been incorporated into relevant documents 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

13. The outcome of the site sign off process is permission to conduct the study in Beaumont Hospital.