

Short SOP for Investigators Conducting Research and Clinical Trials in Beaumont Hospital and applying to Beaumont Hospital REC (Phase 3)

From **1st January 2025**, investigators conducting research studies and clinical trials in Beaumont Hospital and applying to Beaumont Hospital REC 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 involving RCSI only
2. All investigators conducting research studies and clinical trials in collaboration with RCSI must await go ahead from RCSI to proceed to next step – <i>go ahead equals a signed Clinical Research Registration Form or Material Data Information Form or confirmation from RCSI that neither apply:</i> https://www.beaumontethics.ie/home/sponsorship_office.htm	RCSI requirement - applies to research studies involving 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. The REC administrator will act as liaison between the DPO and the investigator until such time as DPO review is a complete and all recommendations from the DPO have been incorporated into relevant documents to the satisfaction of the DPO.	Beaumont Hospital requirement
Legal Review	
8. The REC Administrator will advise the investigator to send the contracts for legal review to legalresearch@beaumont.ie (studies which require contracts with third parties other than RCSI only)	
REC Review	
9. The submission will be scheduled for REC review.	
10. The REC administrator will forward feedback and review comments from the REC to the investigator.	
11. The REC administrator will schedule responses from the investigator for review.	

12. The REC administrator will communicate further feedback or final decision of the REC to the investigator.

After REC Review

Legal / Insurance / Finance

13. **On a trial basis**, where applicable, **for studies which require contracts with RCSI only**, the REC administrator will contact RCSI Contracts on behalf of the investigator to request a Letter of Agreement (LoA) be drafted and sent to Beaumont Legal Services for review

Beaumont Hospital requirement
Please allow 2 – 4 weeks for legal/insurance and finance approvals to issue **for studies which fall within the scope the trial only**

14. **On a trial basis**, where applicable, **for studies which do not require contracts or which require contracts with RCSI only**, the REC administrator will contact AON Healthcare on behalf of the investigator to request Insurance approval

15. **On a trial basis**, where applicable, **for studies which do not require contracts or which require contracts with RCSI only**, the REC administrator will contact the Finance Department on behalf of the investigator to request Finance Approval

16. **For studies which fall outside of scope of the trial**, the investigator will have sent contracts for legal review to legalresearch@beaumont.ie themselves (see point 8). Once legal approval is in place, investigators must obtain insurance and finance approvals themselves as per hospital sop - [SOP Site Sign Off, V10, 05.24](#)

Beaumont Hospital requirement

Quality

17. Once all relevant approvals (data protection, research ethics, legal, insurance, finance) in place, the investigator must request permission to conduct the study / or that contracts be executed via the Quality and Patient Safety Department using their form: [SOP Appendix 1 \(Request for Signature Form\), 05.24](#)

Beaumont Hospital requirement
Please allow 2 weeks for permission / executed contracts to issue

18. Once permission to conduct the study / or executed contracts are in place, the investigator must request Green Light from RCSI Sponsorship to commence – sponsorship@rcsi.ie

RCSI requirement – **applies to research studies involving RCSI only**
Please allow 2 weeks for Green Light to issue