

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

From 1st July 2024, investigators conducting research studies and clinical trials in Beaumont Hospital and applying to Beaumont Hospital Ethics (Medical Research) Committee must:

<b>Before applying to REC</b>	
1. Contact the Royal College of Surgeons in Ireland (RCSI) Sponsorship Office - <a href="mailto:sponsorship@rcsi.ie">sponsorship@rcsi.ie</a> See RCSI SOP - <a href="https://www.beaumontethics.ie/home/sponsorship_office.htm">https://www.beaumontethics.ie/home/sponsorship_office.htm</a>	RCSI requirement - <b>applies to research studies in collaboration with RCSI only</b>
2. All investigators conducting research studies and clinical trials in Beaumont Hospital <b>in collaboration with RCSI</b> must wait for 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> <a href="https://www.beaumontethics.ie/home/sponsorship_office.htm">https://www.beaumontethics.ie/home/sponsorship_office.htm</a>	RCSI requirement - <b>applies to research studies in collaboration with RCSI only</b>
<b>Apply to REC</b>	
3. Apply to Beaumont Hospital REC - <a href="https://www.beaumontethics.ie">https://www.beaumontethics.ie</a>	
4. The Beaumont REC administrator will validate the submission ahead of DPO review.	
<b>DPO Review</b>	
5. The Beaumont REC administrator will direct the investigator to submit <u>specified</u> validated documents to the Hospital DPO.	Beaumont Hospital requirement
6. The investigator will revert back to the REC once DPO review is <u>fully complete</u>	
7. The REC administrator will validate the submission ahead of REC review.	
<b>REC Review</b>	
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](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.