

Clinical Trial/Study approval process between RCSI and Beaumont

The procedure below applies to the approval of clinical studies led by RCSI investigators involve Beaumont Hospital's patients, patient tissue and/or data, regardless of the source of funding, use of IMP or device.

If an RCSI investigator is involved as sub-investigator/collaborator in a study led by Beaumont clinician, he/she should ignore the procedure below and engage with the RCSI Research Contract Team (researchcontracts@rcsi.ie) as early possible, prior to the submission of any document to Beaumont ethics committee and DPO

The purpose of the procedure is:

- (a) to identify as early possible the role of RCSI and Beaumont in the study as well as institutional regulatory and contractual requirements (as applicable)
- (b) to enable RCSI and Beaumont to make Investigators aware of institutional, regulatory and contractual requirements early in the study planning/set up process
- (c) to enable Investigators, RCSI Sponsorship Office, RCSI Research Contracts Team to put in place the necessary requirements in a coordinated and timely manner

Step	Action	Responsible
1	At study planning stage, the Principal investigator (PI) or Chief Investigator (CI) notifies by email the Sponsorship Office (sponsorship@rcsi.ie) of the plan to undertake a clinical study	RCSI/ PI/CI
2	The Sponsor Officer engages with the Principal Investigator and clarifies if the study is interventional or observational <ul style="list-style-type: none"> (a) If the study is observational and does not involve RCSI, Sponsorship Officer communicates with PI and clarifies that the process involving RCSI terminates here. (b) If the study is interventional or observational involving a large amount of funding and/or a high risk procedure, the Sponsorship Office engages with the PI/CI and Beaumont Hospital in accordance with the process and procedures outlined below (c) If the study is a low risk observational study and involves RCSI, the Sponsor Officer puts in touch the PI/CI with RCSI Research Contracts Team (researchcontracts@rcsi.ie) which will manage the study contractual requirements and engagement with Beaumont in accordance with a separate process and procedures 	RCSI/ PI/CI
3	If (b) above applies, the Sponsorship Office will ask the PI/CI to complete the Clinical Study Registration Form (CSRF)	RCSI
4	The CI/PI completes CSRF and sends it to RCSI Sponsorship Office (sponsorship@rcsi.ie)	PI/CI
5	<ul style="list-style-type: none"> (a) RCSI Sponsorship Office gives the CSRF a reference number. (b) RCSI Sponsorship Officer reviews CSRF and in the comment section clarifies the following: <ul style="list-style-type: none"> • study classification (i.e. observational, interventional non regulated and regulated) • role of RCSI and Beaumont with respects to the clinical trial (i.e. sponsor role (if applicable), and role (if any) of the other party) • study risk level and insurance cover • any regulatory and institutional approval and oversight requirements • whether there is sufficient funding to support the trial and cover sponsorship activities 	Sponsorship Office

	<ul style="list-style-type: none"> whether RCSI can sponsor the study <p>(c) Upon completion of the form the Sponsorship Office shares the form with RCSI research contract team</p>	
6	<p>(a) RCSI research contract team reviews CSRF and in the comments section clarifies the following:</p> <ul style="list-style-type: none"> Contractual requirements (CTA, MTA, MTDSA) Data protection roles of RCSI, Beaumont and third party, where applicable, (i.e. independent/ joint/sole controller, processor) <p>(b) Upon completion of the legal/data protection review, the Research Contract Team shares the CSRF with the Sponsorship Office</p>	Research Contract team / sponsorship Office
7	Sponsorship Office shares CSRF with PI/CI	RCSI Sponsorship Office
8	PI/CI reviews comments and requirements, engages with Sponsorship Office for clarifications (if necessary), signs declaration/undertaking section of the CSRF and emails signed form to sponsorship@rcsi.ie .	PI/CI RCSI Sponsorship Office
9	<p>For non-regulated trials: the PI prepares and submits the PIL/Consent form and/or, if applicable, consent declaration application form, to Sponsorship Office for review/approval.</p> <p>For regulated trials: PI/CI prepares and submits DPIA, PIL, Patient consent form and/or, if applicable, consent declaration application form and, submits the documentation to the Sponsorship Office for review/approval</p>	PI/CI
10	Upon Sponsorship Office approval (as applicable), CI submits DPIA, PIL and consent form to DPO of the institution(s) who act(s) as data controller for the research project for review/feedback/approval. If Beaumont Hospital is data processor for the purpose of the clinical trial, Beaumont Hospitals DPO approval of the DPIA is required	PI/CI
11	DPO(s) reviews documentation, provides feedback, and, when appropriate, approves DPIA	DPO
12	If the study is regulated the Sponsorship Office and CI prepare and submit documentation (protocol, PIL, patient consent form, insurance certificate, application form) to the competent authority for regulatory approval	RCSI Sponsorship Office & CI
13	<p>For non-regulated trials: PI/CI (or SO for regulated trials) submits signed CSRF, approved DPIA, Ethics application, PIL, Patient consent form, and/or, if applicable, consent declaration to ethics committee.</p> <p>For regulated trials: the PI/Sponsorship office follows Competent Authority approval process. Upon approval, PI/CI follows BH ethics sign off process</p>	PI/CI
14	<p>Research Contracts Team draft agreements using, where possible, agreed templates. Changes to the templates are tracked</p> <p>Draft agreements (+accompanying documents) are submitted to Beaumont Legal (by email) for review</p> <p>Accompanying documents include:</p> <ul style="list-style-type: none"> CSRF Protocol PIL Ethics application (for non-regulated trials) DPIA & outcome of DPO review 	RCSI Research Contracts Team

15	Beaumont Hospital legal team reviews agreement and engages with RCSI Research Contracts Team for feedback/revisions	Beaumont Legal and RCSI Research Contracts Team
16	RCSI Research Contracts Team sends partially executed finalised agreement (including Beaumont legal review documentation) to Sponsorship Office Operations Assistant	RCSI Research Contracts Team
17	<p>(a) The PI/CI submit to Beaumont Hospital Insurance Department (lynneherbert@beaumont.ie / 01 809 2611) the following documents:</p> <ul style="list-style-type: none"> - Sponsor Insurance Certificate (minimum value €6.5M) (if applicable) - Clinical Trial Indemnity Form <p>(b) The Insurance Dept. will liaise with AON and then issue confirmation from AON that appropriate insurance and / or clinical indemnity is in place</p>	
18	<p>(a) PI/CI engages with Director Finance (kennethruigrok@beaumont.ie) and submit the following documents to the Director of Finance</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>(b) 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>	
19	<p>Sponsorship Office files agreement + legal documentation and waits until The PI/CI confirms that all the documents required for Beaumont approval and the execution of the agreement(s) are available</p> <ul style="list-style-type: none"> - <i>“Request for Signature Document for Research Purposes”</i> form - HPRA approval (where applicable) - HRCDL declaration (if applicable) - Ethics approval letter - DPIA + confirmation of approval - Beaumont Legal Review documentation - Proof of Insurance (from Sponsorship Office) - Confirmation that study is covered under the Clinical Indemnity Scheme (validation memo from AON) - Finance validation memo 	Sponsorship Office PI/CI

	When the PI/CI confirms that the documents are in place, the Sponsorship Office Operations Assistant shares partially executed contract with PI	
20	<p>PI submit to Director of Quality and Patient Safety the following documents in hard copy (1 copy only):</p> <ul style="list-style-type: none"> - <i>“Request for Signature Document for Research Purposes”</i> form (available at - HPRA approval (where applicable) - Partially executed agreement(s) - Beaumont Legal Review documentation - Ethics approval - DPIA + confirmation of approval - HRCDC declaration (where applicable) - Proof of Insurance (validation memo from AON) - Finance validation memo - 	PI/CI
21	Director of Quality and Patient Safety manages Contract execution	Director of Quality and Patient Safety
22	Director of Quality and Patient Safety notifies the PI/CI that fully executed copy of agreement is ready for collection.	Director of Quality and Patient Safety
23	Director of Quality and Patient Safety sends a copy of <i>“Request for Signature Document for Research Purposes”</i> form and fully executed agreement to Beaumont Ethics (Medical Research Department)	Director of Quality and Patient Safety
24	PI/CI sends electronic copy of the agreement to Sponsorship Office (Sponsorship@rcsi.ie)	PI/CI
25	Sponsorship Office sends electronic copy of fully executed agreement to RCSI Research Contracts Team	Sponsorship Office
26	Sponsorship Office ensure that all requirements set out in the CSRF are met before giving Green Light	Sponsorship Office