**TOP TIPS FOR FASTER SITE SET UP / SITE SCOPING**

**(trials seeking to take place in Beaumont Hospital and applying for external REC Approval)**

**Do you want to set up a trial in Beaumont Hospital? Planning to apply to an external REC?**

For Studies other than Cancer which are managed by the Cancer Clinical Trials Unit[[1]](#footnote-1), proceed as follows:

1. Do you need DPO input before applying to an external REC? Email the DPIA, PIL/CF and Study Protocol to [researchdpo@beaumont.ie](mailto:researchdpo@beaumont.ie)

**(pre-ethics step – required by some external RECs)**

* Top Tip: the local Data Protection Impact Assessment Form is here: <https://www.beaumontethics.ie/home/t_dpia.htm>
* Note – A national Data Protection Impact Assessment will be released in due course.

1. Do you need a signature on a Site Suitability Form before applying to an external REC, email a statement from the Principal Investigator of the suitability of the site facilities/equipment/human resources to conduct this trial, the Site Suitability Form and the study protocol to [jenniferbrannigan@beaumont.ie](mailto:jenniferbrannigan@beaumont.ie)

**(pre-ethics step – required by some external RECs)**

**TOP TIPS FOR FASTER SITE SIGN OFF**

**(trials seeking to take place in Beaumont Hospital which have external REC Approval)**

**Do you already have REC approval from an external REC? Need Hospital Sign Off on a Contract?**

For Studies other than Cancer which are managed by the Cancer Clinical Trials Unit[[2]](#footnote-2), proceed as follows:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. Collate the documents needed by each department: | | | | |
| **Data Protection** | **Legal** | **Finance** | **Insurance** | **Quality and Pat.Safety** |
|  |  | Evidence of Ethics Approval – usual format is either  a screenshot of the approval from the CTIS system to include a list of sites approved, and a list of docs approved with their version numbers or an approval letter from a REC | Evidence of Ethics Approval – usual format is either a screenshot of an approval from the CTIS system to include a list of sites approved, and list of docs approved with their version numbers or an approval letter from a REC | Evidence of Ethics Approval – usual format is either a screenshot of an approval from the CTIS system to include a list of sites approve and list of docs approved with their version numbers of an approval letter from a REC |
|  |  |  | Evidence of HPRA Approval  **(where applicable)** | Evidence of HPRA Approval  **(where applicable)** |
| Data Protection Impact Assessment |  |  |  |  |
| Copy Participant Information Leaflet / Consent Form |  |  |  |  |
| HRCDC declaration  **(if required)** |  |  |  | HRCDC declaration  **(if required)** |
|  | 3rd party contract / agreement e.g. Data Sharing / Material Transfer / Clinical Trial Agreement | Approved 3rd party contract / agreement e.g. Data Sharing / Material Transfer / Clinical Trial Agreement | Approved 3rd party contract / agreement e.g. Data Sharing / Material Transfer / Clinical Trial Agreement | Approved 3rd party contract / agreement e.g. Data Sharing / Material Transfer / Clinical Trial Agreement |
|  |  |  | 3rd party signed Clinical Trial Indemnity Form  **(clinical trials only)** | 3rd party signed  Clinical Trial Indemnity Form  **(clinical trials only)** |
|  |  | 3rd party insurance cert (6.5 million)  **(clinical trials only)** | 3rd party insurance cert (6.5 million)  **(clinical trials only)** |  |
|  |  | Any other relevant 3rd party insurance letters / certs | Any other relevant 3rd party insurance letters / certs |  |
|  |  |  |  | Evidence of DPO Review |
|  |  |  |  | Legal Approval |
|  |  | Insurance Approval |  | Insurance Approval |
|  |  | Memo/cover letter declaring that there is no financial implications to BH and whether any drugs or equipment are being provided to the hospital  **(need to type this)** |  | Finance Approval |
|  |  |  |  | Site Sign Off Form |

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| 2. email docs needed for dpo review to researchdpo@beaumont.ie  **(ignore this step if already completed during site set up / scoping)** |
| Top Tip: the local Data Protection Impact Assessment Form is here: <https://www.beaumontethics.ie/home/t_dpia.htm>  Note: a national Data Protection Impact Assessment will be released in due course. |
| 3. email docs needed for legal approval to [legalresearch@beaumont.ie](mailto:legalresearch@beaumont.ie) |
| 4. email docs needed for insurance approval to [crm@beaumont.ie](mailto:crm@beaumont.ie) |
| 5. email docs needed for finance approval to [financesecretary@beaumont.ie](mailto:financesecretary@beaumont.ie) |
| Top Tip – while waiting for approvals to come back in, complete the Site Sign Off Form  Top Tip – the Site Sign Off Form is here - <https://www.beaumontethics.ie/home/sign_off.htm>  Top Tip – if you need to notify the Radiation Safety Committee about your trial / study – use the RSC Notification Form - <https://www.beaumontethics.ie/home/radiation_studies.htm> **(this is a notification form only)** |
| 6. Once approvals in, finalise the Site Sign Off Form, collate the docs needed for Quality and Patient Safety Approval post or drop in hard copies to Department of Quality and Safety, Room 12, St. Raphael’s Portacabins, Beaumont Hospital, Dublin 9. Any questions contact - [jenniferbrannigan@beaumont.ie](mailto:jenniferbrannigan@beaumont.ie) |
| 7. The Quality and Patient Safety Department will contact you when the contract has been signed by the CEO. |

DRAFT ONLY - Apr 2024

1. For Cancer Studies, contact [keithegan2@beaumont.ie](mailto:keithegan2@beaumont.ie) [↑](#footnote-ref-1)
2. For Cancer Studies, contact [keithegan2@beaumont.ie](mailto:keithegan2@beaumont.ie) [↑](#footnote-ref-2)