National Research Ethics Committee for Clinical Trials (NREC-CT)

Application Checklist

**Please complete this checklist and submit it with your application.**

• Submit a copy of each document

• All accompanying documents must bear version numbers and dates

• Select ‘yes / no’ as applicable

|  |  |  |  |
| --- | --- | --- | --- |
| General  (Each Item is Mandatory) | Enclosed | Recommended File Name | Date |
| **Application Form** | Mandatory | \_Application Form | Click or tap to enter a date. |
| **Clinical Trial Protocol** | Mandatory | \_Protocol | Click or tap to enter a date. |
| **Summary CV for Principal Investigator** | Mandatory | \_CV | Click or tap to enter a date. |
| **Research Participant Information Leaflet** | Mandatory | \_PIL | Click or tap to enter a date. |
| **Research Participant Consent Form** | Mandatory | \_Consent Form | Click or tap to enter a date. |
| **Insurance/Indemnity Certificate** (for Each Site) | Mandatory | \_Insurance Cert | Click or tap to enter a date. |
| **Data Protection Impact Assessment** (or Statement why not required) | Mandatory | \_DPIA | Click or tap to enter a date. |
| **Evidence of Fee Payment** | Mandatory | \_Payment | Click or tap to enter a date. |
| **Site Suitability Form / Site Specific Assessment Form** (for Each Site) | Yes No | \_SSA | Click or tap to enter a date. |
| **Letter of Invitation for Participant** | Yes No | \_LoI | Click or tap to enter a date. |
| **Investigators Brochure** | Yes No | \_IB | Click or tap to enter a date. |
| **Cover Letter** (on headed paper) | Yes No | \_Cover Letter | Click or tap to enter a date. |
| **Details of any Data Monitoring Committee** | Yes No | \_DMC | Click or tap to enter a date. |
| **Case Report Form** | Yes No | \_Case Report | Click or tap to enter a date. |
| **Validated Questionnaire** | Yes No | \_Validated Questionnaire | Click or tap to enter a date. |
| **Non-validated Questionnaire** | Yes No | \_Non-Validated Questionnaire | Click or tap to enter a date. |
| **Copies of Advertisement Material for Research Participants, e.g. posters, newspaper adverts, website. For video or audio recordings, please also provide the printed script.** | Yes No | Click or tap here to enter text. | Click or tap to enter a date. |