National Research Ethics Committee

for COVID-19-related Research

# Document submission checklist

**Please enclose a completed version of this checklist with your application and documentation for ethical review by the NREC COV-19 (and HRCDC if required)**

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| **Document type** | **Enclosed Y/N** | **Date** | **Version number** |
| **General (Mandatory)** |  |  |  |
| Application form **(Mandatory)** | Yes No |  |  |
| Evidence of secured funding (or conditional funding) **(Mandatory)** | Yes No |  |  |
| Summary C.V. for Chief Investigator **(Mandatory)** | Yes No |  |  |
| Research Participant Information Sheet **(Mandatory)** | Yes No |  |  |
| Research Participant Consent Form) **(Mandatory)** | Yes No |  |  |
| Evidence of Insurance or Indemnity **(Mandatory)** | Yes No |  |  |
| **Clinical Trial (Mandatory)** |  |  |  |
| Clinical Trial Protocol **(Mandatory)** | Yes No |  |  |
| Site specific assessment form (for each site) **(Mandatory)** | Yes No |  |  |
| **Consent Declaration assessment (Mandatory)** |  |  |  |
| Data Protection Officer feedback **(Mandatory)** | Yes No |  |  |
| Data Protection Impact Assessment **(Mandatory)** | Yes No |  |  |
| **General (required if available)** |  |  |  |
| Covering letter | Yes No |  |  |
| Study protocol | Yes No |  |  |
| Next-of-Kin study Information Leaflet & Assent form | Yes No |  |  |
| Investigators brochure | Yes No |  |  |
| Letter of Invitation for participant | Yes No |  |  |
| Summary, synopsis or diagram  (flowchart) of protocol in nontechnical language | Yes No |  |  |
| Details of any Data Monitoring  Committee | Yes No |  |  |
| Sample diary card/patient card | Yes No |  |  |
| Validated questionnaire | Yes No |  |  |
| Non-validation questionnaire | Yes No |  |  |
| 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 |  |  |
| **Consent Declaration assessment (required if available)** |  |  |  |
| Next-of-Kin study Information Leaflet & Assent form | Yes No |  |  |
| Contractual or other arrangements in place between the data controllers, joint data-controllers and/or data processors | Yes No |  |  |
| Transparency notices and/or data protection policy of the data controller organisation | Yes No |  |  |