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| RESEARCH OFFICE  STUDY REGISTRATION FORM | Research OfficeContact Details |

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| * ***This form should be completed before the research project commences.*** * ***Principal Investigator refers to the PI at the Research Site ( or Chief Investigator for a single site study)*** * ***This form should be consistent with the planned or submitted Research Ethics Committee application*** * ***Please return completed form along with any supporting documents to the appropriate Research Office*** |

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| **RESEARCH OFFICE** | | | |
| Research Site: | |  | |
| Study Registration number: (to be completed by Research Office) | |  | |
| **STUDY DETAILS** | | | |
| Study Title: | | | |
|  | | | |
| Short Study title: | | | |
|  | | | |
| Study Information: Please provide a brief lay (plain English) description of the study. Please ensure the language used in your answer is at a level suitable for use in a research participant information leaflet. | | | |
|  | | | |
| Expected Start Date: | | |  |
| Expected Duration in months: | | |  |
| Is this a multi-site study? | | | Choose an item |
| **STUDY TYPE**  **(Decide which option applies to your study and then select from the corresponding dropdown)** | | | |
| **Option 1 - Interventional: Regulated Clinical Trial[[1]](#footnote-1)**  Before they can start Regulated Clinical Trials need approval from both the HPRA and the applicable National Research Ethics Committee (NREC). | | | Choose an item |
| **Option 2 - Interventional: Non-Regulated Clinical Trial1**  These are studies that meet the definition of a Clinical Trial but are not regulated.  *Non- IMP clinical trial*: where the intervention isn’t a Drug or device for example nutritional, cosmetic, surgical procedures, radiological procedures, behavioural treatments, process-of care changes, or preventive care.  *Ionizing radiation*: research projects where the radiological procedure is a primary focus of the research, i.e. is undertaken to assess the safety, performance or effectiveness of a medical radiological procedure, and/or research projects that propose a medical radiological procedure that significantly deviates from standard care. | | | Choose an item |
| **Option 3 - Non-Interventional: Additional Assessment**  A study that doesn't directly intervene in the care journey but involves additions to the standard of care, i.e. testing or procedures that are only conducted because the service user is enrolled in the study. | | | Choose an item. |
| **Option 4 - Non-Interventional: - Observational only**  A study that doesn't intervene in the care journey or require additional testing or procedures. for example an observational clinical study that involves non-invasive data collection only i.e. surveys | | | Choose an item. |
| Option 4 – Other (more details) | | |  |
| **PRINCIPAL INVESTIGATOR** | | | |
| Principal Investigator Prefix/Title: | Choose an item. | | |
| Principal Investigator name: |  | | |
| Principal Investigator Position: |  | | |
| Principal Investigator Organisation Affiliation: |  | | |
| Principal Investigator Address: |  | | |
| Principal Investigator Email Address: |  | | |
| Principal Investigator Contact Number: |  | | |
| **LEAD CONTACT**  **(if different to Principal Investigator)** | | | |
| Lead Contact Prefix/Title: | Choose an item. | | |
| Lead Contact name: |  | | |
| Lead Contact Position: |  | | |
| Lead Contact Organisation Affiliation: |  | | |
| Lead Contact Address: |  | | |
| Lead Contact Email Address: |  | | |
| Lead Contact Phone Number: |  | | |
| **ADDITIONAL DETAILS** | | | |
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1. Clinical trial: A clinical trial is a type of health research. These types of studies prospectively assign human participants or groups of humans to one or more health related intervention in order to evaluate the effects on health outcomes. Interventions include, but are not restricted to, drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, process-of care changes, or preventive care. Clinical Trials can be regulated or non-regulated [↑](#footnote-ref-1)