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| **STUDY INFORMATION FORM** |
| **Short Title:** | Enter full title of study |
| **R&D Number:** |  |
| **IRAS Number:** | Enter IRAS Project ID |
| **Principal Investigator(s)** |  |
| **Site(s) in NHS Lothian:** |  |

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| **PART A: RESEARCH TEAM** |

To allow us to arrange the appropriate access permissions for researchers, please provide details of ALL the local research team in the table below. This should include non-NHS or HRC investigators that require an honorary research contract (HRC) (e.g. substantively employed by a University).

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| --- | --- | --- |
| Team Member Name | Research Role | NHS Lothian Contract  |
|  | Choose an item. | Choose an item. |
|  | Choose an item. | Choose an item. |
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| **PART B: SUPPORT DEPARTMENTS** |

To allow us to obtain appropriate departmental authorisations and consider financial implications, please provide details of ALL interventions and/or tests which are additional to standard care as part of this research study (if there are no interventions, state N/A). It is highly recommended that you make contact with the departments that will be supporting your study to avoid delays in receiving Head of Service and Support Department approval.

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|  Support Department | Intervention or Test | Location(e.g. RIE, WGH, SJH) | Total as per Protocol | Total as per Standard Care |
| Labs / Tissue Governance | **No** |  |  |  |  |
| Pathology | **No** |  |  |  |  |
| Radiology | **No** |  |  |  |  |
| Pharmacy | **No** |  |  |  |  |
| Edinburgh Imaging | **No** |  |  |  |  |
| Medical Photography | **No** |  |  |  |  |
| Medical Physics | **No** |  |  |  |  |
| CRF | **No** |  |  |  |  |
| Other (please specify below) |  |  |  |  |  |
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| **PART C: IG/IT SECURITY** |

If Information Governance (IG) oversight is required for your study, an IT Security risk assessment may be required. It is important for you to seek advice and initiate an IG review as early as possible to ensure R&D management approval is not delayed. If your study involves any of the following, it is recommended that you contact the R&D Information Governance Lead at pavlina.mcgovern@nhs.scot

* Use of any online video conferencing platforms, i.e. MS Teams, Zoom, NearMe, etc
* Online consenting, surveys, questionnaires, etc and/or electronic upload of paper-based consent forms, surveys, questionnaires, etc.
* Audio/video recording and transcribing of interviews
* Use of Apps, Websites, cloud-based software, wearable devices, artificial intelligence (AI)
* Identifiable data being sent out with NHS Lothian, including upload to online study databases including audio/video recordings.
* Identifiable data being sent out with the UK
* Personal data (incl pseudonymised data) being sent out with the UK/EU where the country has not been granted adequacy status, i.e USA
* Accessing patient/staff or participant data for research without consent and/or use of deferred consent.

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| 1. **Have you made contact with the R&D Information Governance team?**
 | **No** |

1. **Additional information/comments (if required):**

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| **PART D: LOTHIAN CI & PI INFORMATION** |

We will require CV’s and GCP certificates for the Lothian PI and CI, where applicable. Please note that your CV should be signed and dated within the last 2 years. GCP certification is mandatory for all CTIMP studies. GCP certification has a 2-year validity period.

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| 1. **CV provided for Lothian PI:**
 | **No** |
|  **CV provided for Lothian CI (if applicable):** | Choose an item. |

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| 1. **GCP certification provided for Lothian PI:**
 | **No** |
|  **GCP certification provided for Lothian CI (if applicable):** | Choose an item. |

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| **PART E: STUDIES INVOLVING DEVICES** |

Studies involving the use of any devices including items such as fitness trackers and movement monitors require to be notified to Medical Physics. MP approval can often result in a lengthy delay therefore we highly recommend that this is flagged to them as early as possible.

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| 1. **Does this study include the use of any devices?**
 | **No** |
| 1. **Device details**
 |  |
| 1. **Is the device CE Marked and being used for its intended purpose?**
 | Choose an item. |
| 1. **Is the device CE Marked and being used out with its intended purpose?**
 | Choose an item. |
| 1. **Have you contacted Medical Physics regarding this device?**
 | Choose an item. |

If you have not alerted Medical Physics, please contact them at: loth.physicsiras@nhs.scot

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| **PART F: PORTFOLIO ADOPTION** |

Studies funded by non-eligible funders that are adopted via the NIHR CRN extended review process will be eligible for financial support in Scotland through NRS.

To allow us to assess the study suitability for adoption to the NIHR CRN portfolio and NRS support, please answer the following questions:

1. **Who is the funder for this study?**

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1. **Which countries of the UK is the study recruiting from?**

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| 1. **Was funding for this study awarded in open national competition?**
 | **No** |
| 1. **Has the study been peer reviewed as part of the funding process?**
 | **No** |

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| **PART G: DECLARATION BY PI OR LOCAL COLLABORATOR** |

By sending the above information to NHSL R&D by email, you’re agreeing to the following;

* The information in this form is accurate to the best of my knowledge.
* I am aware of and have agreed to discharge my responsibilities in line with the UK Policy Framework for Research and Social Care.
* I have considered and mitigated any conflicts of interest that I may have.

**Please ensure all blue areas are complete prior to returning to** **loth.accord@nhs.scot**