|  |  |
| --- | --- |
| **COMMERCIAL STUDY INFORMATION FORM** | |
| **Short title:** |  |
| **IRAS number:** |  |
| **Principal Investigator(s)** |  |
| **Location(s) in NHS Lothian:** |  |
| **Target recruitment:** |  |
| **Target start date (NHSL):** |  |

|  |
| --- |
| **Part A: Research team** |

Please complete the table below with any additional study team contacts for the R&D team (e.g. Research nurses):

|  |  |  |
| --- | --- | --- |
| Team member name | Role | E-mail address |
|  | Choose an item. |  |
|  | Choose an item. |  |
|  | Choose an item. |  |
|  | Choose an item. |  |

|  |
| --- |
| **Part B: Clinical area and support department authorisation** |

Please provide R&D with the appropriate authorisations for your study. These are as follows:

1. **Service authorisation:**

Please provide details of the clinical services involved in this study.

|  |
| --- |
| Clinical Service |
|  |
|  |
|  |

1. **Support department authorisation:**

Please provide details in the table below of ALL support departments involved in this study (if a support department is not involved, state N/A).

|  |  |  |
| --- | --- | --- |
| Support Department | | Location (RIE/WGH/SJH etc.) |
| Labs / Tissue Governance | Choose an item. |  |
| Pathology | Choose an item. |  |
| Radiology | Choose an item. |  |
| Pharmacy | Choose an item. |  |
| Edinburgh Imaging | Choose an item. |  |
| Medical Photography | Choose an item. |  |
| Medical Physics | Choose an item. |  |
| Clinical Research Facility | Choose an item. |  |
| Other  (please specify below) |  |  |
|  |  |  |
|  |  |  |

|  |
| --- |
| **Part C: Studies involving exposure to ionising radiation** |

If your study involves patient or staff exposure to ionising radiation, a Medical Physics Expert (MPE) review and IRMER review will be required.

|  |  |
| --- | --- |
| Does the study require Medical Physics Expert (MPE) and IRMER review? | Choose an item. |

|  |
| --- |
| **Part D: Information Governance/IT Security** |

If Information Governance (IG) oversight is required for your study, an IT Security risk assessment may be required. It is important that we 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, please provide details below.

* Use of any online video conferencing platforms e.g. MS Teams, Zoom,
* Online consenting, surveys, questionnaires and/or electronic upload of paper-based consent forms, surveys, questionnaires,
* Audio/video recording and transcribing of interviews (patients & staff)
* Use of applications (‘Apps’), websites, cloud-based software, wearable devices, artificial intelligence (AI),
* Personal identifiable information being sent out with NHS Lothian, including upload to online study databases and including audio/video recordings,
* Personal identifiable information being sent outwith the UK,
* Accessing patient/staff or participant data for research without consent and/or use of deferred consent.

|  |  |
| --- | --- |
| 1. **Does your study involve any of the above IG concerns?** | Choose an item. |

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

|  |
| --- |
|  |

|  |
| --- |
| **Part E: Lothian Chief Investigator (CI) & Principal Investigator (PI) information** |

We will require CV’s and GCP certificates for the Lothian PI and CI, where applicable. Please note that CV’s 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.

|  |  |
| --- | --- |
| 1. **CV provided for Lothian PI:** | Choose an item. |
| **CV provided for Lothian CI (if applicable):** | Choose an item. |

|  |  |
| --- | --- |
| 1. **GCP certification provided for Lothian PI:** | Choose an item. |
| **GCP certification provided for Lothian CI (if applicable):** | Choose an item. |

|  |
| --- |
| **Part F: 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. Medical Physics approval is required prior to management approval for investigational devices that are not CE/UKCA marked or are used outside of intended purpose. Please note that items such as video/audio recorders are **not** devices that require MP approval.

|  |  |  |
| --- | --- | --- |
| 1. **Does this study include the use of any devices?** | | Choose an item. |
| 1. **Device details** |  | |
| 1. **Is the device UKCA/CE marked and being used for its intended purpose?** | | Choose an item. |
| 1. **Is the device UKCA/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. |

|  |
| --- |
| **Part G: Priority** |

If you have multiple commercial studies awaiting R&D management approval, please could you indicate the order of priority.

|  |
| --- |
|  |
|  |
|  |

|  |
| --- |
| **Part H: Edge budget uploads** |

If you have not received training for how to upload a study budget to edge, the governance team can do this.

|  |  |
| --- | --- |
| **I would like the governance team to upload the budget to Edge** | Choose an item. |

|  |
| --- |
| **Part I: Contract/budget Questions** |

Site specific costs for staff out of hours working and participant travel expenses can be entered into the contract.

|  |  |
| --- | --- |
| **Do you anticipate out of hours working to be required for this study?** | Choose an item. |
| **Do you expect participant to be traveling from outside of the local area?** | Choose an item. |

**If you have answered yes to the above questions, please provide additional information below:**

|  |
| --- |
|  |

|  |
| --- |
| **Part J: PI/research team declaration** |

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**](mailto:accord@nhs.scot)