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| Form number | **51.010E** | Version  | **2.0** |
| Title | **R&I Study Strategic Plan** |

Teams Involved (Consider Head of Departments/ Service Manager approval and costs):

|  |  |  |
| --- | --- | --- |
| [ ] CRF | [ ] Pharmacy | [ ] CRIF |
| [ ] Safe Haven | [ ] NHS Biorepository | [ ] Pharmacovigilance |
| [ ] PMU | [ ] Monitoring | [ ] Information Governance |
| [ ] RCB | [ ] GO CTU | [ ] GU PM |

\*Should be completed by Sponsor Representative

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| 1. **Overview**
 |
| * 1. **\*R&I reference number:**
 |  |
| **Study Title:** |  |
| * 1. **Name of CI:**
 |  |
| * 1. **Substantive employer:**

*If not NHSGGC, do they have an honorary contract with NHSGGC?* |  |
| * 1. **\*Sponsor:**

*Refer to SOP 51.007 for guidance. If multiple international Sponsors also state the Lead Sponsor. If Co-Sponsored, Co-Sponsorship agreement required* |  |
| * 1. **Project Manager:**

*Who is providing PM? Confirm costs and capacity* | N/A [ ]  |
| * 1. **\*IRAS definition of project type**
 | Choose an item. |
| * 1. **Is this study considered a pilot or feasibility project?**
 |  |
| * 1. **Is this study linked to a previous study submitted to R&I?**
 |  |
| * 1. **Number of sites**
 | Scotland:UK:International: |
| * 1. **International sites**

*List countries and describe Sponsorship model. Consider associated costs e.g. ethics applications, insurance, translation of documents etc.* | N/A [ ]  |
| * 1. **Include brief summary**
 |  |
| * 1. **Length of Project**

*Minimum 6 months set-up for CTIMP. If commercial company involved, consider contract negotiation time. If more than 1 arm or WP state for each.* | set-up:recruitment:treatment:follow-up:close-out/analysis:**Total:** |
| * 1. **Number of Participants**

*Total/Scotland/UK/international* |  |

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| 1. **Funding**
 |
| * 1. **Name of funder(s)**
 |  |
| * 1. **Has funding been awarded?**
 | Yes [ ]  No [ ]  N/A [ ]  |
| * 1. **\*Funding type**

*Refer to SOP 51.010* |  |
| **\*Is peer review required?***Refer to SOP 51.003. Required for NEF studies and for NIHR portfolio adoption. If peer review is required, CI to recommend two independent reviewers that meet criteria.* |  |
| * 1. **\*Does the study require a SoECAT?**

*For completion of SoECAT and ETC actions refer to WI 51.010B* | [ ]  Required by Funder[ ]  ETCs involved[ ]  Not required (SoE to be completed) |
| * 1. **Which institution is administering the funds?**
 |  |
| * 1. **\*Type of contract with funder(s)**

*Refer to SOP XXX for considerations e.g. IP, liability, data and reporting obligations, etc.*  |  |
| * 1. **\*Have any project milestones been agreed with the funder(s)?**

*If Yes, ask SRA to add these to SReDA. What is the first milestone? Are they linked to contract sign off? If no, when will they be available?* |  |
| * 1. **\*Which NHS resources/staffing costs need to be considered?**

*Detail more as required* |

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| [ ] Sponsor Systems  | [ ] Pharmacy support |
| [ ] CRF  | [ ] Monitoring |
| [ ] Project Management  | [ ] Pharmacovigilance  |
| [ ] Pharmacy  | [ ] Safe Haven |
| [ ] CRIF | [ ] Biorepository  |
| [ ] Laboratories | [ ] Consumables |

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| 1. **Participant Pathway**

Section N/A [ ]  |
| * 1. **Are any vulnerable participants involved?**

*(i.e. children, adults lacking capacity or prisoners/ young offenders)* |  |
| * 1. **Are non-English speakers being considered?**

*If yes, which languages? Consider patient population. Consider costs for translating documents including any future amendments and translator if recruiting out with CRF* |  |
| * 1. **Is co-enrolment considered?**

*(for CTIMPS the type of trial to co-enrol with needs to be confirmed with MHRA)* |  |
| * 1. **What methods are used to identify participants?**

*(e.g. patient database, electronic medical records, referral from PICs/ clinics/ other departments, advertising websites, etc.)* |  |
| * 1. **Are there PIC sites?**

*Name the PIC sites, have they agreed? Consider contracts (e.g. MNC-PICA), are there any financial implications?* |  |
| * 1. **Will there be a study website, social media platforms or poster used to facilitate or promote the study?**

*Consider if this needs to be reviewed by the REC, cost implications, maintenance and potential risks* |  |
| * 1. **How are participants approached?**

*If recruited from established databases – have they consented previously to be contacted? If CRF are involved, please confirm costs and capacity* |  |
| * 1. **Will the consent be taken in person or remotely?**

*for eConsent further considerations are included in the Data management section* |  |
| * 1. **How many visits and where will they take place?**

*If CRF are involved, please confirm costs and capacity* |  |
| * 1. **How long are participants expected to be in the study for?**
 |  |
| * 1. **Will travel costs or any other payments be provided to participants?**

*If so, who will administer these payments? (preference for this to sit with GU when possible)* |  |
| * 1. **Which activities are standard of care?**
 |  |
| * 1. **Which activities are additional and who performs these activities?**
 |  |
| * 1. **Are participants going for treatment at other centres?**

*As this has costs implications for NHSGGC this needs to be agreed with R&I Finance.* |  |
| * 1. **Are participants being referred to NHSGGC for treatment who would normally receive treatment from another board?**

*As this has costs implications for NHSGGC this needs to be agreed with R&I Finance.* |  |

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| 1. **Data and Imaging**
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| **Data** |
| * 1. **Who is data controller?**

*This should be an institution. Can be different at different stages of study and after end of study. State on the data flow diagram and clearly document in relevant contracts.* |  |
| * 1. **Who is providing data analysis?**

*List any parties involved in data processing/sharing for the study (need to be insured and legally covered for all study activities).* |  |
| * 1. **Who is providing statistics?**
 | N/A [ ]  |
| * 1. **Who is providing health economics?**
 | N/A [ ]  |
| * 1. **How is study data collected?**

*e.g. password protected Excel spreadsheet, paper CRF or eCRF? If eCRF, which platform is used (i.e., CTU, RedCap, Castor, etc).* |  |
| * 1. **Is eCRF designed by parties other than an accredited CTU?**

*If so will need DPIA and CSSP approvals in place and follow SOP 51.038 (associated forms to be approved by PV Manager). Is identifiable data recorded on eCRF? Will it be used for e-consent?* |  |
| * 1. **Will study team require data from eCRF?**

*If so, each request needs to be agreed with the Sponsor(s) as there are restrictions about what data can be accessed and by who. This should be done via a formalised report to ensure consistency and a study specific SOP is required.* |  |
| * 1. **\*Is a DPIA required?**

*If so, requires sign off from Data Protection Officer.* |  |
| * 1. **Is there any data transfer (including imaging) outside the board?**

*If so, where and if outside UK to which countries?* *What type of data? (i.e. identifiable, non-identifiable, pseudoanonymised, etc.). If anonymised data, DSA required. If identifiable data, DPA required.* |  |
| * 1. **How is the transfer made?**

*i.e. via eCRF, images through PACS, DICOM files, XNAT, file transfer through protected link, etc. To be detailed in contract.* |  |

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| * 1. **\*Is an IT Risk Triage form and/or Cloud System Security Policy (CSSP) required?**

*Required for any data stored on a cloud (including eCRF). If so, this will need IT Office review and approval.* |  |
| * 1. **\*Is Caldicott Guardian, PBPP or CAG approval required?**

*Required for access to unconsented data, NHSGGC, across Scotland or across England respectively. If yes, consider associated costs.* |  |
| * 1. **Where will data be stored?**

*How long for? Consider TMF responsibilities (CTIMPs) and archiving. Consider cost implications.* |  |
| * 1. **Who holds the key to any pseudoanonymised data?**

*Will this need to be passed on during or after the end of study?* |   |
| **Long-term Data** Section N/A [ ]  |
| * 1. **Does study involve long term data collection/data linkage?**

*If so, is this through medical records or through national databases? Consider cost implications* |  |
| * 1. **Which third party will prepare application and submit to national database on behalf of NHSGGC?**

*Must be ISO 27001 compliant. Name national databases: eDRIS (Scotland), NHS England (England), Sail (Wales)*  |  |
| * 1. **What linkers are to be used for this purpose?**

*E.g. NHS /CHI number, clearly state these in PIS and consent form. Sole data controllership will need to be included in the contract with the third party for data linkage purpose.* |  |
| * 1. **Type of data to be extracted and at which time points?**
 |  |
| * 1. **How many extractions?**
 |  |
| * 1. **Who will process this data linkage?**

*Consider which contract is going to be used for Third party data processor for data linkage. i.e. DPA, Collaboration agreement, SLA, etc.*  |  |
| **Imaging**Section N/A [ ]  |
| * 1. **What scans are involved in the research study?**

*Note if any of these are SOC* |  |
| * 1. **Are NHSGGC CRIF involved?**

*If so, Form 58.004B should be completed and approved along with the provided costs by the Research Imaging team*  |  |
| * 1. **Is an external scanner being used?**

*i.e. 7T scanner (GU), National PET scanner (GU & UoE) etc. If so, DPIA will be required. Consider costs and contracts required i.e. DPA, DSA etc.* |  |
| * 1. **Are contrast agents used?**

*If so, involve R&I pharmacy for review* |  |
| * 1. **Are COILs used?**

*Are they being used within their CE marked licence? If not, consult with PV Manager as could be considered a device* |  |
| * 1. **\*Is ARSAC required?**

*Required for* *administration of radioactive substances* |  |
| * 1. **\*Is Radiation Assurance required?**

*Required for ionising radiation exposures e.g. X-ray, MUGA, CT, etc.*  |  |

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| * 1. **Who is analysing the scans?**

*Consider contracts required (e.g. DSA, DPA, etc.). Consider cost implications* |  |
| * 1. **What is the pathway for incidental findings?**
 |  |
| * 1. **Where are the images stored?**

*Consider contracts required (e.g. DSA, DPA, etc.). Consider cost implications* |  |

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| 1. **Materials**

Section N/A [ ]  |
| **Material taken from participants**Section N/A [ ]  |
| * 1. **What biological samples are required from participants?**

*(i.e. bloods, urine, stool, saliva, biopsies, etc.)*  |  |
| * 1. **Who takes these and where?**

*Are these surplus from standard of care, taken alongside standard of care procedures or additional to standard of care? Consider financial implications for sample tubes, equipment needed, etc.* |  |
| * 1. **Is NHSGGC Biorepository supporting with tissue collection?**

*If so, form 60.804 should be completed and approved along with the costs provided by the Biorepository team* |  |
| * 1. **What types of test or analysis will be carried out on the samples?**

*Consider cost implications for processing, analysis transport, packaging and storage (including long term storage for future ethically approved research)* |  |

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| * 1. **Are samples or results being sent outside the board for analysis and reporting?**

*Consider cost implications and contracts (e.g. MTA). What associated data will be accompanying the samples? What is the overall tissue flow including analysis (if complex, attach a diagram at the end of document)* |  |
| **Laboratories** |
| * 1. **Are laboratories involved?**

*If so, Form 51.028A should be completed by research team and signed off by SRC.* |  |
| * 1. **Is there a central lab?**

*If so, is this NHS? Where is it based? Consider costs of kits and couriers*  |  |
| * 1. **Are external laboratories involved?**

*If GU labs involved, confirm with GU RRC team that the laboratory is appropriate for the type of study and analysis required. Consider contracts involved (e.g. MTA, SLA etc.) For CTIMPs using third party laboratories, include TMF and archiving plan in contract. Confirm when costs provided are valid until.* |  |
| * 1. **List all laboratory tests and corresponding category**

*Category 1: Standard test i.e. validated and in use in clinical practice within NHS Category 2: Standard test with specific requirements**Category 3: Non-standard test i.e. research tests* |  |
| * 1. **Are sample handling manuals and laboratory manuals in place?**

*Refer to SOP 51.029 and SOP 51.030* |  |
| * 1. **Is additional equipment required?**

*i.e. freezers, centrifuges, CE devices. Are these subject to maintenance and maintenance records / calibration certificates? Who will provide these services?* |  |
| * 1. **Is additional equipment being provided by a third party or loaned/ purchased as part of research?**

*Is insurance required to cover loan/purchased equipment? (CNORIS does not provide cover for loss or damage to third party property.)* *Do they provide maintenance/calibration and insurance? Consider contracts involved* *(i.e SLA)* |  |
| * 1. **Is a vendor assessment required for any vendors?**

*Refer to SOP 51.015, If so, consider vendor TMF plan. For non-CTIMPs this is only carried out if considered high risk.* |  |
| **Biobanks**Section N/A [ ]  |
| * 1. **Is NHSGGC Biorepository supporting storage?**

*If so, form 60.804 should be completed and approved along with the costs provided by the Biorepository team* |  |
| * 1. **Are other Biobanks involved?**

*Which ones? UK and/or international? Consider financial implications for processing, storage (including long term storage for future ethically approved research) and analysis. Have these been requested?* |  |
| **Other services**Section N/A [ ]  |
| * 1. **Are there any other NHS or non-NHS services required?**

*If Yes list all parties and associated costs. How and where will these services be delivered? Contracts to be consider which contracts are needed and if vendor assessment is required (refer to SOP 51.015)* |  |

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| 1. **Medicines and Devices**
 |
| **Medicines** Section N/A [ ]  |
| **Which medicines are involved?***If there are different arms please list these all here. Please note which are standard of care. If CTIMP, consider MHRA costs* |  |
| * 1. **What are the doses and route of administration?**

*Please note if these are different to standard practice* |  |
| * 1. **Are patients randomised?**

*If so, what is the ratio? What is the method of randomisation?* |  |
| * 1. **Is the study blinded?**

*Who is blinded? What is the method of emergency unblinding?* |  |
| * 1. **\*Is Pharmacy Assurance required?**

*Required for CTIMP, done as part of generic review process.* |  |
| **Devices**Section N/A [ ]  |
| * 1. **\*Is there a device involved?**

*When the study involves a medical device, Form 51.010D should be completed in addition to this to capture all relevant study information* |  |

# Feasibility Considerations:

Has this project been discussed with Head of Department and/or research nurse staff at the local site? If not arrange a meeting to discuss study strategy and address the points below:

|  |
| --- |
| Please review local resources and database of subject medical records from the previous (insert number) months against the exclusion/exclusion criteria. |
| 1. How many patients do you anticipate the site would recruit to this trial per year? (*take into account conflicting trials and staff resource*) |  |
| 2. Would any of the inclusion / exclusion criteria represent any substantial difficulty for recruiting subjects into this study? |  |
| 3. Do you have any current or potential new trials which may compete against or affect recruitment to this trial? |  |
| 4. Are you aware of any national or local guidelines that will impact on the recruitment of this trial? |  |
| 5. Do you have the staff capacity and equipment to undertake this study? |  |
| 6. Do supporting department(s) at your site have the capacity to undertake this trial? |  |
| 7. If long term follow up from medical records is required, can this be provided? |  |
| 8. Please include any other local site considerations |  |

# Multi-functional team meetings (if applicable):

Include details of any relevant meetings that impact the project in the table below:

|  |  |  |  |
| --- | --- | --- | --- |
| **Date of meeting** | **Attendees** | **Summary**  | **Actions** |
|  |  |  |  |
|  |  |  |  |

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