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| Form number | **Form 51.010E** | Version | **1.0** |
| Title | **R&I Study strategic plan** | | |

The objective of the R&I study strategic plan is to understand the overall vision of the project, discuss sponsorship and the resources required to be achieved in the agreed timelines:

* identify the appropriate departments and other third parties required
* understand participant pathway, data flow, materials, financial implications and contractual arrangements
* assess the feasibility of conducting the study
* can be used as an evolving document to address all developmental stages of the study

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| **Name of CI:** |  |
| **Substantive employer:** |  |
| **Honorary contract with NHSGGC** | Yes/No |
| **R&I reference number**: |  |
| Study Title: |  |
| **Sponsorship: GG&C or Co-sponsored with GU** (Refer to SOP 51.007) | Do GU need to consider non CTIMP sponsorship Yes/No |

**Include details of any important multi-functional team meetings and relevant strategic decisions that impact the project at Section D** (if applicable):

# Section A: General information

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| 1. **General information** | |
| IRAS definition of project type |  |
| Is this study considered a pilot project or educational project? |  |
| Is this study linked to a previous study submitted to R&I? |  |
| Include brief summary |  |
| Length of project and define End of study |  |
| Peer review required for NEF studies and for NIHR portfolio adoption  *If peer review is required can CI please recommend two independent reviewers that meet criteria below?\**  *(Reviewers will need to complete the form 51.003A as evidence of peer review)* | If required, provide contact for two reviewers: |
| \*Peer review must be independent, expert, and proportionate:  **Independent:**At least two individual experts should have reviewed the study. The definition of independent used here is that the reviewers must be external to the investigators’ host institution and not involved in the study in any way. Reviewers do not need to be anonymous.    **Expert:** Reviewers should have knowledge of the relevant discipline to consider the clinical and/or service based aspects of the protocol, and/or have the expertise to assess the methodological and statistical aspects of the study.    **Proportionate:** Peer review should be commensurate with the size and complexity of the study. Large multicentre studies should have higher level (more reviewers with broader expertise and often independent review committee or board), and potentially international peer review. | |
| Number of participating sites:  *(Single-site/ Multi-site/ UK/ Scotland only)* |  |
| 1. **Are any International sites involved?** | |
| If Yes, list countries and other details |  |
| Will there be a Sponsor in each country? Who is the lead? |  |
| Are the associated costs known? (i.e. per patient fee, ethics application, insurance, translation of documents, etc) |  |
| 1. **Participants information** | |
| 1. Number of participants to be recruited (in total/UK/International) |  |
| 1. Are any vulnerable participants involved (i.e. children, adults lacking capacity for consent) or prisoners/young offenders? |  |
| 1. How long is expected for participants to be in the study |  |
| 1. What methods are used to recruit participants?  * *patient database* * *electronic medical records* * *referral (e.g satellite centers, clinics, other departments)* * *advertising* * *websites, etc.* |  |
| 1. How are participants approached? If recruited from established databases – have they consented previously to be contacted? |  |
| 1. Are you considering non-English speakers (if yes, in which languages? Consider costs for translating of documents including any future amendments as well as costs for in person translator) |  |
| 1. Will the consent be taken in person or remote eConsent will be considered? *(for eConsent further considerations are included in the Data management section)* |  |
| 1. What is the legal basis used for:  * Participation in research * Processing participants data   (i.e consent or public task – this needs to be decided with investigator depending on type of study).  When consent is used as legal basis for participation in research and public task for processing participant’s data - the participants can withdraw the consent to participate in research but cannot withdraw consent for processing their data.  This should be described in a paragraph and included in the PIS.  (i.e “**Consent for your participation in research and legal basis for processing your data**:  - We will always ask for consent for your participation in research.  - The legal basis for processing your personal data is Article 6(1)(e) of the UK GDPR. Our processing is necessary for the performance of a task carried out in the public interest, and for special category data we rely on UK GDPR Article 9(2)(j) as our processing is for scientific research purposes by way of Schedule 1 Part 1 Paragraph 4 of the Data Protection Act 2018 ” |  |
| 1. Will travel costs or any other payments be provided to participants? Who will administer these payments? |  |
| 1. **Describe Patient Pathway and Schedule of events (if study is complex please include a diagram at the end of the document).** | |
| 1. How many visits and where |  |
| 1. What activities are standard of care |  |
| 1. Which activities are additional and who performs these activities |  |
| 1. Are participants going for treatment at other centers? As this has costs implications for NHSGGC and needs to be agreed and confirmed with R&I Finance. |  |
| 1. **Are any devices involved?** | |
| When the study involves a medical device, Form 51.010D should be completed in addition to this to capture all relevant study information |  |
| 1. **Is co-enrolment considered?**   (for CTIMPS the type of trial to co-enrol with needs to be confirmed with MHRA) |  |
| 1. **Will there be a study website or other social media platforms used to facilitate or promote the study?**   If yes, describe the scope and how this is managed |  |
| 1. Will the website contain participant facing information?   *If so, this will need to be reviewed and approved by REC* |  |
| 1. Are there any cost implications? |  |
| 1. Consider additional meeting at a later stage to discuss the risks below:  * To participants safety * Data integrity * Security and privacy issues * Licensing and legal considerations * Risk of damage to organisational reputation in event of issues arising with study website * Recovery timelines for server disruptions and how these can impact on study * Scheduled maintenance times for host platform and potential impact on study * Quality and reliability of website content * Retention of website content for trial reconstruction (for CTIMPs) * Are Social Media and Links to other organisations to be included on the website (if so, are these appropriate?)   The above should be included in the formal study Risk assessment (if applicable). |  |

# Section B: Operational impact of the study, funding and contractual arrangements

Funding type (Refer to SOP 51.010):

1. NEF (Non-eligible funding) ([ELIGIBLE FUNDERS.doc (live.com)](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.sehd.scot.nhs.uk%2Fcso%2FSuppScience%2FEligible%2520funders%2FELIGIBLE%2520FUNDERS.doc&wdOrigin=BROWSELINK)) – all project costs and staff time must be covered by departments supporting/delivering the study protocol.
2. Fully eligible – AcoRD ([Microsoft Word - AcoRD - Guidance Scotland.doc (nhsresearchscotland.org.uk)](https://www.nhsresearchscotland.org.uk/uploads/tinymce/AcoRD-Guidance-Scotland.pdf) funding rules apply. Costs are identified, reviewed and attributed as either Research, Support or Treatment.
3. Mixed model of charity/government funding and industry support – AcoRD funding rules apply as above. Sponsor staff salaries paid by Infrastructure funds should not be included for this study type.
4. Investigator-initiated fully funded by Pharmaceutical company(s) – AcoRD funding rules may not apply. The study should be fully costed and funded as research and additionally for this scenario all sponsor costs, including staff time for Sponsor representatives and Management should be included. In addition, a Board overhead may be applied to NHS costs.

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| **Operations, funding and contractual arrangements** | |
| 1. **Funding type (Refer to SOP 51.010) as above** |  |
| 1. **What organization(s) is/are providing/will provide the funding?** |  |
| 1. **Has funding been secured?** |  |
| 1. **Does the study require a SoECAT?**   If Yes, do you expect any Excess treatment Costs (ETCs)?  (for completion of SoECAT and ETC actions refer to WI 51.010B) |  |
| 1. **Who is administering the funds?** NHSGGC or University of Glasgow? |  |
| 1. **Type of contract with the funder**   *Are standard contracts being used for commercially funded investigator-led study?* |  |
| If No, will CLO review be required? And for how many contracts? |  |
| Are there any clinical/academic collaborators involved?  *If Yes, please list all collaborators and include if there are associated costs to be confirmed with their finance office* |  |
| *Type of contract where collaborators are included. Is the schedule of worked agreed and confirmed with all collaborators?* |  |
| *Are there any unusual IP considerations?* |  |
| 1. **Have any project milestones been agreed with the funder?** | |
| *If Yes, please describe the earliest ones (i.e REC approval, first patient first visit, etc)* |  |
| *If No, when will these be available?* |  |
| *Are milestones linked to contract negotiations/sign off?* |  |
| 1. **What NHS resources/staffing costs are associated with this study**   Indicate if any of the Head of Departments/ Service Managers have been approached about the study. | |
| **Sponsor Systems team time e.g. Co-ordinator/SRA/Manager** |  |
| **CRF involvement; Nursing support required (include location)** |  |
| **Project Management (PMU, RCB, University of Glasgow, CRUK, other third party PM?)** |  |
| **Pharmacy support (for IMP and medicines/medicinal products)** |  |
| **Monitoring** |  |
| **Pharmacovigilance** |  |
| **Safe Haven** |  |
| **Imaging:** | |
| * For imaging using NHSGGC CRF facilities, Form 58.004B should be completed and approved along with the provided costs by the Research Imaging team   (completed form should be emailed to [ggc.studymanagement@ggc.scot.nhs.uk](mailto:ggc.studymanagement@ggc.scot.nhs.uk)) |  |
| * Is ARSAC required? |  |
| **Biorepository/tissue collection arrangement** | |
| * For NHSGGC Biorepository support with tissue collection or storage form 60.804 should be completed and approved along with the costs provided by the Biorepository team |  |
| * Which Biobanks? 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? |  |
| * Include any additional tissue sample arrangements e.g. samples being sent outside the board for analysis and reporting |  |
| * confirm tissue sample flow and data flow associated with analysis (if complex, attach a diagram at the end of document) |  |
| * List all contracts required (i.e SLA, MTA, as applicable) |  |
| **Biological samples taken from participants** | |
| * What biological samples are required (i.e. bloods, urine, tissue, etc? |  |
| * Who takes these and where? Are these surplus from standard of care, taken alongside standard of care procedures or additional to standard of care? |  |
| * What types of test or analysis will be carried out on the samples? |  |
| * Consider the financial implications for processing, storage (including long term storage for future ethically approved research if applicable), courier and analysis |  |
| * Include any additional biological samples arrangements e.g. samples or results being sent outside the board for analysis and reporting; |  |
| **Laboratories** | |
| * Are NHS laboratories involved?   *For CTIMPs use Form 51.028A (Categorising Laboratory Tests undertaken within CTIMPS Sponsored by NHS GG&C or Co-Sponsored by NHS GG&C and University of Glasgow)* |  |
| * Is there a central lab?   *If so, is this NHS? Where is it based? Consider costs of kits and courier.* |  |
| * Are Glasgow University laboratories involved?   *If so, confirm with University of Glasgow Head of Research Regulation and Compliance and Research that the laboratory is appropriate for the type of study and analysis required.* |  |
| * Are sample handling manuals and laboratory manuals in place? |  |
| * confirm biological sample flow and data flow associated with analysis (if complex, attach a diagram at the end of document) |  |
| * 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? |  |
| * If additional equipment is required is this 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.* |  |
| * If equipment is provided by third party, what are their requirements for provision of equipment for the study? Do they provide maintenance/calibration and insurance? |  |
| * List all contracts required (i.e SLA, MTA, as applicable) |  |
| * For CTIMPs using third party laboratories include TMF and archiving plan in contractual arrangements |  |
| *Other NHS support required (consider costs and contracts)* |  |
| 1. **Are there any non-NHS services required** | |
| * If Yes list all parties and associated costs |  |
| * How and where will these services be delivered? |  |
| * Contracts to be considered |  |
| * Consider vendor TMF plan (if CTIMP) |  |
| * Do they need to be vendor assessed? |  |
| 1. **Data management –** indicate who is providing the below and include a clear/detailed study data flow at the end of the document | |
| * *data analysis* |  |
| * *statistics* |  |
| * *health economics* |  |
| List any other parties involved in data processing/sharing for the study *(these need to be insured and legally covered for all study activities)* |  |
| For any third party data processors are there any governance checks required?  Is a DPIA required? (fill in the “Is a DPIA required” form) |  |
| 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, combination, etc) |  |
| How is the transfer made (via eCRF, images through PACS, DICOM (Digital Imaging and Communications in Medicine) files, file transfer through protected link, etc. |  |
| Does it need Information Governance review and approval? |  |
| Does it need IT Office review and approval? i.e Risk Triage form and/or Cloud System Security Policy (CSSP)? |  |
| Is PBPP or Cladicott Guardian approval required (if yes consider associated costs) |  |
| Who is data controller (at different stages of study and after study is complete?) *(to be marked on the data flow and clearly documented in the relevant contracts)* |  |
| Where will data be stored? - consider TMF responsibilities (CTIMPs) and archiving |  |
| For pseudoanonymised data - who holds the key? Will this need to be passed on at any time during or after the end of study? |  |
| **Does study involve long term Data linkage?** If so, is this through medical records or through national data bases? |  |
| *If national data bases are used - have financial implications been considered* |  |
| *Which third party (ISO 27001 compliant) will prepare application and submit to eDRIS (Scotland), NHS Digital (England), Sail (Wales) (as required) on behalf of NHSGGC?* |  |
| *What linkers are to be used for this purpose? Sole data controllership will need to be included in the contract with the third party for data linkage purpose. Clearly state these in PIS and consent form* |  |
| *Type of data to be extracted and at which time points?* |  |
| *How many extractions?* |  |
| *Third party data processor type of contract for data linkage - DPA, Collaboration agreement, SLA, etc* |  |
| **Other Data considerations** | |
| *How is study data collected? Password protected Excel spreadsheet, paper CRF or eCRF?* |  |
| *If data is collected through eCRF, which platform is used, who designed it and who manages this? (i.e., CTU, RedCap, Castor, etc)* |  |
| *If eCRF is designed by parties other than an accredited CTU, a project specific DPIA and IT Risk Assessment should be put in place* |  |
| *If eCRF is designed by parties other than an accredited CTU - use SOP 51.038 and associated forms (User access request log and user access matrix forms) to state individuals that will have access to participants' personal data recorded on eCRF during the study. This will need to be approved by PV manager.* |  |
| *What information will be stored on the eCRF? (if identifiable will need DPIA and CSSP approvals in place)* |  |
| *Will the eCRF platform be used for remote eConsent purposes? (will need DPIA and CSSP approvals in place)* |  |
| *If research team requests to download and access study data from eCRF this needs to be agreed with the sponsor/co-sponsor. This should be done via a formalised report to ensure consistency. A study specific SOP is required detailing why, when and what type of data is needed and by whom.*  *There are restrictions about what data can and can't be accessed and who can and can't access the outputs of this data i.e. is not allowed to access the primary endpoint for example while outputs like accrual are acceptable.* |  |
| 1. **Additional considerations** | |
|  | |

# Section C - Project Feasibility Considerations:

The objective of this section is to assess the feasibility of conducting the study and

- assess the support you would require

- confirm the estimated number of subjects that may be eligible for participation in the study

**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 |  |

# Section D - Multi-functional team meetings (if applicable):

Include details of any important multi-functional team meetings and relevant strategic decisions that impact the project in the table below:

|  |  |  |  |
| --- | --- | --- | --- |
| **Date of meeting** | **Attendees** | **Decisions** | **Follow-up** |
|  |  |  |  |
|  |  |  |  |