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| **RESEARCH AND DEVELOPMENT INITIAL ADVICE REQUEST** |

R&D ENQUIRY REFERENCE

ENQ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| --- | --- | --- | --- |
| LEAD INVESTIGATOR DETAILS | | | |
| NAME |  | EMAIL |  |
| DESIGNATION |  | EXTENSION |  |
| DIRECTORATE |  | SPECIALITY |  |

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| PROJECT TITLE |
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| AIM |
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| PROJECT TYPE | TICK |
| Clinical trial of an investigational medicinal product2 |  |
| Clinical investigation or other study of a medical device3 |  |
| Combined trial of an investigational medicinal product and an investigational medical device |  |
| Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice4 |  |
| Basic science study involving procedures with human participants5 |  |
| Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology |  |
| Study involving qualitative methods only |  |
| Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)6 |  |
| Study limited to working with data (specific project only)7 |  |
| Research tissue bank |  |
| Research database |  |
| Unsure |  |

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| SPONSORSHIP | | | | |
| Is there a Sponsor1 identified for the study? | Y / N | Will the Trust be asked to act as Sponsor? | | Y / N |
| Is any aspect of the study being undertaken as educational project e.g. PhD / Masters? | Y / N | At which institution is the course registered? |  | |

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| METHODOLOGY | | | | | | | |
| Does study involve: | Healthy volunteers | | | Y / N | Only previously collected data | | Y / N |
| Patients | | | Y / N | Only previously collected tissue | | Y / N |
| Adults lacking capacity and/or Children9 | | | Y / N | Will data be anonymous at point of analysis to researcher11? | | Y / N |
| Will written informed consent10 be obtained? | | | Y / N |
| Is the investigator member of normal clinical care team12? | | | | | | Y / N |
| Detail: *Include information about when and how participants will be identified, approached and consented; what will happen to participants during the study; what data be collected and how. Continue on a separate sheet as necessary.* | | | | | | | |
| Total sample size | |  | Has statistical input been obtained | | | Y / N | |
| Number of NHS Sites | |  | Name of statistician consulted | | |  | |
| Proposed start date | |  | Proposed length of study | | |  | |

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| STUDY ARRANGEMENTS | | Provide additional details |
| Are there other study sites proposed | Y / N | *e.g .lab tests to be undertaken; scans etc* |
| Will pharmacy be involved | Y / N |
| Will samples be sent to the Trust’s laboratory | Y / N |
| Is radiology involved | Y / N |
| Are any external parties involved | Y / N |

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| FUNDING | Provide additional details | | | | | |
| Approximate cost of study13  e.g. Include investigator time, laboratory tests, drug costs, nurse/CTA time, trial management, shipping or storage of samples, travel, postage, equipment, archiving |  | | | | | |
| Has funding been secured | | Y / N | Source of funding |  | Amount | £ |

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| --- | --- |
| FURTHER DETAILS | |
| Lead Investigator GCP14 trained? | Y / N / Not Known |
| Does Lead Investigator have previous Research Experience?  Add details if appropriate |  |
| Any other information or potential issues you would like to mention at this stage then please use a separate sheet or the accompanying email | |

RETURN COMPLETED FORM BY EMAIL TO RESEARCH.ADVICE@YORK.NHS.UK

**NOTES**

1. The sponsor is the individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project. All research falling under the remit of the Secretary of State for Health must have a formal sponsor. This includes all research in health and social care that involve NHS patients, their tissue or information. The sponsor is normally expected to be the employer of the chief investigator in the case of non-commercial research or the funder in the case of commercial research.
2. Tick this option for medicinal trials falling within the scope of the EU Clinical Trials Directive and the Medicines for Human Use (Clinical Trials) Regulations 2004. Medicinal products are substances or combinations of substances which either prevent or treat disease in human beings or are administered to human beings with a view to making a medical diagnosis or to restore, correct or modify physiological functions in humans. A clinical trial is an investigation in human subjects which is intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more medicinal products, identify any adverse reactions or study the absorption, distribution, metabolism and excretion, with the object of ascertaining the safety and/or efficacy of those products. This definition includes pharmacokinetic studies.   
   The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for advising on the Regulations and requirements for clinical trial authorisation (CTA).  More detailed guidance is available at:   
   <http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=723>   
   Section 2 of the guidance links to an algorithm to help you decide whether or not your research is a clinical trial of an investigational medicinal product (CTIMP).
3. This option should be ticked for any clinical investigation or other research study of a medical device.  Do not select this option where the research protocol involves use of a CE marked device within its intended purpose but is not designed to investigate the device itself.
4. This option should be ticked for clinical research not involving investigational medicinal products or medical devices.   
   For example, this option would be appropriate for research involving:

* Surgery
* Radiotherapy
* Imaging investigations
* Mental health investigations or therapies
* Physiological investigations
* Trials of products not defined as medicines or medical devices (e.g. nutritional)
* Complementary or alternative therapies

1. This option may involve patients or healthy volunteers as participants, but the study does not affect any clinical care that the participant may be receiving. It is appropriate for scientific investigations involving procedures with participants that are additional to any clinical care, but not studying a novel clinical intervention or involving randomisation between treatment groups or any other change in existing clinical care.

For example, it would be suitable for studies involving:

* Imaging investigations (MRI, ultrasound etc)
* Physical examinations
* Physical tests
* Computer tests
* Sample-taking

1. *Research in this category is based entirely on the analysis data and/or use of human tissue samples or other human biological material. It must involve no change to the normal clinical care or treatment of participants. There will be no participant contact or observation other than to collect samples and seek informed consent where appropriate.*
2. *Research in this category is based entirely on the use of data from patients, service users or other data subjects.  It must involve no change to the normal clinical care or treatment of participants.  There will be no participant contact or observation other than to seek informed consent where appropriate.*
3. *Please answer Yes if it is possible that the research could at any stage include adults (aged 16 or over) who are unable to consent for themselves due to physical or mental incapacity (including temporary incapacity).*
4. *Please answer Yes if the research will include participants aged under 16, or use of their samples or data.   
   You should still answer Yes if some or all of the participants will be able to consent for themselves under the Gillick principles.*
5. *People who volunteer to take part in research should be provided with succinct, relevant, user-friendly information in a proportionate manner. This is usually in the form of a Patient Information Sheet (PIS). Written consent is then obtained from the participant.*
6. *All research has a cost. It is important to consider this cost and to agree how this will be funded or covered. All research activity above normal standard care should therefore be considered and documented here.*
7. *Good Clinical Practice (GCP) is a set of internationally recognised ethical and scientific quality requirements that must be followed when designing, conducting, recording and reporting clinical trials that involve people.*