**LHP SPARK**

**SPONSORSHIP APPLICATION FORM**

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| --- |
| ***Office Use Only*** |
| *Date Received* |  | *Reference Number* |  |

If you require any additional assistance or further information, please contact the proposed sponsor.

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| **PART A – PROJECT INFORMATION** |
| **A1** | Full title of project |       |
| **A2** | Acronym/Short Title |       |
| **A3** | Study Summary |       |
| **A4** | Chief Investigator name |       |
| **A5** | Lead NHS Trust[[1]](#footnote-1) | Name:      |
|  |  | Reference:       |
|  |  | Name of PI:       |
| **A6** | Type of Study | 1. | [ ]  | Clinical trial of an investigational medicinal product |
|  |  | [ ]  Phase 1 | [ ]  Phase 2 | [ ]  Phase 3 | [ ]  Phase 4 |
|  |  | [ ]  Type A | [ ]  Type B | [ ]  Type C |
|  |  | 2. | [ ]  | Clinical investigation or other study of a medical device (including Performance Evaluation of an in vitro diagnostic device)*Please complete Part L of the application form*  |
|  |  | 3. | [ ]  | Combined trial of an investigational medicinal product and an investigational medical device |
|  |  | 4. | [ ]  | Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice – please provide further information |
|  |  | 5. | [ ]  | Research Tissue Bank |
|  |  | 6. | [ ]  | Human tissue (tissue samples and data) [newly obtained, identifiable or obtained from surplus] |
|  |  | 7. | [ ]  | Human tissue samples [anonymous to investigator] |
|  |  | 8. | [ ]  | Basic science study involving procedures with human participants |
|  |  | 9. | [ ]  | Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology |
|  |  | 10. | [ ]  | Study involving qualitative methods only |
|  |  | 11. | [ ]  | Study limited to working with data |
|  |  | 12. | [ ]  | Research database |
|  |  | 13. | [ ]  | Other – please specify |
| **A7** | Is this research to be submitted in part/fulfilment of an academic qualification?  | [ ]  YesPlease go to **A7** | [ ]  NoPlease go to **Part B** |
| **A8** | Student name ***(Please give details as a co-applicant in Part C)*** |       |
| **A9** | Title of qualification |       |

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| **PART B - CHIEF INVESTIGATOR DETAILS** |
| **B1** | Trust Directorate (if applicable) |       |
| **B2** | CI Substantive employing organisation |       |
| **B3** | Proposed Sponsoring Organisation |       |
| **B4** | Honorary contract type (if applicable) | [ ]  Honorary Clinical Contract  |
| [ ]  Honorary Research Contract  |
| [ ]  Letter of Access |
| [ ]  None  |
| **B5** | Preferred email address |       |
| **B6** | Has the CI received GCP training in the past 3 years? | [ ]  Yes Date of training       /       /       |
| [ ]  No**GCP training is essential for CTIMPs. Please complete training before commencement of study** |
| **B7** | Has the CI received appropriate human material training[[2]](#footnote-2) in the past 3 years? (UoL applications only) | [ ]  Yes Date of training       /       /       |
| [ ]  No |

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| **PART C - RESEARCH TEAM DETAILS** |
| **C1** | **Co-applicant 1** |
| Name |       |
| Employing organisation |       |
| Role in study |       |
| If student project please indicate if Primary or Secondary Supervisor |       |
| Email address |       |
| Include in correspondence? | [ ]  Yes  | [ ]  No  |
| **C2** | **Co-applicant 2** |
| Name |       |
| Employing organisation |       |
| Role in study |       |
| If student project please indicate if Primary or Secondary Supervisor |       |
| Email address |       |
| Include in correspondence? | [ ]  Yes  | [ ]  No  |
| **C3** | **Co-applicant 3** |
| Name |       |
| Employing organisation |       |
| Role in study |       |
| If student project please indicate if Primary or Secondary Supervisor |       |
| Email address |       |
| Include in correspondence? | [ ]  Yes  | [ ]  No  |

**\*\*If there are more than three co-applicants please continue list on a separate sheet**

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| **PART D – PEER REVIEW****Please see guidance for advice** |
| **D1** | Has the research protocol been through scientific peer review? | [ ]  Yes**Please provide copies****If peer review from Funder,** continue to **Part E** | [ ]  NoPlease go to **D2** |
| **D2** | Will the research protocol be reviewed as part of a grant funding process or any other scientific peer review process? | [ ]  YesPlease complete **D3**  | **[ ]  No**Please complete **D3** |
| **D3** | Please give details of any pending/planned peer review process including contact details where available.  |       |

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| **PART E – FUNDING** |
| **E1** | Has an external funding grant been secured for this project? | [ ]  YesPlease go to **E3** | [ ]  NoPlease complete **E2 and proceed to E9** |
| **E2** | Please provide details of funding provision for this study |       |
| **E3** | Details of funding |
| **Name of funder** | **Expected funding[[3]](#footnote-3)** | **Commercial/ Non commercial** | **Funding start date** | **Funding end date** |
|  | 1. |       | £      |       |       |       |
|  | 2. |       | £      |       |       |       |
|  | 3. |       | £      |       |       |       |
|  | *Please add more rows if necessary* |
| **E4** | Institution Funding will be paid into |       |
| **E5** | Has the funding been approved by the University Research Support Office? | [ ]  Yes | **[ ]** No |
| **E6** | Has the study been costed by the lead NHS Trust? | [ ]  Yes | **[ ]** No |
| **E7** | Has the study been adopted by the NIHR | [ ]  Yes | **[ ]** No | **[ ]** To be Confirmed |
| **E8** | Have any contracts been agreed/in negotiation for this study? | [ ]  YesPlease go to **E9** | [ ]  NoGo to **Part F** |
| **E9** | Please provide details of agreed contracts or contracts in negotiation |       |

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| **PART F – PROJECT DETAILS** |
| **F1** | Have you actively involved patients, service users or carers in the research design? | [ ]  Yes | [ ]  No | If yes, please provide details; |       |
| **F2** | Is a CTU managing the study? | [ ]  Yes | [ ]  No | If yes, please provide name of CTU; |       |
| **F3** | Intended duration of study |       years      months | Intended Start Date |       |
| Proposed End Date |       |
| **F4** | Please define the end of study (e.g. end of recruitment, data lock, completion of analysis). ***Please ensure this is clearly defined in the protocol.*** |       |
| **F5** | Will the study involve participant contact? | [ ]  YesGo to **F6** | [ ]  NoGo to **F7** |
| **F6** | Total number of participants to be recruited | NHS Patients  |       |
| NHS Staff |       |
| Healthy Volunteers |       |
| Other |       |
| **F7** | If your study will involve data collection **only** please detail amount of data you expect to review |       |
| **F8** | How many participants to be recruited at lead site? |       |
| **F9** | Will any participants be seen outside of NHS premises? | [ ]  YesPlease go to **F10** | [ ]  NoPlease go to **F11** |
| **F10** | Where will participants be seen outside of NHS premises? |       |
| **F11** | Please list all proposed recruitment sites |
| **UK Sites** | **Non UK Sites** |
| NHS Sites | Non NHS Sites |
|       |       |       |

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| **PART G – DETAILS REQUIRED FOR INDEMNITY AND INSURANCE** |
| **G1** | Does the study include medical intervention involving contraception? | [ ]  Yes | [ ]  No |
| **G2** | Does the study deliberately aim to recruit any of the following | [ ]  Children under the age of 5 [ ]  Pregnant Women [ ]  Participants without capacity to consent  |
| **G3** | Have any requests for insurance cover been requested from any other organisations? | [ ]  YesPlease go to **G4** | [ ]  NoPlease go to **Part H** |
| **G4** | Please provide details of these requests |       |

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| **PART H – DATA STORAGE** |
| **H1** | Will data be anonymised? *N.B. Applying a unique ID with a link to identifiable information is Pseudo anonymisation*  | [ ]  No Please go to **H3** | [ ]  **Pseudo** Please go to **H2**   | [ ]  Yes Please go to **H2** |
| **H2** | Please give details of pseudo / anonymisation process |       |
| **H3** | What format will data be in?(*i.e. password protected computer file or paper)* |       |
| **H4** | Where will the data be stored?*(e.g. building, floor, room, computer / cupboard)* |       |
| **H5** | What are the archiving arrangements (i.e. where, by whom and for how long). ***Please ensure these details are clearly indicated in the protocol.*** |       |
| **H6** | Will this data be transferred out of the Trust?  | [ ]  Yes Please go to **H7** | [ ]  No Please go to **H8**  |
| **H7** | Where will the data be transferred to?  |       |
| **H8** | Will external data be transferred into the Trust  | [ ]  Yes Please go to **H9**  | [ ]  No Please go to **H10**  |
| **H9** | Where will the data be transferred from? |       |
| **H10** | **If applicable** please confirm that Information Governance Officer at Lead Trust have been informed of storage/transfer arrangements | [ ]  Yes | [ ]  No |

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| **PART I – SAMPLES, MEDICINAL PRODUCTS, SURGICAL PROCEDURES RADIATION AND USE OF DEVICES** |
| **I1** | Will human material samples be collected for this project? | [ ]  YesPlease go to **Part J** | [ ]  No |
| **I2** | Does the project involve a drug (including any placebo)? | [ ]  YesPlease go to **Part K** | [ ]  No |
| **I3** | Does the study involve a device?  | [ ] Yes Please go to **Part L**  | [ ]  No  |
| **I4** | Does the project involve a surgical procedure? | [ ]  YesPlease go to **Part M** | [ ]  No |
| **I5** | Does the study involve Imaging/ Radiation exposures to:* Confirm eligibility or provide data regarding disease status at baseline
* Provide radiotherapy as a treatment
* Provide information on disease response at formal time points within the Protocol
* Is there a requirement in the Protocol for how the imaging is done?
* Are procedures guided by images whilst the patient is on the study.
 | [ ]  Yes to any pointsPlease go to **Part N** | [ ]  No to all points |
| If you have answered yes to any of the above please complete the corresponding section.If you have answered no to all of the above please go to **Part O**. |

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| **PART J – HUMAN MATERIAL SAMPLE COLLECTION** |
| **J1** | Please list all samples to be collected per subject and total number of samples |
|  | Sample Type(*e.g. biopsy, urine, sputum, blood)* | Number of samples to be collected per subject | Total number of samples to be collected |
|  | 1. |       |       |       |
|  | 2. |       |       |       |
|  | 3. |       |       |       |
|  | *Please add more rows if necessary* |
| **J2** | Will informed consent be taken? | [ ]  Yes  | [ ]  No Reason:       |
| **J3** | Where will samples be processed?(*Building, floor & room)* |       |
| **J4** | Where will samples be stored?*(building, floor & room)* |       | **For how long?** |       |
| **J5** | Will samples be stored for use in future unspecified research (with ethical approval)? | [ ]  YesRegistered Research Tissue Bank & Custodian:       | [ ]  No |
| **J6** | Will samples be transferred between different institutions?  | [ ]  YesPlease go to **J7** | [ ]  NoPlease go to **J8** |
| **J7** | Please give further details of the transfer of samples into and out of Trust premises[[4]](#footnote-4) |
|       |
| **J8** | Will tissue be taken from deceased participants? | [ ]  Yes | [ ]  No |
| THIS SECTION IS FOR HUMAN MATERIAL SAMPLE COLLECTION FOR CTIMPS **ONLY** |
| **J9** | Are any of the CTIMP Endpoints related to laboratory analysis? | [ ]  YesPlease go to **J10** | [ ]  NoPlease go to **J11** |
| **J10** | Please provide details of the GCP compliant Laboratory that will be contracted to process and analyse the Endpoint analysis. Please provide copy completed GCP Laboratory Self-Assessment Questionnaire available from SPARK office. |       |
| **J11** | Are any of the CTIMP Exploratory Endpoints related to the laboratory analysis? | [ ]  YesPlease go to **J12** | [ ]  No |
| **J12** | Please detail the exploratory/translational/tertiary Endpoints related to laboratory analysis and the laboratory that will be contracted to perform processing and analysis \* please note any laboratory endpoint should be conducted to GCP for laboratory standards. Sponsor will assess the Protocol and proposed laboratory questionnaire on a proportionate and risk based basis  |
| Endpoint | Intended laboratory | GCP compliant Laboratory? *N.B. please provide GCP Laboratory Self-Assessment Questionnaire (TEM013)* |
| 1. |       |       | [ ]  Yes | [ ]  No |
| 2. |       |       | [ ]  Yes | [ ]  No |
| 3. |       |       | [ ]  Yes | [ ]  No |
| 4. |       |       | [ ]  Yes | [ ]  No |
| 5. |       |       | [ ]  Yes | [ ]  No |

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| **PART K – PHARMACY** |
| **K1** | Name of drug(s) ***(please list all including any placebo)***  | Intended supplier | Type of Use: Indication or off label | License status in UK;[[5]](#footnote-5) |
|  | 1. |       |       |       |       |
|  | 2. |       |       |       |       |
|  | 3. |       |       |       |       |
|  | *Please add more rows if necessary* |
| **K2** | Confirm Trust pharmacy has been contacted to discuss project | [ ]  Yes  | [ ]  No**Contact Trust R&D** |
| **K3** | For the above named medicinal product(s), have you secured any free of charge or at a discount? | [ ]  Yes  | [ ]  NoPlease go to **K5** |
| **K4** | Please give further information |       |
| **K5** | Is this a randomised trial? | [ ]  Yes  | [ ]  NoPlease go to **K7** |
| **K6** | Please give details of randomisation  |       |
| **K7** | Is this a blinded study? | [ ]  Yes  | [ ]  No Please go to **K10** |
| **K8** | Has the emergency code break procedure been established? | [ ]  Yes  | [ ]  No**Please speak to pharmacy** |
| **K9** | Please give further information on the emergency code break system |       |
| **K10** | If you cannot source your own drug or placebo and require assistance please contact the lead trust Pharmacy department for further information |
| **K11** | Please confirm that all medicinal products for clinical trials will be ordered through lead Trust Pharmacy | To confirm **Please initial here:** |

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| **PART L – DEVICES** |
| **L1** | If this application is for a Clinical Investigation of a Medical Device please define the type of study; |
| a. | [ ]  | Clinical study of a non-CE marked device where commercialisation of the product is intended |
| b. | [ ]  | Clinical study of a non-CE marked device for use within the institution, where commercialisation is not intended |
| c. | [ ]  | Clinical study of one or more CE marked devices for an off-label indication |
| d. | [ ]  | Clinical study of one or more CE marked devices for a labelled indication, involving a change to standard care or randomisation between groups  |
| e. | [ ]  | Clinical study of one or more CE marked devices for a labelled indication, involving no change to standard care or randomisation between groups |
| f. | [ ]  | Pre-clinical device development or performance testing |
| **L2** | Please give details of device and supplier |       |
| **L3** | Has this device been approved by the Lead NHS Trust devices committee? | [ ]  Yes**Please provide evidence** | [ ]  No |
| **L4** | Is the Device CE marked? | [ ]  Yes**Please provide evidence** | [ ]  No |
| **L5** | Please provide details of who will indemnify the device; |
| Against harm to the patient |       |
| Against theft or loss of the device |       |
| **L6** | Is there a maintenance contract in place? | [ ]  YesPlease go to **L7** | [ ]  No |
| **L7** | Please provide details of who this contract is with |       |

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| **PART M – SURGICAL PROCEDURES** |
| **M1** | Please give details of all surgical procedures to be undertaken for the purposes of the research |
| Name and details of surgical procedure | Number of procedures per participant | Total number of procedures for study |
|  | 1. |       |       |       |
|  | 2. |       |       |       |
|  | 3. |       |       |       |
|  | *Please add more rows if necessary* |

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| **PART N – RADIATION PROCEDURES** |
| **M1** | Please give details of radiation exposure assessments undertaken  |
| Please provide the details of the Radiation and Medical Physics experts who have undertaken assessments of the proposed procedures. |
| Name | Contact details |
|  |  |
| **M2** | Please give details of all imaging/radiation exposures to be undertaken for the purposes of the research |
| Name and details of imaging/radiation procedure | Number of procedures/amount of exposure per participant | Total number of procedures for study |
|  | 1. |       |       |       |
|  | 2. |       |       |       |
|  | 3. |       |       |       |
|  | *Please add more rows if necessary* |

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| **PART O – DECLARATION AND DOCUMENTATION** |
| **I confirm that the information provided in this form is accurate to the best of my knowledge** |
| Chief Investigator name |       |
| Chief Investigator signature |  |
| Date |       |
| **Please return this form, together with any documentation related to the study.** |
| **Essential documentation for all applications:** |
| [ ]  | Completed Application form (in Word format) |
| [ ]  | Comprehensive Project protocol or Clinical Investigation Plan |
| [ ]  | Evidence of peer review |
| [ ]  | \*Risk Assessment |
| [ ]  | \*Delegation of Responsibilities Log |
| [ ]  | \*Completed GCP Laboratory Self-Assessment Questionnaire (TEM013) for each laboratory |
| **The following documentation is not essential, but please return if available** |
| [ ]  | Participant Information Sheet  |
| [ ]  | Participant Consent Form  |
| [ ]  | Other participant documentation (i.e. GP letter, Invitation letter, Questionnaire etc.) |
| [ ]  | Chief Investigator 2 page CV |
| [ ]  | Evidence of CI Training  |
| [ ]  | Data Management Plan  |
| [ ]  | \*CI GCP Certificate |
| [ ]  | Grant award letter |
| [ ]  | \*DMC Terms of Reference |
| [ ]  | \*TSC Terms of Reference |
| [ ]  | \*Monitoring Plan |
| \*Applies only to CTIMPS |

1. For non NHS Trust please enter relevant lead site/centre information [↑](#footnote-ref-1)
2. <https://www.liverpool.ac.uk/intranet/media/intranet/humanmaterialgovernance/HumanMaterialCodeofPractice.pdf> [↑](#footnote-ref-2)
3. Include expected in kind contributions [↑](#footnote-ref-3)
4. This study will require an MTA please contact Trust R&D or University Contracts Team to arrange [↑](#footnote-ref-4)
5. Unlicensed (anywhere), UK Unlicensed (not licensed in the UK, but is licensed elsewhere), Unlicensed Use (UK Licence, but used in new indication), Licensed Use [↑](#footnote-ref-5)