**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? | | | | | | Yes  Please go to **A7** | | | No  Please 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** | No  Please go to **D2** |
| **D2** | Will the research protocol be reviewed as part of a grant funding process or any other scientific peer review process? | Yes  Please 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? | | | | Yes  Please go to **E3** | | | | | No  Please 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? | | | | | | Yes  Please go to **E9** | | | | No  Go 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? | | | Yes  Go to **F6** | | No  Go 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? | | | Yes  Please go to **F10** | | No  Please 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? | Yes  Please go to **G4** | No  Please 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? | Yes  Please go to **Part J** | No |
| **I2** | Does the project involve a drug (including any placebo)? | Yes  Please 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? | Yes  Please 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 points  Please 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)? | | | | | Yes  Registered Research Tissue Bank & Custodian: | | | | | | No | | | | |
| **J6** | Will samples be transferred between different institutions? | | | | | Yes  Please go to **J7** | | | | | | No  Please 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? | | | | | | | | Yes  Please go to **J10** | | | | | | No  Please 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? | | | | | | | | Yes  Please 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 | | | | No  Please go to **K5** | |
| **K4** | Please give further information | |  | | | | | | |
| **K5** | Is this a randomised trial? | | | Yes | | | | No  Please 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? | | | | Yes  Please 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)