**LIVERPOOL HEALTH PARTNERS JOINT RESEARCH OFFICE**

**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 organisation.

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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** | CI Substantive employing organisation | | |  | | | | | | | |
| **A6** | Proposed Sponsoring Organisation | | |  | | | | | | | |
| **A7** | Lead NHS Trust[[1]](#footnote-1) | | | Name: | | | | | | | |
|  |  | | | Reference: | | | | | | | |
|  |  | | | Name of PI: | | | | | | | |
| **A8** | 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) | | | | | | | |
|  |  | 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 | | | | | | | |
| **A9** | Is this research to be submitted in part/fulfilment of an academic qualification? | | | | | Yes  Please go to **A10** | | | No  Please go to **Part B** | | |
| **A10** | Student name ***(Please give details as a co-applicant in Part C)*** | | | | |  | | | | | |
| **A11** | Title of qualification | | | | |  | | | | | |

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| **PART B - CHIEF INVESTIGATOR DETAILS** | | | |
| **B1** | CI Trust Directorate OR University Department |  | |
| **B2** | Is the CI an Early Career Researcher[[2]](#footnote-2)? | Yes | No |
| **B3** | Honorary contract type (if applicable) | Honorary Clinical Contract | |
| Honorary Research Contract | |
| Letter of Access | |
| None | |
| **B4** | Preferred email address |  | |
| **B5** | Has the CI received GCP training in the past 3 years?[[3]](#footnote-3) | Yes  Date of training Click or tap to enter a date. | |
| No | |
| **B6** | Has the CI received appropriate human material training[[4]](#footnote-4) in the past 3 years? (UoL applications only) | Yes  Date of training Click or tap to enter a date. | |
| 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 | Choose an item. | |
| 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 | Choose an item. | |
| 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 | Choose an item. | |
| 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** | | | |
| **D1** | Has the research protocol been through scientific peer review? | Yes  **Please provide copies**  **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 E8** | | | |
| **E2** | Please provide details of funding provision for this study | | | |  | | | | | | | | |
| **E3** | Details of funding | | | | | | | | | | | | |
| **Name of funder** | | | **Expected funding[[5]](#footnote-5)** | | **Commercial/ Non commercial** | | | **Funding start date** | | | | **Funding end date** |
| 1. |  | | £ | | Choose an item. | | | Click or tap to enter a date. | | | | Click or tap to enter a date. |
| 2. |  | | £ | | Choose an item. | | | Click or tap to enter a date. | | | | Click or tap to enter a date. |
| 3. |  | | £ | | Choose an item. | | | Click or tap to enter a date. | | | | Click or tap to enter a date. |
| *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; | |  |
| If no, please define the arrangements for Study Management | |  |
| **F3** | Intended duration of study | years        months | | | Intended Start Date | | Click or tap to enter a date. |
| Proposed End Date | | Click or tap to enter a 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** | **Please list all collaborating organisations and define their role. Please do not list recruitment sites here, please list these in Part G.** | | | | | | |
| Name of organisation | | Role in study[[6]](#footnote-6) | | | Is an agreement in place? | |
|  | |  | | |  | |
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| *Please add more rows if necessary* | | | | | | |

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| **PART G – RECRUITMENT DETAILS** | | | | | | | | | | |
| **G1** | Intended duration of recruitment | | years        months | | Intended Recruitment Start Date | | | Click or tap to enter a date. | | |
| Proposed Recruitment End Date | | | Click or tap to enter a date. | | |
| **G2** | Will the study involve participant contact? | | | | Yes  Go to **G3** | | No  Go to **G4** | | | |
| **G3** | Total number of participants to be recruited | | | | NHS Patients | | | | |  |
| NHS Staff | | | | |  |
| Healthy Volunteers | | | | |  |
| Other | | | | |  |
| International Healthcare patients | | | | |  |
| **TOTAL** | | | | |  |
| **G4** | If your study will involve data collection **only,** please detail amount of data you expect to collect/review | | | |  | | | | | |
| **G5** | How many participants to be recruited at lead site? | | | |  | | | | | |
| **G6** | Will any participants be seen outside of NHS premises? | | | | Yes  Please go to **G7** | | No  Please go to **G8** | | | |
| **G7** | Where will participants be seen outside of NHS premises? | | | |  | | | | | |
| **G8** | **Please list all proposed recruitment sites – please provide full names of organisations** | | | | | | | | | |
| **Name of site** | **Type of site** | | **State if recruiting site or PIC[[7]](#footnote-7)** | | **Proposed number of participants to be recruited** | | | **Has site feasibility been completed?** | |
|  | Choose an item. | | Choose an item. | |  | | | Choose an item. | |
|  | Choose an item. | | Choose an item. | |  | | | Choose an item. | |
|  | Choose an item. | | Choose an item. | |  | | | Choose an item. | |
|  | Choose an item. | | Choose an item. | |  | | | Choose an item. | |
| *Please add more rows if necessary* | | | | | | | | | |

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| **PART H – DETAILS REQUIRED FOR INDEMNITY AND INSURANCE** | | | |
| **H1** | Does the study deliberately aim to recruit any of the following | Children under the age of 5  Pregnant Women | |
| **H2** | Have any requests for insurance cover been requested from any other organisations? | Yes  Please go to **H3** | No  Please go to **Part I** |
| **H3** | Please provide details of these requests |  | |

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| **PART I – DATA PROTECTION AND STORAGE** | | | | | | | | |
| **I1** | Will data be anonymised?[[8]](#footnote-8) | Yes Please go to **I2** | | Yes - Pseudo  Please go to **I2** | | | | No  Please go to **I3** |
| **I2** | Please give details of pseudo / anonymisation process |  | | | | | | |
| **I3** | Has a Data Protection Impact Assessment (DPIA) been completed for this study[[9]](#footnote-9)? | Yes | | No | | | Not required as defined by the Sponsor Trust | |
| **I4** | Is there a data management plan in place for this study[[10]](#footnote-10)? | Yes | | | No | | | |
| **I5** | What format will data be in[[11]](#footnote-11)? | Choose an item. | | | | | | |
| **I6** | Will data be stored at the recruiting NHS Trusts? | Yes  Please go to **I7** | | | No  Please go to **I8** | | | |
| **I7** | Where will the data be stored in the NHS Trusts? | If paper-based data;  Building  Floor  Room  Cupboard | | | If electronic data;  specify storage type | | | |
| **I8** | Will this data be transferred out of the recruiting NHS Trusts? | Yes  Please go to **I9** | | | No  Please go to **I11** | | | |
| **I9** | Where will the data be transferred to? |  | | | | | | |
| **I10** | How will data be transferred? |  | | | | | | |
| **I11** | Will external data be transferred into the recruiting NHS Trusts? | Yes  Please go to **I12** | | | No  Please go to **I14** | | | |
| **I12** | Where will the data be transferred from? |  | | | | | | |
| **I13** | How will data be transferred? |  | | | | | | |
| **I14** | Will data be transferred between any other organisations? | Yes  Please go to **I15** | | | No  Please go to **I18** | | | |
| **I15** | Where will the data be transferred from/to? |  | | | | | | |
| **I16** | How will data be transferred? |  | | | | | | |
| **I17** | Where will data be stored at the Third-Party organisation? |  | | | | | | |
| **I18** | Will data be stored at UoL? | Yes  Please go to **I19** | | | No  Please go to **I20** | | | |
| **I19** | Where will the data be stored at UoL? | If paper-based data;  Building  Floor  Room  Cupboard | | | If electronic data;  Choose an item. | | | |
| **I20** | Will all electronic transfers of data sent externally from University of Liverpool be encrypted to AES 256[[12]](#footnote-12)? | Yes | | | No | | | |
| **I21** | What are the archiving arrangements?[[13]](#footnote-13) | Location  Custodian  Retention Period | | | | | | |
| **I22** | 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 J – SAMPLES, MEDICINAL PRODUCTS, USE OF DEVICES, SURGICAL PROCEDURES AND RADIATION** | | | |
| **J1** | Will human material samples be collected for this project? | Yes  Complete **Part K** | No |
| **J2** | Does the project involve a drug (including any placebo)? | Yes  Complete **Part L** | No |
| **J3** | Does the study involve a device? | Yes  Complete **Part M** | No |
| **J4** | Does the project involve a surgical procedure? | Yes  Complete **Part M** | No |
| **J5** | Does the study involve Imaging/ Radiation exposures? This includes Standard of Care procedures included in the protocol | Yes  Complete **Part O** | No |
| 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 P**. | | | |

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| **PART K – HUMAN MATERIAL SAMPLE COLLECTION** | | | | | | | | | | | | | |
| **K1** | Please list all samples to be collected per participant and total number of samples | | | | | | | | | | | | |
| Sample Type  (*e.g. biopsy, urine, sputum, blood)* | | | | Number of samples to be collected per participant | | | | Total number of samples to be collected | | | | |
| 1. |  | | |  | | | |  | | | | |
| 2. |  | | |  | | | |  | | | | |
| 3. |  | | |  | | | |  | | | | |
| *Please add more rows if necessary* | | | | | | | | | | | | |
| **K2** | Will informed consent be taken?  *Provide copies of Participant Information Sheet and Consent forms for review* | | | | | Yes | | | | No  Reason: | | | |
| **K3** | Where will samples be processed? | | | | | Name of Laboratory  Building, floor & room | | | | | | | |
| **K4** | Where will samples be stored? | | | | | Name of Laboratory  Building, floor & room | | | | | | | |
| **K5** | How long will samples be stored for? | | | | | years | | | | | | | |
| **K6** | Will samples be stored for use in future unspecified research (with ethical approval)? | | | | | Yes  Go to **K7** | | | | No  Go to **K8** | | | |
| **K7** | Provide details of the laboratory OR Research Tissue Bank that will store samples future unspecified research[[14]](#footnote-14) | | | | | Name of Laboratory  Custodian | | | | Name of Research Tissue Bank  Custodian | | | |
| **K8** | Will samples be transferred between different institutions? | | | | | Yes  Go to **K19** | | | | No  Go to **K10** | | | |
| **K9** | Please give further details of the transfer of samples between different institutions[[15]](#footnote-15) | | | | |  | | | | | | | |
| **K10** | Do the samples require specialist storage or transport conditions? (i.e. Dry ice, liquid nitrogen etc.) | | | | | Yes  Go to **K11** | | | | No  Go to **K12** | | | |
| **K11** | Provide details of the specialist storage or transport conditions | | | | |  | | | | | | | |
| **K12** | Will samples be taken from deceased participants? | | | | | Yes | | | | No | | | |
| THIS SECTION IS FOR HUMAN MATERIAL SAMPLE COLLECTION FOR CTIMPS **ONLY** | | | | | | | | | | | | | |
| **K13** | Are any of the CTIMP Endpoints related to laboratory analysis? | | | | | | | Yes  Go to **K14** | | | | No | |
| **K14** | Please detail the Endpoints related to laboratory analysis and the laboratory that will be contracted to perform processing and analysis. 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 description** | | | **Primary, Secondary or Exploratory Endpoint?** | | | **Intended laboratory** | | | | **GCP compliant Laboratory?[[16]](#footnote-16)** | | |
| 1. | |  | Choose an item. | | |  | | | | Yes | | No |
| 2. | |  | Choose an item. | | |  | | | | Yes | | No |
| 3. | |  | Choose an item. | | |  | | | | Yes | | No |
| 4. | |  | Choose an item. | | |  | | | | Yes | | No |
| 5. | |  | Choose an item. | | |  | | | | Yes | | No |

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| **PART L – PHARMACY AND INVESTIGATIONAL MEDICINAL PRODUCTS** | | | | | | | | |
| **L1** | Name of IMP ***(please list all including any placebo)*** | | Intended supplier | | Type of Use | | | License status in UK |
| 1. |  |  | | Choose an item. | | | Choose an item. |
| 2. |  |  | | Choose an item. | | | Choose an item. |
| 3. |  |  | | Choose an item. | | | Choose an item. |
| *Please add more rows if necessary* | | | | | | | |
| **L2** | Confirm Lead Trust pharmacy has been contacted to discuss project | | | Yes | | | No  **Contact Lead Trust R&D** | |
| **L3** | For the above-named medicinal product(s), have you secured any free of charge or at a discount? | | | Yes  Go to **L4** | | | No  Go to **L5** | |
| **L4** | Please give further information | | |  | | | | |
| **L5** | Does the IMP require aseptic preparation? | | | Yes  Go to **L6** | | | No  Go to **L7** | |
| **L6** | Where is this planned to be undertaken? | | |  | | | | |
| **L7** | Is this a randomised trial? | | | Yes  Go to **L8** | | | No  Go to **L9** | |
| **L8** | Please give details of randomisation | | |  | | | | |
| **L9** | Is this a blinded study? | | | Yes  Go to **L10** | | | No  Go to **L12** | |
| **L10** | Has the emergency code break procedure been established? | | | Yes  Go to **L11** | | | No  **Contact Lead Trust Pharmacy** | |
| **L11** | Please give further information on the emergency code break system | | |  | | | | |
| **L12** | Please confirm that all medicinal products for clinical trials will be ordered through lead Trust Pharmacy | | | Yes | | No  **Contact Lead Trust Pharmacy** | | |
| If you cannot source your own drug or placebo and require assistance please contact the lead trust Pharmacy department for further information | | | | | | | | |

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| **PART M – DEVICES** | | | | | |
| **M1** | If this application is for a Clinical Investigation or other study of a Medical Device please define the type of study[[17]](#footnote-17); | | | | |
|  | Clinical study of a non- UKCA/CE marked device where commercialisation of the product is intended | | | |
|  | Clinical study of a non- UKCA/CE marked device for use within the institution, where commercialisation is not intended | | | |
|  | Clinical study of one or more UKCA/CE marked devices for an off-label indication | | | |
|  | Clinical study of one or more UKCA/CE marked devices for a labelled indication, involving a change to standard care or randomisation between groups | | | |
|  | Clinical study of one or more UKCA/CE marked devices for a labelled indication, involving no change to standard care or randomisation between groups | | | |
|  | Pre-clinical device development or performance testing | | | |
| **M2** | Please give details of device and supplier/manufacturer | |  | | |
| **M3** | Has this device been approved by the Lead NHS Trust devices committee? | | Yes  **Provide evidence** | | No |
| **M4** | Please provide details of who will indemnify the device; | | | | |
| Against harm to the patient | |  | | |
| Against theft or loss of the device | |  | | |
| **M5** | Is there a maintenance contract in place? | | Yes  Go to **M7** | No | |
| **M6** | Please provide details of who this contract is with | |  | | |

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| **PART N – SURGICAL PROCEDURES** | | | | |
| **N1** | 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 O – IMAGING AND RADIATION PROCEDURES** | | | | | |
| **O1** | Please provide the details of the Radiation and Medical Physics experts who have undertaken assessments of the proposed procedures. | | | | |
| **Name** | | | **Contact details** | |
|  | | |  | |
| **O2** | 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 P – 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 Sponsorship Application form (in Word format) | |
|  | Comprehensive Project protocol or Clinical Investigation Plan | |
|  | Evidence of peer review | |
|  | Participant Information Sheet and Participant Consent Form [[18]](#footnote-18) | |
| **The following documentation is not essential, but please return if available** | | |
|  | Other participant documentation (i.e. GP letter, Invitation letter, Questionnaire etc.) | |
|  | Signed and dated Chief Investigator 2-page CV | |
|  | Evidence of CI Training (GCP and Human Material training) where appropriate | |
|  | Data Management Plan | |
|  | Grant award letter | |
|  | Medical device instructions for use and declaration of conformity or UKCA/CE certificate | |
|  | \*Risk Assessment | |
|  | \*Completed GCP Laboratory Self-Assessment Questionnaire (TEM013) for each laboratory | |
|  | \*Delegation of Responsibilities Log | |
|  | \*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. Selecting this option will signal the potential need for extra support during your application process. We use the UKRI definition of early career researcher stages; 1) Researchers within eight years of their PhD award, or equivalent professional training OR 2) Within six years of their first academic appointment  [↑](#footnote-ref-2)
3. GCP training is essential for CTIMPs [↑](#footnote-ref-3)
4. <https://www.liverpool.ac.uk/intranet/health-and-life-sciences/clinical/clinical-research-governance/human-material/training/> [↑](#footnote-ref-4)
5. Include expected in kind contributions [↑](#footnote-ref-5)
6. Examples of collaborator roles – laboratory, Clinical Trials Unit (CTU), provision of expertise (clinical, statistical etc) [↑](#footnote-ref-6)
7. PIC = Participant Identification Centre [↑](#footnote-ref-7)
8. Applying a unique ID with a link to identifiable information is Pseudo anonymisation [↑](#footnote-ref-8)
9. A DPIA is process that helps to understand and mitigate data protection or privacy risks in a project. Please contact your Sponsor Data Protection Office for more information and guidance [↑](#footnote-ref-9)
10. A Data Management Plan (DMP) is a document describing how you will handle your data throughout your research project. It is part of good research practice and will help you plan for and manage the issues surrounding your data.

    University of Liverpool researchers are expected to write a DMP for all research projects. Please contact your Sponsor office for more information and guidance. [↑](#footnote-ref-10)
11. If multiple formats are required please detail all formats in the text box [↑](#footnote-ref-11)
12. Advice can be obtained on encryption from UoL IT Services. Search ‘How to encrypt’ on the IT services Self-Service Portal [↑](#footnote-ref-12)
13. Ensure these details are clearly indicated in the protocol [↑](#footnote-ref-13)
14. It is recommended that samples are stored within a Research Tissue Bank [↑](#footnote-ref-14)
15. This study will require an MTA [↑](#footnote-ref-15)
16. Provide GCP Laboratory Self-Assessment Questionnaire (TEM013) for each laboratory [↑](#footnote-ref-16)
17. For further information, refer to <https://www.myresearchproject.org.uk/help/hlpcollatedqsg-sieve.aspx> [↑](#footnote-ref-17)
18. Required for all research collecting or using Human Material [↑](#footnote-ref-18)