TCTU Collaboration Form

### Please complete this form if you are requesting collaboration with TCTU. Once completed, email this form and any supporting documentation to TCTU@dundee.ac.uk

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| TRIAL CONTACT |
| Chief Investigator |  |
| CI Organisation |  |
| Email address |  |
| Telephone |  |
| TCTU contact |  |

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| TRIAL TITLE |
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| TRIAL INFORMATION |
| Type of trial | [ ]  CTIMP  | [ ]  Non-CTIMP  | [ ]  Device  | [ ]  Complex intervention  |
| Estimated number of participants |  |
| Estimated number of sites |  |
| How many sites have confirmed willingness to participate? |  |
| Countries | [ ]  Scotland  | [ ]  England  | [ ]  N.Ireland  | [ ]  Wales | [ ]  Europe  | [ ]  Outside Europe  |

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| SPONSOR INFORMATION |
| Anticipated sponsor | [ ]  UofD / NHST | [ ]  Other (please specify) |  |
| Sponsor status | [ ]  Submitted | [ ]  Pending | [ ]  Approved |

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| FUNDING / GRANT INFORMATION |
| Funding source |  |
| Funding status | [ ]  In preparation | [ ]  Submitted | [ ]  Awarded |
| Grant submission date |   |

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| BRIEF OUTLINE OF TRIAL |
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| TRIAL DESIGN |
| Participant group |  |
| Intervention |  |
| Control |  |
| Outcomes |  |
| Trial design |  |
| Evidence of sample size calculation |  |
| Details of planned and/or actual participant and public involvement |  |

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| PROPOSED TIMELINES | dd-mm-yy |  | Duration (months) | Cumulative (months) |
| Anticipated project start |  | Trial set-up |  |  |
| First patient first visit |  | Recruitment |  |  |
| End of recruitment |  | Follow-up period |  |  |
| Last patient last visit |  | Complete CRFs, data entry |  |  |
| Data lock |  | Data cleaning, data extraction |  |  |
| End of project |  | Analysis |  |  |

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| APPROVALS |
| Regulatory approvals | [ ]  MHRA | [ ]  REC | [ ]  NHS R&D | [x]  Sponsorship | [ ]  Other |

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| FEASIBILITY ASSESSMENT |
| Has the proposed trial been externally reviewed? | [ ]  Yes | [ ]  No |
| If YES, provide details of review |  |
| Is the proposed trial feasible in terms of: | [ ]  experience of trial personnel | [ ]  ability to recruit target number |
| Describe recruitment plan (if known) |  |

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| TCTU SUPPORT : TRIAL MANAGEMENT |
| [ ]  None | [ ]  Protocol preparation | [ ]  Regulatory submissions | [ ]  Trial set-up | [ ]  Trial management |

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| TCTU SUPPORT : DATA MANAGEMENT |  |
| [ ]  None | [ ]  Oversight | [ ]  Mid DM package | [ ]  Full DM package |  |

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| TCTU SUPPORT : STATISTICAL ANALYSIS |
| [ ]  None | [ ]  Oversight | [ ]  Interim | [ ]  DMC | [ ]  Final |

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| TCTU SUPPORT : RANDOMISATION |
| [ ]  None | [ ]  Randomisation | [ ]  IMP oversight |  |  |

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| FURTHER INFORMATION |
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| NAME |  | DATE |  |

TCTU USE ONLY

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| ROLE: TRIAL MANAGEMENT |
| Date collaboration form received |  |
| Decision of senior management team |  |
| Date of collaboration meeting |  |
| Meeting attended by |  |

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| ROLE: TRIAL MANAGEMENT |
| **Role** | **% of FTE** | **Duties** |
| Senior Trial Manager |  |  |
| Trial Manager |  |  |
| Trial Coordinator |  |  |
| Trials Assistant |  |  |
| Admin Assistant |  |  |

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| ROLE: DATA MANAGEMENT |
| **Role** | **% of FTE** | **Duties** |
| Data Manager |  |  |
| Database Manager |  |  |
| SAS Programmer |  |  |
| Data Coordinator |  |  |

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| ROLE: STATISTICAL |
| **Role** | **% of FTE** | **Duties** |
| Statistician |  |  |

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| HIC REQUIREMENTS |
| HIC Services | [ ]  TRuST  | [ ]  PMS  | [ ]  Safe Haven  | [ ]  Other  |

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| ROLE: HIC |
| **Role** | **% of FTE** | **Duties** |
| IWRS Programmer |  |  |

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| DATA MANAGEMENT REQUIREMENTS |
| Systems required | [ ]  DMS e.g. OC, Castor etc… If other, please specify   | [ ]  Plan to use Excel but would like DM support  | [ ]  LabKey  | [ ]  Other e.g. Results Checker System   |
| MedDRA coding required? | [ ]  Yes | [ ]  No |

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| Data to be included in the pCRF *(generic data)*: |
| [ ]  Consent | [ ]  Demographics | [ ]  Medical history | [ ]  Physical exam | [ ]  Vital signs |
| [ ]  Pregnancy test | [ ]  ConMeds | [ ]  Eligibility bloods | [ ]  Inclusion/exclusion | [ ]  AEs |
| [ ]  Compliance | [ ]  Withdrawal/End of study  | [ ]  Other (please specify) |  |
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| Data to be included in the pCRF *(trial specific data)*:  |
| [ ]  NHS lab results | [ ]  Grip strength | [ ]  ECG | [ ]  Spirometry | [ ]  Swabs |
| [ ]  Sputum samples | [ ]  6-min walk test | [ ]  Questionnaires (specify if known) | [ ]  Health diary | [ ]  Falls diary |
| [ ]  Other (please specify) |  |  |  |

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| External data sources. Please include details if known of the provider/ frequency of data transfer/ processing/ type of data. e.g. Actometer, lab results, genomic, imaging etc… | [ ]  Yes | [ ]  No |
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| Data management packages include: |
| [ ]  Full package | pCRF design, system build & validation, system maintenance, change management, user training, user management, data cleaning, data auditing, MedDRA coding, SAE reconciliation, database lock, provision of data to statistician/health economist etc |
| [ ]  Mid package | Involvement in the design of the pCRF/data capture system, data cleaning, data auditing, MedDRA coding, SAE reconciliation, provision of data to statistician/health economist etc. |
| [ ]  Oversight | Advice role only |