TCTU Collaboration Form

### Please complete this form if you are requesting collaboration with TCTU. Once completed, email this form and any supporting documentation to [TC](mailto:TCTU@dundee.ac.uk)[TU@dundee.ac.uk](mailto:TU@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 | 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 |