**Brighton and Sussex Clinical Trials Unit (CTU) Collaboration Request Proforma**

Please complete this form with as much detail as you have. If you are at a very early stage of study development and details are unknown, leave the section blank.

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| **Study Title** |  |
| **Chief Investigator:** |  |
| **Local Collaborator, if non Brighton CI** |  |
| **Position:** |  |
| **Organisation:** |  |
| **Email:** |  |
| **Telephone:** |  |

Email the completed form to Nicky Perry at **bsctu@bsms.ac.uk.** This email can also be used for general Clinical Trials Unit enquiries. A member of the Clinical Trials Unit will contact you to discuss your proposal and the next steps that you will need to take.

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| 1. Have you contacted the Research Design Service (RDS)
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| If yes: date of meeting If no: You can contact them to discuss your project for methodology, initial stats support if required: http://www.rds-se.nihr.ac.uk/ |

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| **2. Study Overview**  (*Why is the study needed? Max 250 words)* |
| Please complete the following sections or supply an overview from the grant application to include:-**Design, methodology, statistical input i.e. RCT, case controlled, qualitative.** **Primary and secondary endpoints****Estimated number of participants** |
| **3. Timelines** |
| Project start dateRecruitment Start date:Recruitment Completion date: |
| Study completion date: |

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| **4. Estimated number of centres and the locations *(max 150 words)*** |
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| **5a. Funder *(type of grant application – i.e. open competition)*** |
| NIHR Evaluation, Trials and Studies (NIHR NETSCC) |
| **5b. Award Date and amount of funding available:** |
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| **6. Sponsor** |
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To assist with the costings please list what activities you would like the Clinical Trials Unit to support:

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| 7. **Clinical Trials Unit collaboration required (please tick all that are required)** |
|  Grant Development (in collaboration with other host organisations)Study / Clinical Trials Unit costings Protocol developmentStudy/trial designStatistical designStatistical analysis Interim statistical reports for Data Management CommitteeStudy Coordination (to include study and participating site set-up, preparation of all essential study documents, regulatory and ethics submissions, preparation of annual reports etc)Study monitoringRandomisationPharmacovigilance (adverse event monitoring, safety reporting)Study specific procedures development Advice Investigational Medicinal Product management Case Report Form designDatabase build and maintenance, remote data captureData management (including data cleaning processes)Health EconomicsAccess to other methodologist, please specify *( i.e. Patient Related Outcomes)*Regulatory Oversight (for Clinical Trials of Investigational Medicinal Products only)Management of Trial Safety Committee/Data Safety Management BoardSpecimen/tissue management Contribution to preparation of final reportOther, please specify |

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| **8. Signature and Date of Chief Investigator** |
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Please email your completed form to bsctu@bsms.ac.uk.

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| ***For CTU only*** |
| Date application received |  |
| Date of CTU Management Committee meeting to review this trial |  |
| Comments |  |