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

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:** |  |
| **Position:** |  |
| **Local collaborator (if not CI)** |  |
| **Organisation:** |  |
| **Email:** |  |
| **Telephone:** |  |

Email the completed form to [BSCTU@bsms.ac.uk](mailto: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)** |
| Yes  No  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 |
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| **3. Timelines** | |
| 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)*** |
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| **5b. Award Date:** |
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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 development  Study/trial design  Statistical design  Statistical analysis  Interim statistical reports for Data Management Committee  Study 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 monitoring  Randomisation – **please include further information**  Pharmacovigilance (adverse event monitoring, safety reporting)  Study specific procedures development  Advice Investigational Medicinal Product management  Case Report Form design  Database build and maintenance, remote data capture  Data management (including data cleaning processes)  Health Economics  Access 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 Board  Specimen/tissue management  Contribution to preparation of final report  Other, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **All trials run through Brighton and Sussex CTU will have their protocols published online prior to patient recruitment. Costs should be met via the grant / funder of the study.** |

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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](mailto:BSCTU@bsms.ac.uk)

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| ***For CTU only*** | |
| CTU number |  |
| Date application received |  |
| Date database updated |  |
| Date of CTU Management Committee meeting to review this trial |  |
| Date Investigator informed |  |
| Investigator informed by (name) |  |
| Letter of Agreement/terms and conditions sent |  |
| Signed copy returned |  |
| Comments |  |