**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.

|  |  |
| --- | --- |
| **Study Title:** |  |
| **Chief Investigator:** |  |
| **Position:** |  |
| **Local collaborator (if not CI)** |  |
| **Organisation:** |  |
| **Email:** |  |
| **Telephone:** |  |

Email the completed form to 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.

|  |
| --- |
| 1. **Have you contacted the Research Design Service (RDS)**
 |
| [ ]  Yes [ ]  NoIf 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/>  |

|  |
| --- |
| **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** |
| Start date: |  |
| Recruitment Completion date: |  |
| Study completion date: |  |

|  |
| --- |
| **4. Estimated number of centres and the locations *(max 150 words)*** |
|   |

|  |
| --- |
| **5a. Funder *(type of grant application – i.e. open competition)*** |
|  |
| **5b. Award Date:** |
|  |

|  |
| --- |
| **6. Sponsor** |
|  |

To assist with the costings please list what activities you would like the Clinical Trials Unit to support:

|  |
| --- |
| 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.** |

|  |
| --- |
| **8. Signature and Date of Chief Investigator** |
|  |

Please email your completed form to BSCTU@bsms.ac.uk

|  |
| --- |
| ***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 |  |