|  |
| --- |
| Description: UKCRC Registered CTUs Logo - white**Instructions:** Please complete this form in full and submit by email (alternatively you may fax or post it but this may delay the review process):  |
| CTU@southampton.ac.uk |
| **Southampton Clinical Trials Unit** |
| Mail Point 131 |
| Southampton General Hospital |
| Tremona Road |
| Southampton SO16 6YD Tel: +44 (0)23 8120 5154 Fax: +44 (0) 844 7740621 |

# Section 1 – Details of Key Contact Person Date:

|  |  |
| --- | --- |
| **Title:** Prof **[ ]**  Dr **[ ]**  Mr **[ ]**  Mrs **[ ]**  Miss **[ ]** Ms **[ ]**  | **Full Name:** |
| **Job Title:**       | **Employer:**        |
| **Contact address:** |       |
|  | **Post Code:**  |      |
| **Tel/bleep:**  |       | **Fax No:** |  |
| **E-mail:** |       |
| **Best contact method and day/time:** |         |

# Section 2 – Details of Chief Investigator

|  |  |
| --- | --- |
| **Title:** Prof **[ ]**  Dr **[ ]**  Mr **[ ]**  Mrs **[ ]**  Miss **[ ]** Ms **[ ]**  | **Full Name:** |
| **Job Title:** | **Employer:** |
| **Contact address:** |  |
|  | **Post Code:**  |  |
| **Tel/bleep:**  |  | **Fax No:** |  |
| **E-mail:** |  |
| **Best contact method and day/time:** |         |

# Section 3 – Funding

|  |  |  |
| --- | --- | --- |
| **1. Do you already have funding for this proposal?**  | **[ ]** Yes **[ ]** No  | If **yes** please go to **question 4** |
| **2. Have you identified a potential funding body?**  (e.g. HTA, CRC) | **[ ]** Yes **[ ]** No  | If **yes** please go to **question 3**If **no** please go to **question 5** |
| **POTENTIAL FUNDING** |
| **3. a) Which funding body are you considering?** |  |
|  **b) Do you have a deadline for your proposed application?** | **[ ]** Yes **[ ]** No  | If **yes**, please give date: |
|  |  |
| **CURRENT FUNDING**  |
| **4. a) What is the name of your project’s funder?**  |  |
|  **b) What is the amount of the grant award?** |  |

# Section 4 – Support Required

|  |
| --- |
| **5. What kind of support does your project require from the Clinical Trials Unit?** (please tick all that apply): |
| Study design  | **[ ]**  | Statistics  | **[ ]**  |
| Funding application(s) | **[ ]**   | Health Economist | **[ ]**   |
| Writing protocol  | **[ ]**  | Trial management | **[ ]**  |
| Data management | **[ ]**  | Other (please specify): |       |
| **6. Please tell us how you heard about the Clinical Trials Unit?** |  |

# Section 5 – Research Proposal Outline (Please provide as many details as possible)

 **\***All questions marked with an asterisk are mandatory.

|  |  |
| --- | --- |
| **7.**  | **Title of Research Proposal :**  |
| **8.\***  | **Principal research question(s)/endpoint(s) and, secondary if known:**  |
| **9.\***  | **What is already known about your research topic?** (Please be brief. Only essential references are required) |
| **10.\***  | **What will this study add to current knowledge?**  |
| **11.\***  | **Are there any current or known potential competing trials?**  |
| **12.\***  | **Summary of proposed trial:** (Please also tick trial phase) **Phase I [ ]  Phase II** [ ]  **Phase III** [ ]  **Phase IV** [ ]  |
| **13.**  | **What are the proposed interventions (experimental and control), including treatment duration?** |
| **14.**  | **Please provide a summary of the key inclusion/exclusion criteria.**  |
| **15.**  | **What are the proposed outcome measures and how will they be measured?**  |
| **16.**  | **What is the proposed frequency and duration of follow-up?**       |
| **17.\***  | **What is the current estimated/target sample size?**       |
| **18.**  | **What is the estimated recruitment rate?**       |
| **19.\***  | **Where do you plan to conduct the study?** Please provide projected number of sites, if possible. |
|  | **ORGANISATIONS** | **GEOGRAPHICAL LOCATIONS** |
|  | Primary care trusts  | [ ]   | Number: |  | England only | [ ]  | Number: |  |
|  | Secondary care trusts | [ ]  | Number: |  | UK only | [ ]  | Number: |  |
|  | Other (please specify):  | Other (please specify):  |

|  |  |
| --- | --- |
| **20.\*** | **If a statistician has been involved in the design, please include details of the planned analyses, including frequency and plans for subgroup analyses, otherwise leave blank.****Name of Statistician**:      **Details of planned analyses:**       |
| **21.\*** | **Is any associated translational research being planned?** If yes, please give a brief summary**.**      |
| **22.\*** | **Study Time Line** (please specify any deadlines)**:**       |
| **23.** | **Other comments or relevant information:**       |

*Thank you for your application. You should receive an acknowledgement of receipt within 2 working days.*

*For internal use only*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Application no.: |  | Review date deadline: |  |  |
| Date received: |  | Date acknowledged: |  |  |
| Review outcome: |  | Date notified of outcome: |  |  |
| Reviewed by: |  |  |
|  |  |