|  |
| --- |
| Description: UKCRC Registered CTUs Logo - white**Instructions:** Please complete this form in full and submit by email to [CTU\_grants@southampton.ac.uk](mailto:CTU_grants@southampton.ac.uk)  (alternatively, you may post your application, but this may delay the review process): |
|  |
| **Southampton Clinical Trials Unit** |
| Mail Point 131 |
| Southampton General Hospital |
| Tremona Road |
| Southampton SO16 6YD  Tel: +44 (0)23 8120 5154 |

# Section 1 – Details of Key Contact Person Date:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Title:** Prof  Dr Mr Mrs MissMs | | | | **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 MissMs | | | | **Full Name:** | |
| **Job Title:** | | | | **Employer:** | |
| **Contact address:** | |  | | | |
|  | | | | **Post Code:** |  |
| **Tel/bleep:** |  | | | **Fax No:** |  |
| **E-mail:** |  | | | | |
| **Best contact method and day/time:** | | |  | | |
| **Are there any co-applicants for this proposal?** | | | Yes  No | | |
| If **yes,** please give details | | | | | |

# 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?**  **c) If yes, is this a fixed or flexible deadline?**  (Please bear in mind that if you are working towards a very tight deadline, the SCTU may not have capacity immediately.) | | Yes    No  Fixed  Flexible | If **yes**, please give date  and go to **question 3c**:  If **no**, please go to **question 5** | |
|  |  |
| **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

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| --- | --- | --- | --- | --- | --- |
| **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) |  | Trial management | | |  |
| Writing protocol |  | QA / safety / monitoring | | |  |
| Data management |  | | Other (please specify): | |  |
| **6. Are there any other support requirements within your proposal?** (please tick all that apply): | | | | | |
| Qualitative research |  | Health Economist | | |  |
| Other (please specify): |  | | | | |
| **Please tell us if you have had, or are in, discussions with anyone about providing this support** | | | | | |
| **7. Please tell us how you heard about the Southampton Clinical Trials Unit?** | | | | | |
| **8. Have you had, or are you in, discussions with other CTUs about this proposal?** | | | | Yes  No | |
| If **yes,** please give details | | | | | |
| **9. For oncology trials, has your final concept been discussed with any NCRI groups (formerly Clinical Studies Groups) or ECMC (Experimental Cancer Medicine Centre)?** | | | | Yes  No | |
| If **yes,** please give details | | | | | |
| **10. Have you had, or are you in, discussions with potential sponsors for this trial?** | | | | Yes  No | |
| If **yes,** please give details | | | | | |
| **11. Have you had any patient and public involvement (PPI) with individual public contributors or a PPI group about your proposal?** | | | | Yes  No | |
| If **yes,** please give details | | | | | |

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

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

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **12.** | **Title of Research Proposal :** | | | | | | | | |
| **13.\*** | **Principal research question(s)/endpoint(s) and, secondary if known:** | | | | | | | | |
| **14.\*** | **What is already known about your research topic?** (Please be brief. Only essential references are required) | | | | | | | | |
| **15.\*** | **What will this study add to current knowledge?** | | | | | | | | |
| **16.\*** | **Are there any current or known potential competing trials?** | | | | | | | | |
| **17.\*** | **Summary of proposed trial:** (Please also tick trial phase) **Phase I  Phase II**  **Phase III**  **Phase IV** | | | | | | | | |
| **18.** | **What are the proposed interventions (experimental and control), including treatment duration?** | | | | | | | | |
| **19.** | **Please provide a summary of the key inclusion/exclusion criteria.** | | | | | | | | |
| **20.** | **How will you make recruitment to this trial as inclusive as possible to all patient groups and those with accessibility issues?** | | | | | | | | |
| **21.** | **What are the proposed outcome measures and how will they be measured?** | | | | | | | | |
| **22.** | **What is the proposed frequency and duration of follow-up?** | | | | | | | | |
| **23.\*** | **What is the current estimated/target sample size?** | | | | | | | | |
| **24.** | **What is the estimated recruitment rate?** | | | | | | | | |
| **25.\*** | **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): | | | | |
| **26.\*** | **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:** | | | | | | | | |
| **27.\*** | **Have you had, or are you in, discussions with the RDS (Research Design Service) about this proposal?** | | | | | | Yes  No | | |
|  | If **yes,** please give details | | | | | | | | |
| **28.\*** | **Is any associated translational research being planned?** If yes, please give a brief summary**.** | | | | | | | | |
| **29.\*** | **Study Time Line** (please specify any deadlines)**:** | | | | | | | | |
| **30.** | **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: |  | | |  |
|  |  | | | |