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| 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:** | |  | | | |
| **E-mail:** |  | | | **Tel/bleep:** |  |
| **Best contact method and day/time:** | | |  | | |

# Section 2 – Details of Chief Investigator (\*Please fill out our [EDI monitoring form](https://forms.office.com/e/hm4wsyJszt) – see bottom of this form for details)

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| --- | --- | --- | --- | --- | --- | --- |
| **Title:** Prof  Dr Mr Mrs MissMs | | | | **Full Name:** | | |
| **Job Title:** | | | | **Employer:** | | |
| **Contact address:** | |  | | | | |
| **E-mail:** |  | | | **Tel/bleep:** |  | |
| **Best contact method and day/time:** | | |  | | | |
| **Do you have any previous experience as a CI?** | | | Yes  No | | | |
| If **yes,** please give details | | | | | | |
| **Does your employer support you in taking on the role as CI for this study?** | | | | | | Yes  No  TBC |
| **Are you, or your employer, part of CRUK (ECMC, Centre, Institute) or NIHR (BRC, CRF) infrastructure?**  If **yes,** please give details | | | | | | Yes  No |
| **Are there any co-applicants for this proposal?**  If **yes,** please give details | | | Yes  No | | | |
| **Are there any Early Career Researchers (ECRs) linked with this proposal?**  If **yes,** please give details | | | Yes  No | | | |
| If **no,** would you be open to SCTU suggesting an ECR to join the trial team? | | | Yes  No | | | |
|  | | | | | | |

# Section 3 – Funding

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| --- | --- | --- | --- | --- |
| **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 |  | |  |  | |
| **6. Are there any other support requirements within your proposal?** (please tick all that apply): | | | | | |
| Qualitative research/Process evaluation |  | Health Economics | |  | |
| Sample management  Implementation Science |  | Bioinformatics  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-type groups or ECMC (Experimental Cancer Medicine Centre)?** | | | | | Yes  No |
| If **yes,** please give details | | | | | |
| **10. We expect most trials run by SCTU to be sponsored in Southampton, either by the University or NHS Hospital Trust. Are you happy for sponsorship to be in Southampton?** | | | | | Yes  No |
| If **no,** please specify who you would like to sponsor and 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.

|  |  |  |  |  |  |  |  |  |  |
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| **12.\*** | **Title of Research Proposal :** | | | | | | | | |
| **13.\*** | **Lay Summary (no more than 500 words.** (Please make sure this is written in plain English for a non-research audience. This will be reviewed by our public members**):** | | | | | | | | |
| **14.\*** | **Principal research question(s)/endpoint(s) and, secondary if known:** | | | | | | | | |
| **15.\*** | **What is already known about your research topic?** (Please be brief. Only essential references are required) | | | | | | | | |
| **16.\*** | **What will this study add to current knowledge?** | | | | | | | | |
| **17.\*** | **Are there any current or known potential competing trials?** | | | | | | | | |
| **18.\*** | **Summary of proposed trial:** (Please also tick trial phase) **Phase I  Phase II**  **Phase III**  **Phase IV** | | | | | | | | |
| **19.** | **What are the proposed interventions (experimental and control), including treatment duration?** | | | | | | | | |
| **20.** | **Please provide a summary of the key inclusion/exclusion criteria.** | | | | | | | | |
| **21.** | **How will you make recruitment to this trial as inclusive as possible to underserved groups and those with accessibility issues?** | | | | | | | | |
| **22.** | **What are the proposed outcome measures and how will they be measured?** | | | | | | | | |
| **23.** | **What is the proposed frequency and duration of follow-up?** | | | | | | | | |
| **24.\*** | **What is the current estimated/target sample size?** | | | | | | | | |
| **25.** | **What is the estimated recruitment rate?** | | | | | | | | |
| **26.\*** | **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: |  |
|  | International |  |  |  | If international, please provide more details: | | | | |
|  |  |  |  |  |  | | | | |
| **27.\*** | **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:** | | | | | | | | |
| **28.\*** | **Have you had, or are you in, discussions with NIHR the Research Support Service, RSS (formally RDS) about this proposal?** | | | | | | Yes  No | | |
|  | If **yes,** please give details | | | | | | | | |
| **29.\*** | **Is any associated translational research being planned?** If yes, please give a brief summary**.** | | | | | | | | |
| **30\*** | **How do you plan to share any translational samples and/or data with basic scientists to promote further research in this area, e.g. through a Secure Data Environment (SDE)?** Please give a brief summary**.** | | | | | | | | |
| **31\*** | **Does this study involve a new medical device/device changes/external company involvement?** If yes, please provide details. | | | | | | | | |
| **32\*** | **Are there any existing patents or IP associated with the study, or does the trial have the potential to develop, intellectual property?** If yes, please provide details. | | | | | | | | |
| **33\*** | **Are there any methodological sub-studies or SWATs (studies within a trial) planned as part of this proposal?** If yes, please provide details. | | | | | | | | |
| **34\*** | **Are there any potential conflicts of interest (COIs) for the Chief Investigator of this study, e.g. with external companies or IP development?** If yes, please provide details. | | | | | | | | |
| **35\*** | **Have you considered any sustainability goals or climate impact and mitigation options that might be relevant to your trial design?** If yes, please provide details. | | | | | | | | |
| **36.\*** | **Study Time Line** (please specify any deadlines)**:** | | | | | | | | |
| **37.** | **Other comments or relevant information:** | | | | | | | | |

**Section 6 – Equality, Diversity and Inclusion (EDI) Monitoring**

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| **The Southampton Clinical Trials Unit (SCTU) is committed to eliminating discrimination and encouraging equality, diversity, and inclusion across our organisation. As part of this we are trying to build an accurate picture of the researchers and investigators who apply for SCTU support.**  [**Please click on this link to fill in our EDI monitoring form**](https://forms.office.com/e/hm4wsyJszt)**. It should take no more than 5 minutes.  No applicant will be discriminated against regardless of their age, gender or gender identity, disability, ethnicity, race, religion or belief and / or sexual orientation, or if you do not wish to complete the form.   The information you enter on the form is completely anonymous and is not linked to your application for support. It may be shared with other organisations (e.g. funding bodies) as anonymised data and is for monitoring purposes only.** |

*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: |  | | |  |
|  |  | | | |