|  |  |
| --- | --- |
| **CCTU Ref** |  |

**Cambridge Clinical Trials Unit**

**Collaboration Request Form**

Please complete all response fields below and send this form to [cctu@addenbrookes.nhs.uk](file:///\\addstore\bridge\Research%20&%20Development\CTU\Cambridge%20Clinical%20Trials%20Unit\1.%20CCTU%20STAFF\14.%20Grants%20Officer\New%20documents\cctu@addenbrookes.nhs.uk%20).The completed form should be submitted to the CCTU for review at least **5 weeks** prior to the funding application deadline.

The CCTU will be the registered clinical trials unit for the proposed trial if it has oversight of the main activities including coordination, statistical design and analysis. This request will be reviewed internally, after which a decision will be made to either support or not support the trial.

**Note:** Cambridge Sponsored CTIMPs must be run through an accredited CTU; however sponsor oversight will in all instances be delegated to the CCTU regulatory team.

|  |  |
| --- | --- |
| ***General Information:*** | |
| Study Title and Acronym | Click here to enter text. |
| Details of Chief Investigator (CI) | Title  Name  Organisation and Address  Email Address/ Telephone Number |
| Details of Point of Contact | Title  Name  Organisation and Address  Email Address/ Telephone Number |
| Proposed Sponsor of the research | Consider substantive employer of Chief Investigator. |
| 1. **Describe the clinical trials experience of the CI and the current trial team (including collaborators)** | |
| Click here to enter text. | |

|  |  |
| --- | --- |
| ***Research Background:*** | |
| **Select the CCTU Theme which best fits the proposed area of research:** | **Choose a theme** |
| 1. **Summarise the research question(s) aims and objectives** i.e. primary, secondary, exploratory etc.**:** | |
| Click here to enter text. | |
| 1. **Provide background information** i.e. problem, solution provided by this research**:** | |
| Click here to enter text. | |
| 1. **Explain the importance/relevance of this trial to NHS priorities and policies governing clinical practice:** | |
| Click here to enter text. | |

|  |  |  |
| --- | --- | --- |
| ***Research Details:*** | | |
| 1. **Type of trial:** | | |
| Please select this link to learn if your trial is a CTIMP: <https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/317952/Algothrim.pdf> | | |
| Choose an item. | If interventional, check one the following boxes:  CTIMP  Device trial  ATIMP  Other | If CTIMP Choose Phase |
| 1. **Describe the research in terms of PICOS:** | | |
| **P - Patient group and duration of trial for each patient:** Click here to enter text. | | |
| **I - Intervention(s) i.e.** *IMP, placebo and medical device* *Marketing authorisation, dosage, over encapsulation/manufacturing requirements, CE marking status etc.***:** Click here to enter text. | | |
| **C - Control:** Click here to enter text. | | |
| **O - Outcomes and follow up period:** Click here to enter text. | | |
| **S - Statistical/ Trial design**: Click here to enter text. | | |
| 1. **Protocol status** | | |
| None  Outline  Full  Attached  Consort diagram attached | | |
| 1. **Participating sites: Choose an item.** | | |
| If Multisite, how many participating sites: Click here to enter text.  If International, in which countries are the proposed participating sites: Click here to enter text. | | |
| 1. **Sample size** (if already performed or estimated)**:** | | |
| Click here to enter text. | | |
| 1. **Estimated Recruitment Rate and total recruitment period:** | | |
| Click here to enter text. | | |
| 1. **Are there any competing trials that may affect recruitment?: YES  NO** | | |
| If yes, explain the possible effect: Click here to enter text. | | |
| 1. **Are you planning a pilot or feasibility research trial: YES  NO** | | |
| If yes, explain how this will lead to the main trial: Click here to enter text. | | |

|  |
| --- |
| ***Statistics:*** |
| 1. **For trial development and sample size calculations, you will need to provide:**  * **An estimate of your primary outcome measure for the control group (for example response rate expected without the new intervention)** * **Also think about a clinically significant difference you would want to observe between groups for the trial to be convincing (e.g. be worthwhile for funders and patients, change practise)** |
| Please provide sources/justification for these estimates from pilot work/literature. |
|  |

|  |
| --- |
| ***Financial support for your research:*** |
| 1. **Funding plans and status:** |
| Funding status: Click here to enter text.  Proposed funder and funding stream/programme: Click here to enter text.  Application submission deadline: Click here to enter a date.  Expected date of application outcome: Click here to enter a date.  Estimated grant total (if known): Click here to enter text. |
| 1. **Other Sources of financial Support** i.e. Drug supply, Equipment provision, Commercial support etc.**:** |
| Click here to enter text. |

|  |
| --- |
| ***Other involvement:*** |
| 1. **Has this Proposal or a similar one previously been submitted to a funding body? YES  NO** |
| If yes give further details |
| 1. **Have you engaged with a Research Design Service (RDS)? YES  NO** |
| If yes, name of RDS. |
| 1. **Have you approached any other CTUs regarding this trial? YES  NO** |
| If yes, what was the outcome. |
| 1. **Have you engaged with the Office for Translational Research? YES  NO** |
| If yes, what was the outcome. |
| 1. **Is exploratory translational research being planned?**  **YES  NO** |
| If yes, give further details of samples and procedures. |
| 1. **Are Patient and Public Involvement planned? YES  NO** |
| If yes, describe level of patient and public involvement.  If no, please explain why. |

|  |  |
| --- | --- |
| ***Key tasks of the trial:*** | |
| **30. Key tasks of the trial to be performed by:**  **NOTE: CCTU can only act as your registered Clinical Trials Unit provided it has oversight of the main trial activities (coordination, statistics and database provision).** | |
| Please assign each of the tasks below. | CCTU |
| Protocol development |  |
| Statistical design and analysis including production of interim statistical reports for DMC |  |
| Health economics analysis and reporting |  |
| Trial Coordination (including trial and participating site set-up, preparation of all essential documents, regulatory and ethics submissions, IMP sourcing and re-ordering etc.) |  |
| Randomisation set up and maintenance |  |
| Data management and CRF design (including data cleaning and query responses) |  |
| Database build and maintenance (including remote data capture) |  |
| **If your trial is a CTIMP and you wish to have CUH/UoC as Sponsor, please note that the Regulatory team will provide quality assurance and quality control on behalf of the Sponsor**  Regulatory oversight (including site monitoring, pharmacovigilance, and quality assurance) |  |

|  |
| --- |
| **For CCTU use only** |
| CCTU Reference: |
| Date of meeting: |
| Meeting attended by: |
| Outcome of meeting and timelines: |
| Comments/Further details: |
| Form completed by: |

CCTU/FRM083 V6 Approved: 04/03/2020 Reviewed 04/03/2020