**CPTU Collaboration Request Proforma**

Date Submitted to CPTU: Click or tap to enter a date.

First Submission: Yes  No

# Name of Study/Trial

|  |
| --- |
| Click or tap here to enter text. |

# Enquirer

|  |  |
| --- | --- |
| Name: |  |
| Position: |  |
| Employer: |  |
| Email: |  |
| Telephone: |  |

# Chief Investigator (If different from ENQUIRER)

|  |  |
| --- | --- |
| Name: |  |
| Tel: |  |
| Email: |  |

# Funding status:

*Please note that submission timelines to CPTU for outline and full funding submissions must be* ***8 weeks*** *prior to enquiry form and document submission to the CPTU, to allow time for full departmental review*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Is Funding for this project already secured?** Yes  No | | | | | |
| **If Yes, please confirm Funder and Amount** | | | | | |
| **If No, please provide the funding status below** | | | | | |
| **Name of funder** | **Funding call URL / details** | **Deadline for submission** | **Type of Application\*** | **Decision date** | **Estimated grant total** |
|  |  |  |  |  |  |

\* Outline / Full/ One-stage

# 1. RESEARCH OUTLINE – please confirm documents provided

|  |
| --- |
| Outline / synopsis **\*** Please ensure the outline summary of the protocol includes the details specified below  Draft protocol |

**\*Outline of the protocol must include the following**; Aims of the study (objectives, start & endpoint, measures); Background, Disease area, Patient group and target population, Sample size, Study design (RCT, pilot, Single or Multi-Centre, Blinded, Cross-over, UK or international, Study intervention/IMP, Importance/relevance to NHS priorities, PPIE, Literature review, Statistical summary, Study timelines (set-up, recruitment, treatment, follow-up, total study duration).

# 2. CPTU Services ReqUireD

**\*Please indicate which resources will be required**.

If you wish to have the CPTU as your main trial unit, you will receive CPTU oversight for the main activities, and core costings for this will need to be included in your funding application.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Resource** | **Service Component** |  | **Resource** | **Service Component** |
|  | Study/trial design |  |  | Statistical reports for DMC |
|  | Statistical design and analysis |  |  | IMP/NIMP/Device Management |
|  | Costing (Including SOECAT) |  |  | SOP development and CRF design |
|  | Behavioural science review *(enhancing and supporting participants' choices and behaviors to improve recruitment, retention, treatment adherence, etc.)* |  |  | Health Economics |
|  | Literature review |  |  | Specimen / Tissue Management |
|  | Randomisation and unblinding |  |  | Flagging / passive follow-up |
|  | Pharmacovigilance/Safety Reporting |  |  | Patient/Public Involvement & Engagement |
|  | Coordination of DMC/TSC etc. |  |  | Study staff recruitment­ |
|  | Data Management (including data cleaning, monitoring etc.) |  |  | Information technology (REDCap Database by default):  Initial build  Initial build and hosting  Upgrades (recommended) |
|  | Trial/Study management |  |  | Regulatory and Ethics submissions (Including amendments, reports etc.) |
| **Other:** (Please specify e.g. access to other methodologist or report as N/A) | | | | |

# 3. STATISTICAL ANALYSIS

|  |  |
| --- | --- |
| Do you need assistance with the sample size calculation? | Yes  No  If Yes, please provide the following information: |
| An estimate of your primary study outcome for the control group (for example response rate).  State the mean/SD/size, and reference where data has come from (pilot work/literature review) |  |
| What clinically significant difference would you want to observe within groups? |  |
| If available, what is the projected sample size |  |

# 4. Objectives AND TIMELINES

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Please complete the table below, outlining the objectives for the study.   |  |  |  | | --- | --- | --- | | Objectives | Endpoints | Measures | | - | Primary endpoint  - | - | | -  - | Secondary endpoint(s)  -  - | -  - | | |
|  | |
| Estimated duration of:  - Trial set-up  - Recruitment  - Treatment  - Follow-up  - Close out / analysis  - Any passive long-term follow-up  Total duration |  |

# 5. consort diagram

*Please insert a consort diagram here, if not already included in the protocol summary/outline.*

# 6. TRIAL SITES

|  |  |
| --- | --- |
| UK sites |  |
| International sites |  |
| Research setting: Primary/Secondary/Pharmacy care |  |
| How was the number of sites decided upon? Please provide relevant feasibility work supporting site engagement / recruitment |  |

# Other

SPONSOR

Click or tap here to enter text.

Portfolio

Will this study be eligible for the NIHR portfolio\*\*? Yes  No

\*\* <https://www.nihr.ac.uk/documents/eligibility-for-nihr-clinical-research-network-support/23746>

If Yes, which research networks would be involved? (e.g. Comprehensive Local Research Network (CLRN), National Cancer Research Network (NCRN), Primary Care Research Network (PCRN))

|  |
| --- |
|  |

CTU

Have you previously approached another CTU regarding this study? Yes  No

If yes, which and what was the outcome?

|  |
| --- |
|  |

**Please check the above information with the CI before submitting to the CPTU**

## **For CPTU USE ONLY:**

|  |  |
| --- | --- |
| Date for review at CPTU Scientific Committee Meeting: |  |
| Date for review at CPTU Resource Committee Meeting: |  |