Cancer Research UK Prevention Trials Unit (CPTU)
Cancer Prevention Group School of Cancer & Pharmaceutical Sciences
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Director: Professor Peter Sasieni

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
☐	Study/trial design
☐	Statistical design and analysis
☐	Costing (Including SOECAT)
☐	Behavioural science review *(enhancing and supporting participants' choices and behaviors to improve recruitment, retention, treatment adherence, etc.)*
☐	Literature review
☐	Randomisation and unblinding
☐	Pharmacovigilance/Safety Reporting
☐	Coordination of DMC/TSC etc.
☐	Data Management (including data cleaning, monitoring etc.)
☐	Trial/Study management

Resource	Service Component
☐	Statistical reports for DMC
☐	IMP/NIMP/Device Management
☐	SOP development and CRF design
☐	Health Economics
☐	Specimen / Tissue Management
☐	Flagging / passive follow-up
☐	Patient/Public Involvement & Engagement
☐	Study staff recruitment
☐	Information technology (REDCap Database by default): ☐ Initial build ☐ Initial build and hosting ☐ Upgrades (recommended)
☐	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:	