Priment CTU Collaboration Request Form

Please complete the form in as much detail as possible. Questions can be left blank if you are not able to provide answers currently. Please submit the form to priment@ucl.ac.uk.

Study Title:	
Short Title/Acronym	
Disease Area:	Choose an item.
Chief Investigator:	
Person completing this form (if not the CI)	
Position:	
Organisation:	
Email:	
Telephone:	

1. Funding plans and status	
Name of proposed funder:	
Is this a Fellowship Application?	☐ Yes ☐ No
Deadline for submission of funding application:	
Provide a web link to the funding call:	
Type of application:	☐ Outline. ☐ Full. If full, has an outline already been submitted and/or shortlisted ☐ One stage application.
Expected date of application outcome:	
Estimated grant total (if known):	
Is this a new application or a resubmission?	☐ New application. ☐ Resubmission. If a resubmission, please give reasons for previous rejection:

2. Study details	
Anticipated study start date:	
Study duration (months):	
Estimated date of First Patient First Visit (FPFV):	
Duration of recruitment period (months):	
Duration of follow-up period from baseline (months):	
Anticipated number of sites:	UK: International:
How many sites have already confirmed willingness to participate:	
Sample size (if already performed or estimated):	
3. Study setting, design and type	
Study setting:	☐ Primary care ☐ Community care ☐ Secondary care ☐ Other, specify:
Study type:	☐ Non-CTIMP. ☐ CTIMP. ***Please request a copy of the IMP information form (PRM-FRM-001) to complete.*** ☐ Medical device. If device, please give details: ☐ Other. If other, please give details:
Is the CTIMP/device licensed for this disease indication? *(leave blank if not a CTIMP/medical devices trial)*	☐ Yes. ☐ No. If no, please give details
If a medical device trial, who is developing/owns the device? *(leave blank if not a medical devices trial)*	☐UCL/in house ☐Commercial company. If commercial please give details of the company and what support they will provide for the trial:
If a commercial company is developing/owns the device will they want data from the trial for marketing purposes? *(leave blank if not a medical devices trial)*	☐Yes ☐No
Study phase *(tick all that apply)*:	☐ Observational ☐ Feasibility study ☐ Pilot study ☐ Full randomised controlled trial

	☐ Other, specify:
Study design:	☐ Open label ☐ Placebo Controlled ☐ Randomised. *Number of trial arms:* ☐ Blinded ☐ Cross over ☐ Other, specify:
If blinded:	☐ Single blinded. ☐ Double blinded.
Subjects: *(tick all that apply)*	☐ Healthy volunteers ☐ Patients ☐ Patients with poor prognosis/terminal disease ☐ Patients incapable of giving consent personally ☐ Patients in emergency situations (e.g. unconscious) ☐ Children under 5 years of age ☐ Children between 5 -16 years of age ☐ Pregnant or nursing women ☐ Women of child-bearing potential ☐ Other, specify:

4. Please describe your project in terms of PICOS (Patient, Intervention, Control, Outcomes and Study/Statistical design):
P - Patient:
I - Intervention(s):
C - Control:
O - Outcomes and follow up period:
S - Study/Statistical design (e.g. randomised controlled trial, case control study, pilot study)**:**

5. Provide a brief summary of the research question and relevant background information (including patient or subject population/frequency of condition/problem). If you have conducted a feasibility or pilot study to inform a trial, please provide brief details

6. State the aims and objectives of the study. Summarise the principal research questions to be answered
7. Are you planning a pilot or feasibility study?
☐ Yes. If yes, explain how this will lead to the main study: ☐ No.
8. State the co-applicant names and roles. Please provide the names and institution if there are statisticians or health economists already involved.
9. Priment statistical & health economist support
The CTU works with Priment statisticians and health economists to support collaborations. Do you agree to this? ☐ Yes. ☐ No
10. Protocol status
☐ None ☐ Outline (please attach) ☐ Full (please attach) ☐ Consort diagram (please attach)
11. List any other sources of support (drug supply, equipment provision etc.)
12. Proposed Sponsorship for the research:
☐ UCL Sponsorship request ☐ UCL to act as UK Legal Representative (international Sponsor) (CTIMPs only) ☐ Other external Name of external sponsor:
13. Are you working with a Research Support Services (RSS) Hub??
☐ Yes. If yes, please name the RSS Hub: ☐ No.
14. Have you approached any other CTUs regarding this study?
☐ Yes. If yes which ones, what was the feedback and outcome: ☐ No.
15. Have you already approached a Priment member about this study?
☐ Yes. If yes, give details: ☐ No.
16. Has the proposed CI attended a GCP training course?
☐ Yes. ☐ No.

If yes, please provide a copy of the most recent GCP certificate.
17. Briefly describe the clinical trials experience of the Chief Investigator and the current trial team (including collaborators)

Please complete the following information if your proposed study is a CTIMP and/or device trial.

Number of CTIMP/Device trials the proposed CI has been the CI for previously:	☐ 0 (No experience) ☐ <5 (Limited experience) ☐ ≥5 (Experienced)
Number of CTIMPs/Device trials the proposed CI has been a named Principal Investigator for:	☐ 0 (No experience) ☐ <5 (Limited experience) ☐ ≥5 (Experienced)
Where any of these trials multi-centre:	☐ Yes. ☐ No. If yes, please give the number of centres of the largest trial:
Has the CI been involved in a clinical trial of the same phase as the proposed one:	☐ Yes. ☐ No.
1. CI's Experience of IMPs/Device proposed in this trial (where use implies handling, administration and familiarity with IMP/Device safety profile); *add additional rows for each IMP/device*	
1. *[Add Name of IMP/Device]*	☐ No experience ☐ prescribed to <50 patients (limited experience) ☐ prescribed to ≥50 patients (experienced)
Any additional information/comments regarding experience or risk related to IMP, if required:	
2. CI's Experience of Trial Procedures (Complete for study interventions which are HIGH RISK/NOVEL procedures e.g. surgical, non-CE marked device, unlicensed NIMPs); *add additional rows for each trial procedure*	
a. *Does the CI have experience or experienced staff to carry out [insert invasive study assessment (e.g. MRI scan, X-ray etc.) - delete if not applicable]*	☐ No experience ☐ <2 years experience ☐ ≥2 years experience
Any additional information/comments regarding experience or risk related to trial interventions, if required:	

For internal Priment use only	
Priment reference:	
Date of Steering Group meeting:	
Meeting attended by:	
Outcome of meeting:	☐ Accept ☐ Request more information ☐ Request presentation ☐ Decline
Timelines:	
Comments/further details:	
Form completed by:	
Date completed:	