**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](mailto:priment@ucl.ac.uk).

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

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| **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** | |
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| **6. State the aims and objectives of the study. Summarise the principal research questions to be answered** | |
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| **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.** | |
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| **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.) | |
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| **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)** | |
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Please complete the following information if your proposed study is a CTIMP and/or device trial.

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| 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* | |
| 1. *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: |  |

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| **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: |  |