**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.

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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 externalName 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: |  |