INFORMATION ABOUT PRIMENT FOR GRANT APPLICATIONS

1. GENERAL DESCRIPTION

Priment is a UKCRC registered clinical trials unit (registration number 20) with particular expertise in the development and evaluation of interventions in primary care, psychiatric and community settings. Priment receives NIHR CTU support funding.

2. OUTLINE OF PRIMENT STAFF ROLES AND RESPONSIBILITIES:

2.1. TRIALIST

- Provide expertise on trial design, conduct, methodology and evaluation.
- Provide expertise in trial conduct in specific healthcare setting (e.g. primary care, online, mental health services).
- Input into all areas of research proposal, grant application, study protocol and final reports and papers.
- Provide clinical expertise where appropriate.
- Attend Trial Management Group when appropriate.

2.2. SENIOR STATISTICIAN

- Provide expertise in statistical methodology and trial design.
- Design statistical analysis plan (in collaboration with CI and health economist where relevant).
- Supervise trial statistician to conduct analyses and conduct quality assurance processes.
- Input into all areas of research proposal, grant application, study protocol and final reports and papers.

2.3. TRIAL STATISTICIAN

- Conduct statistical analyses under the supervision of the senior statistician.
- Input into the study protocol and final reports and papers.

2.4. HEALTH ECONOMIST

- Provide expertise on health economic evaluations alongside clinical trials and decision analytical models where appropriate.
- Working with the research team (pre and post funding) to develop an economic evaluation analysis plan.
- Attending research team meetings to provide input on the economic evaluation.
- Assisting in development of data collection instruments and case report forms relevant to data required for the economic evaluation.
- Participation in the relevant trial steering group meetings.
- Conducting data analyses in accordance with the economic evaluation analysis plan
- Providing input into reports and publications.
- Oversee the work of the Junior Health Economist

2.5. JUNIOR HEALTH ECONOMIST

- Conduct data analyses under the supervision of the Health Economist.
- Input into the study protocol and final reports and papers.

MEMBERS OF THE OPERATIONAL GROUP:

2.6. TRIAL OPERATIONS MANAGER

- Provide advice and support on trial management, which may include oversight or formal management of trial managers.
- Assist with protocol development and operational delivery.
- Provide information, advice and training on the regulatory requirements, best practice and organisational/CTU standard operating procedures.

2.7. SENIOR DATA MANAGER

- Provide advice and expertise on clinical trial data management.
- Assist with database design, development and testing.
- Work with database providers to ensure the integrity and sustainability of any externally developed systems, including quality checks, SOPs and backup arrangements.
- Assist with design and development of case report form (CRF).
- Training core study team members on database and/or randomisation systems.

2.8. QUALITY CONTROL MONITOR

Provision and/or oversight of trial monitoring activities to oversee trial progress and ensure:

- The rights and well-being of participants are protected.
- The reported study data are complete, accurate and verifiable.
- The study is conducted, recorded and reported in compliance with trial documentation, SOPs and regulatory requirements.

2.9. QUALITY ASSURANCE OFFICER

- Development, implementation and maintenance of systems and processes to provide assurance of study conduct in compliance with trial documentation, organisational/CTU SOPs and regulatory requirements.

2.10. PHARMACOVIGILANCE (PV) Coordinator

- Develop and manage the pharmacovigilance system for the unit.
- Develop and review SOP and associated templates.
- Advise study teams with regards to appropriate trial safety reporting requirements at the trial design stage and while the trial is active.
- Provide training in pharmacovigilance to CTU staff and trial sites as necessary.
- SUSAR unblinding and submission to the regulatory agency.

2.11. CTU ADMINISTRATORS

- Provide Priment costs and letter of support for your application.
- Be a point of contact between the study team and Priment.
- Provide assistance with contracts and agreements post funding.
- Provide access to Priment's SOPs.

3. DATABASE AND RANDOMISATION SERVICE

Priment use an external company to provide a GCP compliant, web based database and randomisation service for the majority of trials. Included in the service is:

- Randomisation set up.
- 24 hour unblinding.
- Database set-up, annual licence, monthly hosting and back-up.
- Standard rules that can be applied to data (e.g. number ranges).
- Some customisations are included such as rules on a particular data field (e.g. calculating a score or checking for a special format on data) and customised blinding (e.g. researcher A can see some parts of the database but not others).
- Trial researchers will be able to collect all data at all the time points.
- Secure log in.
- We include an amount for alterations to the database as from our experience there are changes post the 'go-live' date which cost extra. Any changes that go over this amount will need to be paid for by the trial team.
- Extra services can be added including; further customisations, IMP stock tracking and participant facing website.

4. EXAMPLE ANSWER on CTU Participation

In NIHR application forms section on CTU Participation: "Describe how you have worked with a Clinical Trials Unit in developing your application and what support they will provide if funding is approved"

The CI will work closely with Priment from the early planning stages to ensure the study design and analysis plan are methodologically robust. Priment will provide input and advice on study design and methodology. Priment does not charge for this service.

If funded the CI, the co-applicants and the trial staff will continue to work closely with Priment throughout the trial. The co-applicants include a Priment Trialist, Statistician and Health Economist. Support and expertise in trial methodology, conduct, management, safety reporting and quality assurance monitoring will be provided through the Priment co-applicants and Priment trial operations manager. Priment will advise on trial database development, will develop and implement the statistical and economic analysis plans and will

lead on the health economic and statistical analysis. The Priment team will also contribute to report and paper writing.