Appendix 1 - Keele Clinical Trials Unit (CTU) Collaboration Guide

Keele CTU welcomes collaborative requests.

The following criteria provide a guide about the types of studies that Keele CTU will adopt.

Scope:

- The study requires the services of a CTU (e.g. the study is a randomised controlled trial (RCT) or large clinical, applied research, study involving new data collection)
- The study is a phase III or IV study in design, or is a pilot/feasibility study that is preparing for a future phase III or IV study
- If the study is a Clinical Trial of an Investigational Medicinal Product (CTIMP), then in line with Keele CTU's growing expertise in supporting CTIMPs:
    - Keele CTU is likely to agree in principle to collaborate on type A CTIMPs
    - Keele CTU will consider type B CTIMPs on a case-by-case basis
    - Keele CTU will currently not collaborate on type C CTIMPs
- The study involves UK centres/sites only
- There is evidence of, or plans for, appropriate Patient and Public Involvement and Engagement (PPIE)

Strategic fit:

- Priority will be given to studies that fit with the research of Keele CTU's key Research Institute partners at Keele University (i.e. the Research Institute for Primary Care and Health Sciences and the Research Institute for Applied Clinical Studies)
- The study involves clear collaboration with one or more academic staff from Keele CTU and/or from the Research Institutes and Schools within Keele University

Sponsorship:

- The study fits with Keele University's required sponsorship arrangements

Expertise:

- There is appropriate expertise and experience in the study team to deliver the study

Capacity:

- There is sufficient capacity and resource within the CTU to deliver the study

Funding

- There is sufficient funding available to cover CTU services required