Researchers who plan to engage with the Lancashire Clinical Trials Unit should approach us and apply for our support using the Lancashire CTU request form as early as possible. The Lancashire CTU management team hold fortnightly meetings to consider all requests for support. Therefore, a completed ‘Request for Support’ form should normally be submitted a minimum of 6 weeks before a grant application deadline.

For research calls with shorter deadlines from opening, then please request support as soon as possible. This will enable us to allow adequate time to schedule the review of your application and, if we agree to engage with you, work with you on the development of the grant application (or project protocol for funded projects) and gain the required internal approvals. Request for CTU involvement at short notice, unrelated to the funder timeframes, will likely result in a rejection.

The following criteria will be used when making a decision on which trials the Lancashire CTU engages with:

- **Addresses an important question:** The proposed study must address an important question. For example, “Is there a clinically important difference in self-reported dominant hand pain during activity during the day between patients with rheumatoid or inflammatory arthritis receiving intervention gloves and patients with rheumatoid or inflammatory arthritis receiving placebo gloves, with each type of glove being delivered by clinical rheumatology occupational therapists in addition to usual care?”

- **Identified gap in knowledge:** For example; differences in worldwide nursing practices for a specific aspect of stroke care supports the need for a trial.

- **Appropriate research team:** The project team contains an appropriate skill mix, and the role of the Lancashire Clinical Trials Unit is clearly agreed.

- **Potential to secure funding:** There should be an identified potential source(s) of funding. For example, this may be a commissioned call, or identified priorities for the NHS.

- **Feasible:** The application should be well thought out and timeframes for the development of the protocol and grant application should be realistic.

- **Financially viable:** The minimum expectation is that the Lancashire Clinical Trials Unit will recover the true cost of its engagement in the study - in terms of staff costs and consumables. By costing grant applications at an appropriate level we will ensure the study can be well run. If the costing or available funding is not sufficient for us to be able to add value to the project, we reserve the right to re-evaluate our involvement.
For the majority of trials, Lancashire CTU will expect to run all the functions of the trial. However, it may be possible for us to collaborate on certain aspects. These will be considered on a case-by-case basis. However, in such cases we would expect to have funded in the grant application a minimum of 50% of a Lancashire CTU clinical trials manager and a reasonable proportion (5 or 10%) of a Principal or Senior Trial Manager. Similarly, we would expect the involvement of Lancashire CTU statisticians, typically approximately 5-10% of a senior or principal statistician with support from a junior statistician, the seniority and proportion of which will be driven by the level of design and analysis required. There is an expectation that any staff within Lancashire CTU who meets the criteria for authorship would be co-authors on any published output. For all collaboration requests, involving alternative designs, the level of staff involvement will be considered on a case-by-case basis.

- **Contributes to the Lancashire CTU portfolio:** The Lancashire CTU will assess its engagement in the trial based on whether it contributes to the Lancashire CTU portfolio of high quality, relevant and methodologically excellent studies. The Lancashire CTU will consider each trial on its merits but particular attention will be paid to studies, which are likely to explore methodological advances, add coherence to Lancashire CTU’s research portfolio and enhance the Research Strategy plan of the University of Central Lancashire.

  [http://www.uclan.ac.uk/research/environment/strategy.php](http://www.uclan.ac.uk/research/environment/strategy.php)

- **Communication:**
  - We expect to receive a final draft of any grant application (outline/full/single stage) that is submitted in collaboration with the Lancashire Clinical Trials Unit, before submission and with sufficient time to allow final Lancashire Clinical Trials input and comment (at least 5 working days).
  - We expect to receive a final copy of the submitted grant application for our records within 5 working days of submission.
  - We expect prompt notification of the outcome of the grant application
  - We expect members of the research team and the CI to be in regular communication with involved Lancashire Clinical Trials staff, including the Business and Operations Manager, throughout grant application development, and all relevant aspects of study design and delivery.
  - If any major aspect of the design, (e.g. size or location) changes substantially between initial agreement to collaborate and submission of the bid and/or we have had no communication with the lead investigator regarding this, we reserve the right to re-evaluate the collaborative status of the project.

- **Our pledge:** We will respond to communications and requests for information in a timely manner. We will endeavour to meet the grant deadlines agreed at the time of the initial decision to collaborate. However, should this become unsustainable we will advise investigators accordingly as soon as this becomes clear.
Definitions of Terms within the Lancashire CTU Request for Support Form

**Study design and protocol development:** Provide guidance and advice on studies covering all aspects of the trial, including randomisation strategies, site selection, recruitment strategies, sample sizes.

**Trial Management:** Write or contribute to preparation of protocols, information sheets and informed consent forms, HRA applications and amendments, study guides, case report forms, and any other clinical research related documents; conduct site selection; conduct site initiation; conduct site visits (monitoring) to ensure compliance with study protocol; perform clinical data review; ensure studies are carried out according to the study protocol, SOPs, and ICH/GCP regulations and study-specific manuals and procedures; track and report on progress of study including site activation and patient enrolment; perform site closedown.

**Data Management:** running data reports/ data extraction, input of data, handling data queries

**Information Systems:** Contributing to the database specifications; designing, building and validating the trial database and participant tracker database; performing on-going maintenance of databases.

**Statistical Analysis:** Reviewing trial protocols; provide guidance regarding sample size and randomisation; advice on CRF design and database design, including data coding and data validation checks; write statistical analysis plans; data cleaning and central monitoring; analysis of data sets, and contribute towards writing the final report and other outputs.

**Quality Assurance:** Performing quality assurance of the Trial Management, Data Management, Information Systems and Statistical Analysis functions performed by the CTU to ensure that key quality systems are in place and adhered to throughout the trial.