

## Criteria for securing York Trials Unit collaboration

York Trials Unit (YTU) is a UKCRC fully registered trials unit, which means that we have met certain standards of quality assessment in the design, conduct and analysis of trials. This status is recognised by funding agencies and helps reassure them that any research ran through such a unit will be robust.

Researchers and clinicians who plan to engage with YTU are advised to contact us **as early in the process as possible**. Ideally this should be at least a minimum of **6 weeks** before a research grant deadline. This will enable YTU to provide its experience and knowledge, to give adequate time to schedule the work required and to gain the required University of York approvals. Proposals with very short deadlines will likely result in a rejection. Ongoing discussions or changes to aspects of the planned trial may require longer timescales and a later deadline than initially planned.

The success and reputation of YTU depends on the quality and relevance of the trials we engage with. We aim to work in a collaborative way with investigators in order to ensure that both parties share their expertise most productively. Considerable care is taken when determining which trials YTU can engage with and this is based on the following criteria:

- **Addresses an important question:** The proposed study must address an important question. For example, if the trial is successful, there will be a reasonable expectation of the findings resulting in a worthwhile change in practice or policy.
- **Identified gap in knowledge:** For example; a high quality systematic review supports the need for a trial.
- **Appropriate research team:** The project team has an appropriate skill mix, and there is clear agreement about the role of YTU.
- **Potential to secure funding:** There should be identified potential sources of funding. For example, a commissioned or themed call, or identified priorities for the NHS or other organisation.
- **Feasible:** For example; many trials fail to recruit the required number of participants and so there should be a well thought out strategy for demonstrating that it is feasible to recruit and retain participants. This might include conducting feasibility or pilot work. In addition, timeframes for protocol development and grant application should be realistic.
- **Financially viable:** YTU's involvement in the study must be appropriately financed, with a minimum expectation that YTU recovers the true cost of its engagement in the study - in terms of staff costs and consumables. We seek to cost grant applications at a level that ensures that the study can be run well in accordance with our Standard Operating Procedures and registered status. If the costing is not sufficient for us to be able to add value to the study we reserve the right to re-evaluate the collaborative status of the project.

- **YTU Staff involvement:** For the majority of trials, as well as providing help with the development and design, we oversee randomisation, trial management, data management, analysis and reporting. However, a model is also possible whereby we collaborate on certain aspects and these are 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 YTU trial coordinator and a reasonable proportion (5 or 10%) of a senior researcher. Similarly we would expect the involvement of YTU statisticians, typically approximately 10% of a senior statistician with support from a statistician, the proportion of which will be driven by the level of design and analysis required. As such, there is an expectation that involved YTU staff will be co-authors on any published output. For all collaboration requests involving other methods of research or alternative designs, level of YTU staff involvement will be considered on a case-by case basis.
- **Contributes to the YTU portfolio:** YTU will assess its engagement in the trial based on whether it contributes to the YTU portfolio of high quality, relevant and methodologically excellent studies. YTU 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 YTU's research portfolio** and enhance the **Research Strategy plan of the Department of Health Sciences**.
- **Communication:**
  - We expect to receive a final copy of any grant application (outline/full/single stage) that is submitted in collaboration with YTU, before submission and with sufficient time to allow final YTU input and comment (at least 3 working days).
  - We expect to receive a final copy of responses to referees for any YTU supported grant applications, before submission and with sufficient time to allow final YTU input and comment (at least 3 working days).
  - We expect members of the research team and the PI to be in regular communication with involved YTU staff during all relevant aspects of study design and delivery.
  - If any major aspect of the design, (e.g. size or location) changes substantially between initial YTU 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 YTU's collaborative status of the project.
- **Publication:** There is an expectation that within 12 months of the completion of the main trial analyses that a paper will be submitted to a peer-reviewed journal. If this is not the case, YTU reserve the right to publish the results.
- **Our pledge:** We will attempt 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.

**YTU has a finite capacity. Therefore a key consideration in the decision to collaborate will be whether there is currently sufficient capacity to do so.**