TUF Trials Unit Dragon’s Den Application Guidance

Thank you for your approach to the TUF Trials Unit (TTU).

Please note: Your application may be shared with the relevant BAUS section head (and possibly other experts) for initial comment and review. We may then come back to you to seek clarification on aspects of your application.

The headings below are provided as guidance to the application process. Please send your proposal, using the Application Form, to Louise de Winter at ldewinter@tuf.org.uk

Preliminary Information

Please give some details about yourself and any other proposed applicants or collaborators (name, discipline/speciality, and/or expertise, institution.)

Proposal Outline

1. Title of proposed trial

2. What is your research question?
Your research question should usually identify the intervention to be evaluated, the comparator, main outcome and the relevant population.

3. Why is a trial needed now?
   a) Importance of the health problem
   Please describe the frequency and importance of the health problem in the population and, if possible, its impact on the individual, the health care provider (i.e. the NHS), and wider society.

   b) Summary of the current evidence:
   Please describe any systematic reviews, RCTs, or other relevant studies evaluating the intervention(s) or treatment(s) to be studied. Describe current knowledge and ongoing research.
   How will your proposed research add to what is already known? How will the results of this trial be used?

4. Brief trial description
   a) Population/participants
   Please describe the “population” ie your trial participants - the group for whom you think it is important to evaluate the intervention(s) or treatment(s).

   b) Interventions
   Please describe the intervention(s) or treatment(s) that you wish to compare. Please provide a description of the setting and the health professionals involved? What are the perceived advantages and disadvantages of each? Which, if any, of the interventions or treatments is current practice?
c) Outcomes
What outcomes would you use to measure the effects (benefits and harms) of the intervention(s) or treatment(s) (e.g. quality of life, treatment complications, resource use) and why? At what time points would you measure these outcomes? Which of these outcomes do you consider the most important?

5. Is the trial feasible?
Have you (or a statistician) calculated a sample size for the trial, if so please give details. How will you identify potential trial participants? How many potential participants would you treat in your centre/site? Please give details of any other centres willing to be involved. Do you have any estimates of their potential participant numbers? Please outline any potential barriers to, or problems that you foresee with, either recruiting participants and centres or retaining them within the study.

Are you planning a pilot/feasibility stage? If so, please give brief details.

(NB: Don’t worry if this information is not available at this stage.)

6. What level of support are you seeking from TTU (i.e. randomisation service only or TTU as the supporting Clinical Trials Unit)?

7. Note any other relevant information such as whether ethics may be necessary, whether you have been directed to a particular funding stream/call, etc. Please give brief details.

8. Please send us a maximum of 5 key references for the proposed area of research including a systematic review, if available.

Thank you to the TTU team for the content of this guide.

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