For: Clinical Trial Project Grants

Guidance for detailing your proposed research trial

The outline of your research should not exceed 3500 words.
There is a separate section for references.
We ask that you upload a Gantt chart, and there is a non-mandatory section for additional figure/document uploads.

The following areas should all be incorporated, but not necessarily in the order listed below.

1. **The need for the study and how the research question is relevant to the needs of those affected by stroke**
   - What are the principle research questions the study will address?
   - Why is the study needed?
   - Evidence from the medical literature should be provided, including discussion of the need for the study in light of any systematic reviews that have been completed.
   - Are there any other studies that are currently underway (both nationally and internationally) which are relevant to the proposed study?
   - How will the results of this study be used?

2. **Proposed trial design**

   The adjudication panels have requested that as much detail as possible be given concerning the methodology of the proposed research, including:

- Proposed trial design

  For example, Phase 1/Phase 2 randomised controlled trial (double or single blind).

- Planned trial interventions

  Please give details of both experimental and control interventions. Details should be given of the proposed arrangements for allocating participants to trial groups.

- Sample size

  Control and treatment group sizes should be defined, with a brief description of the power calculations detailing the outcome measures on which group sizes have been based. Event rates, means and medians etc should be included where possible. Justification for the size of difference the study is designed to detect should also be given. Details should include whether the sample size calculation takes into account any loss to follow-up or estimated rate of non-compliance.

- Details of the randomisation method

  If stratification or minimisation are to be used, please give reasons and factors to be included.

- Bias protection

  For example, masking or blinding. If this is not possible, please explain why and give details of any alternative methods proposed, or the implications for the interpretation of the results.

- Planned inclusion/exclusion criteria

  For example, if people with aphasia or cognitive impairment are to be excluded, please provide justification.

- Planned recruitment rate

  Details should be given of how recruitment will be organised and the time period over which recruitment will occur. Please give evidence that the planned recruitment rate is achievable.

- Proposed outcome measures

  The primary and secondary (if applicable) outcome measures, and how they will be measured at follow-up should be defined. Detail should be given of the proposed frequency and duration of follow-up.

- Complex interventions

  Applicants are encouraged to follow the MRC Framework for development and evaluation of RCTs for complex interventions in developing their study available from : http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC003372

- MHRA approval

  Trials involving drugs and also some devices will require MHRA approval.

- Adverse effects

  Applicants should ensure that they have detailed the ways in which they will collate and report adverse effects.

3. Description of the research, its design and methods in the context of previous research/preliminary findings

Please detail how this project has been shaped and influenced by previous research. Please include any relevant data from preliminary or previous studies and a description of how this provides supportive evidence that your proposed study is needed.

Please upload the details/protocol of the main trial if your proposal is for an add-on study in the section below 'Please upload any figures referenced in the project overview.'

4. Predicted outcomes of the research

Please describe what outcomes will be measured in the study.

5. Feasibility and pilot studies

If applicants are applying for a feasibility or pilot study they are required to detail how they propose to undertake the next stage of the research project.

6. Difficulties that can be foreseen and plans for mitigation

Please detail any potential issues that may affect the project and cause the start to be delayed, or affect the smooth progress of the research (e.g. patient recruitment difficulties, access to scanning etc) should be outlined in as much detail as possible. Please outline any mitigation to address such issues. Views from the NIHR Clinical Research Network (NIHR CRN, or equivalent in Scotland, Northern Ireland or Wales) on the feasibility and proposed accrual targets of your study are especially relevant.

7. Team expertise

Applicants should outline the particular contribution each member of the project team will make towards the project. The team should include all the relevant expertise that will enable delivery of the proposed project.

8. Plans to manage and deliver the project

Please detail this. You may refer to a visual aid e.g. a Gantt Chart, but we require specific detail.

9. **Collaboration with NHS research organisations**

   Support in developing studies is available from University Research Support Services, NIHR Research Design Services, UKCRC Registered Clinical Trials Units and devolved stroke research specialties. When preparing their proposal, applicants are encouraged to seek support from these organisations. If a project will involve the use of CRN resources, applicants are encouraged to contact their local research network to discuss support costs, feasibility and recruitment.

10. **Impact of the research**

    Please describe the impact the proposal may potentially have upon research and patient care, or any other impact that the study may have.

11. **Knowledge mobilisation/dissemination plan**

    Please outline how the applicants plan on disseminating the results of the study and outline their knowledge mobilisation plan.