NIHR Research for Patient Benefit (RfPB) Programme
Guidance on Applying for Feasibility Studies

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1. **Definition of feasibility vs. pilot studies**

These definitions have been agreed by the NIHR Efficacy and Mechanism Evaluation (EME), Public Health Research (PHR), Health Technology Assessment (HTA) and Research for Patient Benefit (RfPB) Programmes.

1.1. **Feasibility studies**

Feasibility studies are pieces of research done before a main study in order to answer the question “Can this study be done?”. They are used to estimate important parameters that are needed to design the main study. The design of a feasibility study generally involves listing those parameters which are uncertain and describing the methods for improving their precision so that the main study will have a better chance of success. Examples of such parameters include:

- Standard deviation of the outcome measure, which is needed in some cases to estimate sample size
- Willingness of participants to be randomised
- Willingness of clinicians to recruit participants
- Number of eligible patients, carers or other appropriate participants
- Characteristics of the proposed outcome measure and in some cases feasibility studies might involve designing a suitable outcome measure
- Follow-up rates, response rates to questionnaires, adherence/compliance rates, ICCs in cluster trials, etc.
- Availability of data needed or the usefulness and limitations of a particular database
- Time needed to collect and analyse data

Feasibility studies do not evaluate the outcome of interest; that is left to the main study. Feasibility studies for randomised controlled trials may not themselves be randomised. If a feasibility study is a small randomised controlled trial, it does not necessarily need to have a primary outcome or power calculations. Instead, the sample size is often used to estimate the critical parameters (e.g. recruitment rate) to the necessary degree of precision.

1.2. **Pilot studies**

Pilot studies are a version of the main study that is run in miniature to test whether the components of the main study can work together. It is focused on ensuring that the processes of the main study (e.g. recruitment, randomisation, treatment, and follow-up assessments) all run smoothly. It will therefore resemble the main study in many respects, including an assessment of the primary outcome. In some cases, this will be the first phase of the main study, and data from the pilot phase may contribute to the final analysis; this can be referred to as an internal pilot. Conversely, if at the end of the pilot study, the data is analysed and set aside, this is considered an external pilot.
2. **Feasibility and pilot studies: which NIHR programme should I apply to?**

There are a number of NIHR programmes which will fund feasibility and pilot studies. Applicants must choose the most appropriate programme in the context of the scope and aims for each programme. Some key aspects that should be taken into consideration are below.

**Is the programme appropriate in terms of geography and grant size?**

RfPB funding, for example, can only be accessed through NHS bodies and other providers of NHS services in England and has a maximum grant size of £350,000. Feasibility studies would normally be expected to cost less than £250,000, although well justified exceptions can be taken into account.

**Can a robust case be made for the plausibility of the intervention and clinical importance of any subsequent full trial?**

If there is good proof of concept and/or efficacy data available and there is a clear plan to explore the intervention further in a large clinical trial, then HTA or EME might be considered. The application would be particularly relevant to EME if there are substantial mechanistic elements and laboratory support involved in the project. On the other hand, if the feasibility or pilot study is for a potential trial which might be viewed as more speculative, with no clear plan for a large trial in the very near future, or in which there seems a high risk that the feasibility/pilot study is likely to demonstrate that a full trial is not possible, then RfPB might be seen as more appropriate. The PHR programme also funds feasibility and pilot studies within its remit of evaluating public health interventions delivered outside the NHS.

Note that feasibility and pilot studies should be distinguished from Phase II trials, in which some sort of evidence for efficacy, often in a surrogate marker, is sought prior to embarking on a full Phase III trial. EME might be the most appropriate funding stream for these if there is strong scientific interest in the question. RfPB might be more appropriate if there is a clear potential trajectory to patient benefit.

3. **RfPB policy on funding feasibility and pilot studies**

3.1. **Feasibility studies**

RfPB considers feasibility studies to be good value for money, as they improve the chances of success of more expensive full clinical trials by demonstrating that key elements (such as the ability to recruit patients) are feasible before the full trials are conducted.

Feasibility studies are by nature relatively high risk. This is because the end result may be to confirm that the main study/full trial is not feasible, and even if shown to be feasible, funding for the full trial may ultimately not be obtained. RfPB does fund full randomised controlled
trials, although it is recognised that these may not be feasible within the maximum available funding of £350,000. We continue to work with other NIHR programmes to better integrate RfPB funding for feasibility studies with opportunities to obtain funding for the follow on full trial.

Given the risks associated with feasibility studies, it is expected that they will cost less than £250,000. Costs higher than this will need to be fully justified.

Phase II trials are occasionally submitted to RfPB. These are usually fully powered randomised designs, but involving a ‘surrogate’ endpoint rather than a clinically or patient significant one. Such trials are sometimes funded as they can provide an important step towards a full pragmatic trial. They are, however, that much further removed from patient benefit and are likely to be seen as having lower priority compared with a trial powered on a clinically important endpoint.

It should be noted that an underpowered ‘exploratory trial’ is not the same as a feasibility study and is unlikely to be funded through RfPB.

3.2. Pilot studies
A pilot study is the full trial in miniature and the data can often be incorporated into the data collected in the full trial. Pilot trials are therefore usually funded as part of the phased development of a full trial. In effect, they offer the researchers and funders a stopping point should the trial not prove viable. It is therefore unlikely that RfPB would fund a pilot trial, as continuation would involve a separate application to another funder.

4. **Guidance on applying to RfPB for a feasibility or pilot study**

The research plan for a feasibility study should contain a brief outline of the proposed follow on full trial, a list of the key ‘uncertain’ parameters that are needed to design the full trial, and a list of clear progression criteria to the full trial.

4.1. Outline of the proposed follow-on full trial
Some of these details will depend on the results of the proposed feasibility study, but the research plan should briefly describe, as much as possible, the key elements of the full clinical trial. This might include, if known, whether it will be an individual patient randomised or cluster trial, the number of arms, the inclusion criteria, the nature of the intervention and of the comparator in the control group, the primary endpoint, and the possible range of clinical sites from which patients would be recruited.

4.2. Key parameters which the feasibility study intends to clarify or estimate
The research plan should describe which parameters are to be estimated and how these will be investigated. These parameters may include:
● The number of eligible patients, carers or other appropriate participants
● An exploration of different methods of identifying/recruiting patients
● The willingness of clinicians to recruit and randomise participants
● The willingness of participants to be randomised
● The practicality of delivering the intervention(s) in the proposed setting(s)
● Variation in use or delivery of the intervention in each setting
● Acceptability of the intervention to the users
● Standard deviation of the outcome measure, which is needed in some cases to estimate sample size
● Follow-up rates, response rates to questionnaires, adherence/compliance rates, ICCs in cluster trials, etc.
● Availability of data needed or the usefulness and limitations of a particular database
● The time needed to collect and analyse data
● An exploration of the opportunities for Patient and Public Involvement (PPI) in the research design and its subsequent conduct

The following does not necessarily need to be included in the research plan:

● A randomised design: the design will be determined by how it is proposed to reduce the uncertainty in the parameters described above
● An evaluation of the outcome of interest: that is left to the main study
● A primary outcome: if a feasibility study involves carrying out a small randomised controlled trial it is for the purpose of evaluating/testing trial processes not the intervention
● The usual sort of power calculation: the sample size should be adequate to estimate the critical parameters (e.g. recruitment rate) to the necessary degree of precision

4.3. Progression criteria to a full trial

As part of their assessments, RfPB panels consider the likelihood of a feasibility study progressing to a full trial. Therefore, a clear route of progression criteria to the full trial should be included in the research plan, whether the proposal describes just the feasibility/pilot study, or both the feasibility/pilot study and the full trial together. Applicants are expected to identify the funder of the subsequent full trial and the anticipated timeframe expected to progress to the full trial. To encourage faster progression of feasibility studies into full trials, applicants are expected to include writing the proposal for the full trial, if shown to be feasible, within the timeframe of the RfPB feasibility study.

4.4. Further information

Please see below for further information on best practice in designing and conducting feasibility and pilot studies.
