

Conducting Feasibility Reviews

As the NIHR implements performance management strategies to ensure the delivery of quality research in the UK, it is becoming increasingly important to ensure that KCH supports the studies that are most feasible and able to deliver proposed outcomes. Aside from the risk of financial penalties from NIHR and grant awarding bodies for failure to deliver on approved research, there is the wider moral and ethical issue of funding and conducting studies that prove unfeasible in practice, fail to recruit sufficient numbers of participants, wasting public sector resources as well as participants' time, and even possibly creating risks to participants' safety.

While they do not guarantee success, conducting feasibility assessments can help to ensure that studies are well designed and likely to deliver to time and to target. KCH is committed to maximising the efficiency and impact of research in the Trust and therefore requires the conduct of feasibility assessments prior to research submission

What is the feasibility review?

The concept of feasibility review is to confirm to the Trust that the project can be delivered as described. The review considers the tasks and activities described within the protocol, and how they relate to and impact upon the Trust, department, and available resources. Areas of consideration include, but are not limited to: the available patient population and how it supports the recruitment target, ability to meet the trial timeline, ability to conduct study procedures as described, staff time, resource implications where other departments are involved, source of funding, applicable regulations, and the experience of the Investigator.

When is it required?

Any project that will be conducted within the Trust that will make impact on resources, and involve patient or staff groups, will need to be assessed for feasibility.

- **Grant applications** – work that will be performed within the Trust at a future date needs to be assessed to ensure that the application, if successful, can be conducted as described.
- **Sponsorship** – the responsibilities of the Sponsor, as defined by NRES, requires the Sponsor representative to confirm that the project is indeed feasible as described before authorising the REC submission.
- **Making a submission to R&D** – required before a submission is accepted, to ensure that the design and conduct of the study can be accommodated internally, and that the right resources are available.
- **Extending to another location** - PRUH, DH and Orpington have different set ups and resource implications, and require a feasibility assessment at each location.

How is the feasibility review handled at KCH?

It is important that every project undertaken within the Trust is confirmed to be feasible before a submission for Trust governance approval is made. The review is at a local level using a Trust approved standard format.

The study team complete the Feasibility review template and present at their local Research Governance meeting, or discuss with the R&D Lead directly if no meeting exists. If the R&D lead is also the PI, and no local governance meeting exists, feasibility should be confirmed by the Clinical Director. A project may undergo more than 1 review if determined not to be feasible at the time of presentation.

All clinical and non-clinical activities, and so resource implications for the proposed study, must be identified, indicating what is to be done, how, who by, and where, and how long each activity or task is expected to take. It is important to identify the funding source to ensure that all costs are covered.

Each project and department will have general and specific requirements making no two projects the same, and so the feasibility review must be conducted on a case by case basis for all grants and projects that will be conducted within the Trust, be they sponsored internally or externally. Departments will have additional requirements for feasibility that may not be included within the Trust template, or arise during the conversation with the Investigator. Specific details will be expected to be addressed within department governance meetings when the project is discussed and be fully minuted and/or added to the feasibility review document.

Outcome of the review will be confirmation of feasibility, at which the study team can progress with their submission, and be expected to plan for recruitment readiness in order to meet with national 70 day metric. Guidance on activities that can be conducted in advance of approval is available.

How do I organise a feasibility review?

The Feasibility review form can be downloaded from the KCH website.

Please contact the Research Office, as soon as possible if you have not already done so as part of your grant application or project submission, to prevent delays with your submission.