Developing a Protocol

University Hospitals Bristol NHS Foundation Trust

Clinical Trials Units

Where possible studies should be run through a Clinical Trials Unit.
Having identified an appropriate unit early discussions on what support can be offered is advised.

Potential Funders

Identify potential sources of funding early.

For those expecting to apply for NIHR funding streams additional support is available from RDInfo.

Sponsor

Your sponsor will take responsibility for your study and will require input to your protocol on matters such as indemnity. The sponsor has responsibility for the quality of your protocol, financial arrangements and management of your study. You should identify a potential sponsor early in the process.

Partners

Non-NHS institutions may be involved, for example, if you are a University employee your employer will need to be kept informed.

Service Users/Public

Is there a need for this study?

Involve service users and other members of the public in order to gauge the relevance and practicality of the proposal.

Innovation

Is there potential for intellectual property?
If so, contact the Innovation Manager
before discussing with others.

Is this study 'research'?

Not all studies using research methodologies are considered research under the Research Governance Framework.

Protocol Development

Discuss your ideas with those involved and ensure the feasibility, quality and appropriateness of what you propose before spending too much time on it.

Write your protocol

Your protocol should be detailed enough to enable scientific review, risk assessment and identification of resource use to be carried out.

It should also incorporate any requirements of your sponsor.

Patient information sheets etc form part of the protocol.

Guidance on writing a protocol is available here.

Protocol requirements for UH Bristol sponsored studies

are available on Guidance sheets 3a and 3b.

Support Departments

If your study requires input from others e.g. pharmacy, lab medicine, radiology/radiation protection discuss feasibility and practicality with them at an early stage.

Colleagues

Whether directly or indirectly involved, colleagues will understand the local population and conditions and may be able to offer helpful advice.

Research Design Service (RDS)

Working mainly with projects expected to be funded by the NIHR, the RDS can help you develop a clear and robust study design, give statistical advice and help with preparing applications to funders.

Research and Innovation

The Research and Innovation team can advise on whether the Trust is a suitable host and/or sponsor and whether the study is research.

Finance

If you are intending to apply for funding contact finance early to have your study costed to ensure it is feasible within the funding limit.

Other sites

Consider what other sites you may wish to involve and make contacts at these sites.