Berkshire Healthcare
NHS Foundation Trust

# Guidance for researchers

## Research and Development (R&D)

We're happy to hear from clinicians and other staff that are interested in conducting a research study, and can help with advice and guidance on shaping your study.
If you are thinking of conducting a research study as part of your role then please read the information below to help get you started.

This is a brief overview of the processes involved in conducting a research study with us. important to remember that if you are thinking of conducting a research study within Berkshire Healthcare then it must be approved by Research and Development (R&D).

You should contact us early in the process so that we can guide you.

### Do you have a research question in mind?

A research question is a clear and concise statement about the objectives of the research and exactly what it is you wish to examine. It is the first step in designing your research protocol. Research questions can arise from many sources including your day to day practice, the scientific literature, and/or ideas about improvements or innovations within your service.

Consider these points when formulating your research question:

- What exactly are you trying to find out
- Will your proposed research achieve this
- What method should you use to conduct the research
- Is there a good scientific or clinical basis for the study

#### Resources

NIHR Research Design Service website

**Website** rds-london.nihr.ac.uk/resources/developing-a-research-question-2

Centre for Evidence Based Medicine (CEBM) website

**Website** cebm.net

Clinical Research Network

**Website** nihr.ac.uk/

## Have you considered how you are going to conduct the study?

There are several aspects you need to consider such as:

- Who will be included in your study population
- What equipment you might need
- Whose permission you might need within your clinical service area
- How much will your study cost
- Who will conduct the study

If you are having difficulty with this aspect of your study, you can ask us for guidance. Alternatively, the NIHR have a very good set of resources for helping you consider these aspects on their Research Design Service

Website rds-london.nihr.ac.uk/resources/

## Who will fund your study?

There are different costs to consider such as research costs, support costs, and treatment costs. There are a wide range of sources of research funding available and it is essential that you have costed your project accurately before making a funding application.

Funding may come from commercial funders, government departments, research councils, charities, the National Institute of Health Research, universities, or elsewhere.
The source of your funding is a critical criterion if you intend to apply for your study to be adopted onto the NIHR portfolio of studies.

If you need further advice regarding how to find funding or grants for your study and / or how to accurately cost your research study, then please contact our R&D team.

## Finding a sponsor

A sponsor is an organisation (or group of organisations) which accepts responsibility for ensuring there are proper arrangements to initiate, manage, monitor and finance a study.

The UK Policy Framework for Health and Social care Research requires that all research taking place in an NHS or social care context must have a sponsor.

## What kind of study are you proposing?

All research within the NHS needs to meet a series of regulatory approvals and these are dependent upon what kind of research you are conducting. Some research is classified as a research study and some may be classified as a service evaluation or an audit.

The Health Research Authority have devised an online tool on their website to help you figure out which classification your study falls under.

Website hra-decisiontools.org.uk/research/

## Portfolio adoption

We encourage all researchers to apply for National Institute of Health Research (NIHR) portfolio adoption where appropriate. There are a number of criteria that must be met for a research study to be adopted onto the portfolio, including:

- Declaring the source of your research funding
- If funding is awarded in open competition
- If the study has received a peer review
- If the research is of value to the NHS and fits within the needs and realities of the NHS

Visit the NIHR website for more information about how your study can be adopted onto the portfolio

Website nihr.ac.uk/

## Health Research Authority Approvals (HRA), Research Development, and Ethical Approvals

Any researcher wishing to carry out a study with us must obtain HRA approval for their study. Which approvals you may need may vary dependent upon what kind of study you are conducting. In general, any study that qualifies as research using the HRA tool above will require an application for HRA approval.

Visit the Health Research Authority (HRA) website for more details

Website hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/

All studies must be submitted to HRA and NHS Ethics approval before any research involving NHS patients, staff, data or facilities takes place.

It is the responsibility of the Chief Investigator for the study to apply for HRA and NHS Ethics approval through the Integrated Research Application System (IRAS).

To get your study adopted onto NIHR Portfolio you will need to complete a portfolio adoption form (PAF) during your IRAS application.

If you have any questions about this process, please contact our Research and Development Department for further guidance.

Once you have obtained HRA & Ethics approval you will then need to register your study with the Berkshire Healthcare Research and Development Department (R&D) for Trust approval. Research activities cannot begin until you have a confirmation letter from our R&D Department.

### Student Research

Studies undertaken for the purpose of obtaining an educational qualification should be approached in the same way as other studies taking place in the NHS.
HRA Approval should be sought for any educational study led from England that:

- requires review by an NHS Research Ethics Committee (REC)
- is taking place across more than one NHS organisation
- is applying for support from the NIHR Clinical Research Network website

Website hra.nhs.uk/planning-and-improving-research/research-planning/student-research/

## Indemnity and insurance

It is the sponsor's responsibility to make sure indemnity and insurance arrangements are in place to protect participants in a research study.

For research sponsored by Berkshire Healthcare, the NHS Clinical Negligence Scheme applies. This provides unlimited cover for NHS staff, medical academic staff with honorary contracts, and those conducting research against negligent harm.

Non-negligent harm (i.e. harm that has been caused through no fault of those conducting research) is not covered by this scheme.

For research sponsored by commercial companies, the arrangements for indemnity and insurance are covered in the agreement that R&D negotiates with the company.

## The documents you need to submit when registering your study with Berkshire Healthcare

To obtain your approval for research with us, you will need to provide all relevant documentation. The Sponsor/ Chief Investigator is expected to send the following document package to R&D.

We appreciate you may not have all these documents immediately, so please contact us as early as possible in the registration process to discuss your project.

### Study set up documents

- A copy of the HRA Initial Assessment letter (if one is issued) and the HRA Approval letter (when issued) as well as the final document versions.
- The HRA REC Approval letter (if study involves patients/carers as participants)
- Evidence of Sponsor insurance or indemnity (non-NHS Sponsors only).
- A copy of the research protocol or project proposal [Research Protocol]
- A copy of the IRAS Form (combined REC and R&D form) as submitted for HRA Approval
- Any amendments (if relevant)
- The relevant template contract/model agreement (if needed).
- A costing template (commercially sponsored only) or Schedule of Events (non-commercially sponsored only)
- A summary CV for the Chief Investigator (CI) [CI Brief CV]
- A summary CV for the supervisor & student (for student research)

## Find out more

Contact our team, or visit our website to find out more about our studies and how to work with us.


Email research@berkshire.nhs.uk

Call 0118 378 5264

Website berkshirehealthcare.nhs.uk/RD