TOP TIPS

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Seeking ethical approval

Obtaining necessary ethical approvals for research is essential, regardless of how large or small the project.

Ethical considerations are an important principle in research to ensure patients and participants are cared for appropriately. Research involving NHS patients or carers requires NHS ethics committee, Health Research Authority (in England) and organisational approval. Research involving NHS staff or other participants also requires organisational approvals.

This leaflet provides top ten tips about ethical approval to help plan and conduct research.

Tip 1 Studies not requiring ethical approval

Some studies may not require ethical approval. For example, clinical audits or service evaluations, designed to answer the question "what standard does this service achieve"?

Evaluations are still likely to require local registration and approval. It is essential to check with your organisation's research office for further advice and gain necessary permissions.

Tip 2 Acquiring ethical approval

All clinical research requires a sponsoring organisation and research approval.

Research that typically requires NHS ethics committee approval includes: randomised controlled trials and other clinical studies, investigation of medical devices, studies with tissue samples or analysis of tissue data, questionnaires or interviews with patients and/or carers, and studies involving identifiable patient data

Tip 3 Planning

Studies needing ethical approval require a chief/principal investigator and sponsor, often the host university/Trust. The study protocol should be underpinned by a thorough review of the literature. Key components are: summary, background, aim, objectives, design, methods, analysis, perceived benefits, and resources. Patient and public involvement is key to ensure design and participant information is appropriate.

Tip 4 Participant information sheet

This should provide information about taking part in a research study, written for a lay audience. It includes title, invitation, summary of the study, what participation may involve, possible benefits to the individual, disadvantages and potential risks, expenses, who to contact with queries, and study contact details.
This allows the individual to make an informed decision about taking part.

Tip 5 Consent form

This typically contains study title and name of study investigator, plus statements that the participant has read and understood the participant information sheet, knows their participation is voluntary, their records may be viewed by study staff, General Practitioners may be notified and they can withdraw at any time. Researcher and participant will both sign/date/ retain copies.

Tip 6 General Practice (GP) letter

Not every study warrants informing the GP of the participant's involvement. However, where studies involve pharmacological interventions or medical interventions that could potentially impact on other aspects of health, it is important the GP is aware their patient has been recruited to the study.

If the study may affect patient care, then the GP should be informed as a courtesy.

Tip 7 Health Research Authority (HRA)

HRA approval checks documentation is complete, and is granted separately, once ethical approval is obtained – as a parallel process, via http://www.hra.nhs.uk/

HRA approval is required for studies involving staff or healthy volunteers on more than one site, and possibly for single-site studies also, please liaise with your Trust research office. Approval can be sought by completing an IRAS form.

Tip 8 Integrated Research Application System (IRAS)

IRAS is the online ethics application system for health and social care research in the UK. Applicants need an account on this system to apply for ethical approval, at myresearchproject. org.uk. Guidance is available online. Health Research Authority approval will also be needed, using similar forms, often including when NHS ethics committee approval is not required.

Tip 9 Amendments to on-going research

During the conduct of your research, it is mandatory that you maintain a site file containing all study documentation, and provide progress reports as required.

It is mandatory to apply to the ethics committee, and your Trust research office, should you wish to make any amendments to your study, or for safety information and adverse event incident reports.

Tip 10 End of study

At the end of your research study it will be necessary to notify the sponsor, NHS Trust(s) and review boards that your study has ended. You must provide final reports as required, arrange archiving of your study data for monitoring, ensure close- down of the

recruiting site(s), provide information on results to participants as agreed and present/publish your results.

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