

Fact sheet 13: Ethical considerations in research and evaluation.

This fact sheet aims to give you information about:

- Ethical considerations when carrying out research, evaluation or audit.
- Guidance on when ethical approval may be required
- Information about and a link to National Research Ethics Service (NRES)

It will also provide links to other useful fact sheets and documents that relate to ethics in research and evaluation.

4. Ethical considerations

Research

National Research Ethics Service guidelines dictate that research projects require ethical review. For example, research in the NHS or other health setting (e.g. provided by voluntary/community sector) requires review by a Research Ethics Committee, which seeks to:

- Protect the dignity, rights, safety and wellbeing of participants, patients and staff involved;
- Ensure confidentiality and data storage meets the requirements of Research Governance Framework;
- Consider any disturbance to patients/staff that may result; and
- Enable research that is of benefit to society and that will increase knowledge or provide new knowledge and best practice.

Ethical considerations are particularly important where a new service, intervention or approach is being trialed with participants who may have ordinarily been offered an alternative service.

The reason ethical approval must be given for research projects is to ensure that the rights, safety and wellbeing of those participating in it are taken into account and protected. The ethical approval process is there to ensure no harm, distress or adverse effects are caused to participants as a result of taking part in research. If you are designing a research project that involves human participation you will need to consider ethical issues.

Evaluation

Unlike research, the purpose of evaluation is not to generate new, generalisable knowledge. Generally, because nothing new is being done to participants beyond what they might expect as routine care/service provision, evaluations do not usually involve additional risk (e.g. of intrusion, clinical safety) and therefore do not require the same level of ethical scrutiny as research projects. Research projects may involve greater risk, burden or intrusion for participants, however, it is felt that there is usually minimal disruption when undertaking an audit or service evaluation and as the purpose is usually to monitor or review clinical practice and/or performance management and make improvements, there is generally less cost to human participants involved. As such, service evaluations do not require ethical review under the terms of the National Research Ethics Service guidelines.

For this reason it is very important to be aware of the differences between research and evaluation and what your study or project is defined as. However, it can be difficult to distinguish some types of evaluation from research. Both research and evaluation involve addressing clearly defined questions using systematic and rigorous methods. Evaluation may include elements of research e.g. collecting additional data or changes to choices of treatment, and both research and evaluation may:

- provide cost and/or benefit information on a service;
- use quantitative and qualitative data to explore activities and issues; and
- identify strengths and weaknesses of services.

The key difference is that research seeks to derive new knowledge and test hypotheses beyond what could be considered an expected level of care/service, where evaluation seeks to assess the actual level of care/service delivered. For example, a research project might seek to establish what added benefit results from the introduction of a new way of care or new service not previously tried. An evaluation might seek to assess users experience of existing available care and identify ways in which it could be improved.

Despite all of this, it is still very important that all evaluation is conducted to the highest ethical standards, including due care and attention paid to data protection, health and safety and informed consent for participants. It is important to consider any disturbance to patients/staff that may result from your project and how great any impact on participants will be. Furthermore, there are occasions when audit or service evaluation may require ethical approval, particularly if the service involved relates to vulnerable groups.

Audit

Audits do not usually require review and approval by a Research Ethics Committee. They measure the extent to which accepted standards of care are being met and therefore, as above, do not involve additional risk to any users or staff. In fact, audits should not involve any interruption or disruption of usual practice if they are to be effectively performed.



More on this topic and further reading

Ethical approval:

National Research Ethics Service website: <http://www.nres.nhs.uk/>

See '[Defining Research](#)' leaflet on the National Research Ethics Service website.

NHS Research and Development Forum (2006) [Categorising research within the Research Governance Framework for Health and Social Care](#). Version 2, July 2006.
http://www.rdforum.nhs.uk/docs/categorising_projects_guidance.doc

See [Fact sheet 4: What is the difference between research, evaluation and audit?](#)