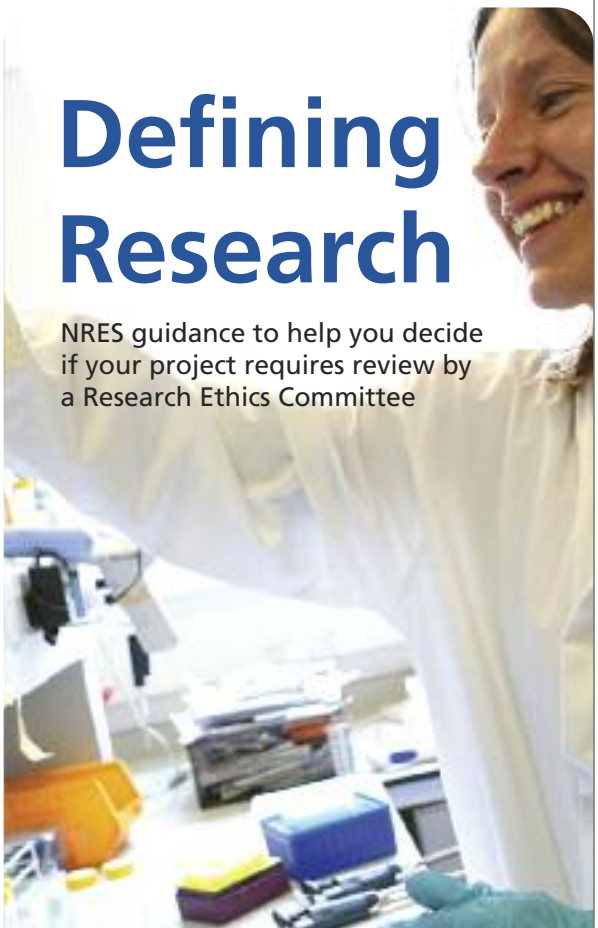
NHS

National Patient Safety Agency

National Research Ethics Service

Defining Research

NRES guidance to help you decide if your project requires review by a Research Ethics Committee



National Research Ethics Service

The National Research Ethics Service (NRES) reviews research proposals to protect the rights and safety of research participants and enables ethical research which is of potential benefit to science and society.

Defining research – guidance from NRES

The purpose of this leaflet is to help you decide if a project is research, which normally requires review by a Research Ethics Committee (REC), or whether it is some other activity such as audit, service evaluation or public health surveillance.

Patients expect health professionals to undertake audit and service evaluation as part of quality assurance. These involve minimal additional risk, burden or intrusion for participants, and are regulated outside of NRES.

Research may involve greater risk, burden or intrusion for participants than standard clinical practice. It may generate conflicts of interest for the researcher, which will require review by an ethics committee. With some exceptions, research requires review by a REC.

The table in this leaflet helps to confirm if your activity is research, audit, service evaluation or public health surveillance.

When is an NHS REC review required?

Review by an NHS REC is required for research within the scope of the UK Health Departments' Governance Arrangements for Research Ethics Committees available at **www.dh.gov.uk/en/Publicationsandstatistics/Publications/DH_4005727**

In addition, some legislation, such as the Clinical Trials Regulations, Human Tissue Act and Mental Capacity Act, requires ethical approval from an appropriately recognised REC whether or not the research takes place within the NHS.

Guidance on whether research requires ethical review under either the law or the policy of the UK Health Departments' can be found on the NRES website at **www.nres.npsa.nhs.uk/applications/apply**

If your project will be taking place within the NHS, your local research and development (R&D) office will be able to advise on whether the project is research and requires management within the Research Governance Framework for Health and Social Care. They will also confirm if ethical review by a REC is required, and advise on local governance procedures for other types of project such as audit or service evaluation.

If you remain uncertain after reading this leaflet, you should approach your R&D office for advice in the first instance. If further clarification is then required, the R&D office can obtain this from the chair of a REC or the NRES queries line.

queries@nres.npsa.nhs.uk

Key discriminants are:

1. Intent

The primary aim of research is to derive generalizable new knowledge, whereas the aim of audit and service evaluation projects is to measure standards of care. Research is to find out what you should be doing; audit is to find out if you are doing planned activity and assesses whether it is working.

Some projects may have more than one intent, in which case a judgement will need to be made on the primary aim of the project.

2. Treatment/service

Neither audit nor service evaluation uses an intervention without a firm basis of support in the clinical or health community.

3. Allocation

Neither audit nor service evaluation allocate treatment or service by protocol. It is a joint decision by the clinician and patient.

4. Randomisation

If randomisation is used, it is research.

Differentiating clinical audit, service evaluation, research and usual practice/surveillance work in public health

RESEARCH	SERVICE EVALUATION*	CLINICAL AUDIT	SURVEILLANCE	USUAL PRACTICE (in public health)
The attempt to derive generalizable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them.	Designed and conducted solely to define or judge current care.	Designed and conducted to produce information to inform delivery of best care.	Designed to manage outbreak and help the public by identifying and understanding risks associated.	Designed to investigate outbreak or incident to help in disease control and prevention.
Quantitative research – designed to test a hypothesis. Qualitative research – identifies/explores themes following established methodology.	Designed to answer: "What standard does this service achieve?"	Designed to answer: "Does this service reach a predetermined standard?"	Designed to answer: "What is the cause of this outbreak?"	Designed to answer: "What is the cause of this outbreak?" and treat.
Addresses clearly defined questions, aims and objectives.	Measures current service without reference to a standard.	Measures against a standard.	Systematic, statistical methods to allow timely public health action.	Systematic, statistical methods may be used.
Quantitative research – may involve evaluating or comparing interventions, particularly new ones. Qualitative research – usually involves studying how interventions and relationships are experienced.	Involves an intervention in use only. The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.	Involves an intervention in use only. The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.	May involve collecting personal data and samples with the intent to manage the incident.	Any choice of treatment is based on clinical best evidence or professional consensus.
Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care.	Usually involves analysis of existing data but may include administration of interview or questionnaire.	Usually involves analysis of existing data but may include administration of simple interview or questionnaire.	May involve analysis of existing data or administration of interview or questionnaire to those exposed.	May involve administration of interview or questionnaire to those exposed.
Quantitative research – study design may involve allocating patients to intervention groups. Qualitative research – uses a clearly defined sampling framework underpinned by conceptual or theoretical justifications.	No allocation to intervention: the health professional and patient have chosen intervention before service evaluation.	No allocation to intervention: the health professional and patient have chosen intervention before audit.	Does not involve an intervention.	May involve allocation to control group to assess risk and identify source of incident but treatment unaffected.
May involve randomisation.	No randomisation.	No randomisation.	No randomisation.	May involve randomisation but not for treatment.
Normally requires REC review. Refer to www.nres.npsa.nhs.uk/applications/apply/ for more information.	Does not require REC review.	Does not require REC review.	Does not require REC review.	Does not require REC review.

* Service development and quality improvement may fall into this category.

Useful references

Casserat D, Karlawish JH, Sugarman J. Determining when Quality Improvement Initiatives should be considered research. *JAMA*. 2000; 283: 2275-80.

National Health and Medical Research Council (NHMRC). *When Does Quality Assurance in Health Care Require Independent Ethical Review?* Canberra: National Health and Medical Research Council. (2003).

Smith R. Audit and Research. *BMJ*. 1992; 305: 905. Available at: **www.bmj.com**

Wade D. *Ethics audit and all shades of grey*. *BMJ*. 2005; 330: 468. Available at: **www.bmj.com**

The National Ethics Advisory Committee (NEAC). *Ethical Review of Observational Research, Audit and Related Activities.* (2003). Available at: **www.neac.health.govt.nz**

More detailed guidance on categorising projects is also available on the website of the NHS R&D Forum at: **www.rdforum.nhs.uk/docs/categorising_projects_guidance.doc**

The National Research Ethics Service can provide further help:

Contact your local REC:
www.nres.npsa.nhs.uk/contacts/find-your-local-rec
Email the queries line: **queries@nres.npsa.nhs.uk**

If your study is taking place in the social care setting the national social care REC can provide further help. Visit: **www.screc.org.uk**

Contact details:

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National Patient Safety Agency
4 – 8 Maple Street
London W1T 5HD

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