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The UK Health Department's Research Ethics Service 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.

Seeking research to guidance from the Research Ethics Service

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, such, 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 burden or research for participants, and are regulated as standard clinical practice outside of the Research Ethics Service.

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 leaflet is available in large print to confirm if your activity is research, audit, service evaluation or public health surveillance.

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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.gov.uk/government/publications/health-research-ethics-committees-governance-arrangements

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 HRA website at <http://www.hra.nhs.uk/resources/before-you-apply/is-nhs-rec-review-required/>

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 HRA Queries Line. hra.queries@nhs.net



Key discriminants are:



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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)
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The attempt to derive

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

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Useful references

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

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 Guidelines for Observational Studies: Observational Research, Audits and Related Activities. (2012). Available at: <http://neac.health.govt.nz/publications-and-resources/neac-publications>

More detailed guidance on categorising projects is also available on the website of the NHS R&D Forum at: <http://www.rdforum.nhs.uk/content/resources/#Deciding>

The Research Ethics Service can provide further help :

Contact your local REC: <http://www.hra.nhs.uk/news/rec/>

Email the queries line: hra.queries@nhs.net

If your study is taking place in the social care setting the national social care REC can provide further help. Visit: <http://www.hra.nhs.uk/news/rec/national-social-care-research-ethics-committee/>

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Contact details:

Health Research Authority
Skipton House
80 London Road
London SE1 6LH

HRA main line: 020 797 22545

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