



Research and Development Forum

**Notes on developing procedures within NHS organisations
for appropriate authorisation and management of research
and related projects**

www.rdforum.nhs.uk

All research involving NHS patients, staff or resources must be assessed by a research ethics committee. Furthermore, to comply with the Department of Health's Research Governance Framework research activities must be formally approved by Trust management; accountability for all research activity resides with the Chief Executive. Seeking Trust and Ethics Committee approval can be a relatively time consuming process regardless of the nature of the research proposed.

Many other activities are not research even though they use similar methodologies. In that case, they do not require assessment by a research ethics committee or formal approval within the Research Governance Framework. The Research Governance Framework describes research in terms of generating new knowledge by systematic and rigorous methods; but in practice the boundaries between research and other activities may not always be clear. The other activities include: clinical audit, local developments of existing research, introducing clinical innovations, service evaluations, patient or staff surveys, and quality assurance programmes.

The additional administrative burden associated with the research governance process in particular is often seen as a deterrent; especially to small-scale studies that do not involve patients. There may also be a reluctance to declare some of the activity that lies in the grey areas. This potentially opens the NHS organisation to risk and undermines the effectiveness of clinical and research governance.

We recommend NHS organisations adopt a systematic approach to deciding how borderline activities should be dealt with. The aim is an integrated set of processes for managing risk, which encourage greater openness about these activities, and build up a consistent case-law on which to base future decisions rather than rely on ad hoc responses.

NHS organisations should set up a process for reviewing proposals that do not clearly fall into a category, in collaboration with other relevant departments, e.g. clinical governance. This need not involve creating new committees. For example, someone with the right experience could be responsible for deciding whether a proposal is to be treated as research, and/or whether other governance systems apply to it. A time limit for the outcome of the review should be agreed. The attached guidance document on categorising projects may be of help in the review process.

The review process should clearly indicate what approval, authorisation or registration process is required for each category of project. All decisions should be recorded and confirmed in writing. For multicentre projects it is important that collaborating centres agree on a consistent approach. This could be coordinated by the "lead" NHS organisation which could make its decision available to the coordinating centres.

The review process should be linked with the organisation's policies for authorising research and handling misconduct in research.

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Categorising research within the Research Governance Framework for Health and Social Care

July 2006

Background

This guidance has been collated by the NHS Research and Development Forum as an aid to researchers and NHS R&D staff in determining what projects should be managed in accordance with the Research Governance Framework in NHS organisations. The guidance has been developed following consultation with researchers, R&D managers, Clinical Effectiveness and Audit staff, and R&D Support Unit staff.

“1.10 Research can be defined as the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods. This document sets out the responsibilities and standards that apply to work managed within the formal research context. Other documents on quality and governance in the NHS and social care set out standards and systems for assuring the quality of innovative work in non-research contexts.”

Research Governance Framework for Health and Social Care, Second edition, 2005
http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4108962&chk=Wde1Tv

It is clear from the above extract from the Framework that although the NHS has a responsibility for assuring the quality of all work undertaken within the service, not all innovative work should be defined and managed as research. The increasing amount of evaluation, practice development, audit and research within the NHS has resulted in a number of grey areas where it is not easy to distinguish research from other forms of innovative work. Some NHS R&D departments may wish to treat all grey areas as research to avoid the risk of any research not being managed correctly. However, this would result in an unnecessary administrative burden to the people undertaking the work, and an unnecessary management burden and cost to the R&D department. Projects that are not defined as research should therefore be managed within other appropriate systems in the NHS.

Where a proposed project seems difficult to categorise, the aims of the project should be assessed. The project should be designed to match the purpose. Furthermore, the management processes governing the project should be proportionate to the risks and implications of the proposed project.

NHS R&D departments are encouraged to develop appropriate links with other relevant departments such as clinical governance and data protection so that procedures are in place to manage the legal and ethical aspects of all types of projects. There are a wide range of legal requirements that apply specifically to research and it is important that NHS organisations have systems to ensure they meet their legal obligations. The legal requirements relating to confidentiality and consent are most likely to be of relevance in grey areas. Where projects are difficult to categorise, the legal implications should be assessed.

This document is not intended to provide a comprehensive or detailed guide, but to provide sufficient information to enable R&D Managers to make decisions about how to manage projects.

Research

“Research can be defined as the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods.”

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http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4108962&chk=Wde1Tv

Research generates evidence to refute or support or develop a hypothesis. Research aims to find out what happens if we add or change (manipulate) clinical or service practice in some way, or aims to find out in a

systematic way the views/ opinions/ experiences/ understandings of stakeholders. It may also require only observation, without any intervention, and may be prospective or retrospective. It may be qualitative or quantitative in approach. Research is designed so that the results of the research or the theories derived from the research should be generalisable or transferable beyond the sample upon which the research was based.

Research is likely to involve one or more of the following ¹:

- Usually involves well-defined, often strict selection criteria for the sample selected
- Should be protocol-driven, although the design of qualitative research may require sufficient flexibility to respond to discoveries during the research process
- Quantitative research is designed so that it can be replicated. It may not be possible to replicate qualitative research, but it should be possible to form a judgement of the validity of the qualitative research process.
- In quantitative research, the sample size is usually defined by statistical methods. In qualitative research, statistical sample calculations and statistical sampling methods may not be applicable. There should however be a clear rationale for the sampling procedure used.
- Quantitative research usually involves statistical analysis to extrapolate from the sample to a wider population. This includes studies where only simple descriptive statistics such as percentages are appropriate.
- May test a new or additional practice, therapy or drug
- May involve contact with participants
- May involve experiments on human subjects, whether patients, patients as volunteers, or healthy volunteers
- May be invasive
- May involve collecting data from medical records
- May solely involve collecting data from medical records
- May involve examining tissue or body samples
- May involve extra disturbance or work beyond that required for normal clinical management
- May use interviews or questionnaires
- Participants may be randomised
- Qualitative research uses a variety of methods, e.g. observation, interview, or other information, to describe, understand or interpret a situation or issue
- It is intended to publish and disseminate the results beyond the organisation, generally at conferences or in academic journals.
- The results may change practice if new interventions, tests, etc are shown to be effective.

Research that is poorly designed and therefore does not have a clearly defined question or systematic and rigorous methods should not be managed as audit or service evaluation.

Clinical Audit ²

“Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery.”

Principles for Best Practice in Clinical Audit, National Institute for Clinical Excellence, 2002
<http://www.nice.org.uk/pdf/BestPracticeClinicalAudit.pdf>
and *Standards for Better Health, DH, 2004*
<http://www.dh.gov.uk/assetRoot/04/08/66/66/04086666.pdf>

Clinical Audit is directly related to assuring services against a standard that has already been set by examining:

1. Whether or not what ought to be happening is happening
2. Whether current practice meets required standards
3. Whether current practice follows published guidelines

¹ The use of “may” means that the inclusion of the item listed does not define the work as research. Other types of work include these items and some types of research do not include these items.

² This section was prepared in consultation with the National Audit and Governance Group and the South East Clinical Effectiveness Network.

4. Whether clinical practice is applying the knowledge that has been gained through research
5. Whether current evidence is being applied in a given situation

Clinical Audit ³:

- May or may not involve patient contact but generally does not involve changes to normal clinical management
- Usually involves no more than administration of a questionnaire but can potentially require substantial patient/carer input and carry risks of distress and psychological harm
- Participants are never randomised to different treatments or services. Participants may receive or have received different treatments or services before the clinical audit
- Results are not transferable to other settings
- May use research methodologies e.g. interviews, random sampling, descriptive (not inferential) statistical analysis
- Standards of good practice are the basis of measurement not hypotheses and/or theoretical constructs
- Clinical audit outcome is the quality assurance of practice; Clinical research outcome is improved knowledge.

Surveys should be designed in such a manner as to cause minimal possible disruption to patients. Where substantial patient/ carer input is necessary ethical approval may be appropriate. This may be from a clinical or university ethics committee. Issues such as confidentiality, validity, questionnaire design and whether participants might be distressed or harmed by their involvement should be reviewed by the NHS organisation but not necessarily by the R&D Department. Information on confidentiality and consent issues relating to audit is available from the Healthcare Commission

<http://www.healthcarecommission.org.uk/InformationForServiceProviders/NationalClinicalAudit/fs/en>.

Student Research

Student projects should be assessed by the same criteria as above and managed as research, where it is research. Where a student project is not research, the project should not be managed as research. Further guidance on student research is available from the Central Office for Research Ethics Committees (COREC) <http://www.corec.org.uk>.

Clinical Investigation

Diagnostic tests may be the subject of a research study by a scientist within or outside the NHS. In situations where diagnosis of disease is difficult, NHS staff may request such a diagnostic test, in an attempt to obtain a diagnosis. Where the purpose of requesting the test is to obtain a diagnosis or to determine the appropriate care for a particular patient (or relatives, in the case of genetic disease), the request for the test should not be regarded as research. The person requesting the test does not need to be included in an ethics application and R&D approval from the NHS organisation of the person requesting the test is not required. Where the purpose for requesting the test is to help the scientist in developing a new diagnostic technique, and the aim is to develop the body of knowledge about the technique or the disease, the request for the test should be regarded as part of the research. For further discussion of this complex area see BMJ 2004;329:624 <http://bmj.bmjournals.com/cgi/content/full/329/7466/624>.

In international collaborations, other countries requirements for ethical approval for participating clinicians may be different.

Case Studies/ Case Reports

Case reports are usually anonymised and there are rarely ethical issues to be considered as long as consent is obtained. However, some journals may require ethical approval prior to publication.

Data Management and Analysis

Data collected in the course of normal administrative functions of the NHS may be analysed to provide management information to monitor current provision or to plan future developments of the service. Routine

³ The use of "may" means that the inclusion of the item listed does not define the work as clinical audit. Other types of work include these items and some types of audit do not include these items.

data management and analysis is not research. Issues about data protection and confidential information should be handled through normal NHS processes.

Consensus Methods

“The focus of consensus methods lies where unanimity of opinion does not exist owing to a lack of scientific evidence or where there is contradictory evidence on an issue. The methods attempt to assess the extent of agreement (consensus measurement) and to resolve disagreement (consensus development).”

J. Jones, D. Hunter; *BMJ* 1995;311:376-380 <http://bmj.bmjournals.com/cgi/content/full/311/7001/376>

Consensus techniques and consensus workshops are a communication process used to inform decision-making where evidence is lacking or contradictory. Consensus methods may be used to agree guidelines, priorities, processes or policy. These include the Delphi method, the nominal group technique and consensus conferences.

Consensus methods:

- may involve interviews and/or questionnaires
- those involved are partners rather than participants and their names are usually included in any report or publication
- may be used to design a research project
- may be used to decide where research is required

Consensus methods would not normally require ethical approval. Consensus methods may also form part of a research project and, if so, should be managed as research.

Service Evaluation

“Evaluation was seen as ‘a set of procedures to judge a pilot’s merit by providing a systematic assessment of its aims, objectives, activities, outputs, outcomes, and costs’”

J. Newton, J. Graham, K. McLoughlin, A. Moore, D. McTavish, *Journal of Management in Medicine* 2000; 14:37-47 quoting Evans, D, Steiner, A 1997; *NHS Executive, Leeds*

Evaluation provides practical information to help decide whether a development or service should be continued or not. Evaluation also involves making judgements about the value of what is being evaluated.

Evaluation:

- May provide cost and/or benefit information on a service
- Uses quantitative and qualitative data to explore activities and issues
- May identify strengths and weaknesses of services
- May include elements of research e.g. collecting additional data or changes to choices of treatment

If a large or complex evaluation study includes a research project (as defined above), the research should be managed within the Research Governance Framework. Where evaluation includes a clinical audit project (as defined above), the audit should be managed through the organisation’s clinical audit management systems. In many cases, service evaluation will require collaboration between a number of departments within an organisation. Appropriate management of the evaluation should be agreed across the organisation, and the evaluation should not proceed without permission through the organisation’s agreed process.

It can be difficult to distinguish some types of evaluation from research. Although both research and evaluation may involve addressing clearly defined questions with systematic and rigorous methods, research aims to derive generalisable new knowledge. Service evaluation may result in generalisable knowledge but the potential for generalisability is not part of the design of the project. Often a service evaluation is performed to meet specific local needs. The generalisability of service evaluation may arise through a report or publication where context and methodology are described and readers are able to judge whether the situation is sufficiently representative to their own situation.

Proper governance of research is essential to ensure that the public can have confidence in, and benefit from, quality research in health and social care. Research can involve an element of risk, both in terms of return on investment and sometimes for the safety and well-being of the research participants. Managing innovative work within the NHS requires an assessment of the risks involved and appropriate systems to manage these risks. In assessing the appropriate systems to manage projects which are difficult to

categorise, a risk-based approach would include assessment of the risks to others of undertaking the work without appropriate rigour.

Service evaluation which is relevant only to the population or setting upon which it is based would generally be low risk. Evaluation concerned with producing internal recommendations for improvements that are not intended to be generalised beyond the setting in which the evaluation took place should therefore not be managed within the Research Governance Framework, and other appropriate systems should be used. These might include for example authorisation and oversight by a clinical effectiveness manager or a senior person in the department/ unit in which the evaluation is based.

If it is intended that the results of the service evaluation are to be used to influence practices or processes outside the immediate setting and the work was not managed within the Research Governance Framework, there would be a risk of the public being exposed to changes without a sound evidence base. Where it is intended to publish the results of an evaluation in a form that aims to generalise the results to others situations, the evaluation should therefore be managed within the Research Governance Framework.

Ethical review of research

“2.2.1 The dignity, rights, safety and well-being of participants must be the primary consideration in any research study.

2.2.2 The Department of Health requires that all research involving patients, service users, care professionals or volunteers, or their organs, tissue or data, is reviewed independently to ensure it meets ethical standards.”

Research Governance Framework for Health and Social Care, Second edition, 2005

http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4108962&chk=Wde1Tv

Ethical review by an NHS Research Ethics Committee is required in the circumstances set out below:

“3.1 Ethical advice from the appropriate NHS REC is required for any research proposal involving:

- a) Patients and users of the NHS. This includes all potential research participants recruited by virtue of the patient or user’s past or present treatment by, or use of, the NHS. It includes NHS patients treated under contracts with private sector institutions.*
- b) Individuals identified as potential research participants because of their status as relatives of carers of patients and users of the NHS, as defined above*
- c) Access to data, organs or other bodily material of past or present NHS patients*
- d) Fetal material and IVF involving NHS patients*
- e) The recently dead in NHS premises*
- f) The use of, or potential access to, NHS premises or facilities*
- g) NHS staff – recruited as research participants by virtue of their professional role”*

Governance Arrangements for NHS Research Ethics Committees, July 2001 <http://www.dh.gov.uk/assetRoot/04/05/86/09/04058609.pdf>

In addition, the Medicines for Human Use (Clinical Trials) Regulations 2004 require that all clinical trials of investigational medicinal products falling within the remit of the regulations should receive a favourable opinion from an appropriate ethics committee. (The Medicines for Human Use (Clinical Trials) Regulations 2004 <http://www.hmsa.gov.uk/si/si2004/20041031.htm>)

Research meeting the above criteria requires ethical review by an NHS Research Ethics Committee. However, ethical issues are raised in other forms of innovative work, particularly where direct interaction with patients, service users or carers will take place. Where clinical or university ethics committees are not available this work may be referred to an NHS Research Ethics Committee, who may undertake to review the project. Review of these projects within the NHS Research Ethics Committee system does not mean that the project is required to follow the NHS permission process for research as set out in the Research Governance Framework.