**York Foundation Trust R&D Unit**
**Guidance Document**
**R&D/G04**

# Classifying Investigative Projects

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This Document will normally be reviewed every three years unless changes to the legislation or Trust processes require otherwise

## Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

| Version | Date Implemented | Details of significant changes |
|---|---|---|
| 1.0 | 2006 | |
| 2.0 | 1st May 2010 | Guidance document put into revised template. Minor revisions and clarification |
| 3.0 | 1st August 2010 | Revision to take into account pre-screening of types of project within organisations. Minor changes to wording of section 3 as suggested by Chair of R&D Committee; modifications to para 13 following consultation with Alliance member organisations; with minor consequential change to wording of Summary box |
| 4.0 | 1st November 2010 | Change to clause 13 – modified to read 'Lead Clinician for Research and Development'. York Hospital updated to York Teaching Hospital. |
| 5.0 | 16th September 2013 | Change of Author and change of SOP Controller. Removal of references to the North and East Yorkshire R&D Alliance. Very minor reformatting changes |
| 6.0 | 3rd April 2015 | Updates to reflect national changes e.g. changes to approvals for studies accessing retrospective data, Confidential Advisory Group has replaced NIGB, Health Research Authority has replaced NRES. Some clarifications to 'ethical committee approval' to make clear this is NHS REC approval. Added reference to guidance on writing up audit/service evaluation projects |
| 7.0 | 2nd February 2017 | General update to removed references to NHS Permission |
| 8.0 | 14th August 2017 | Additional references to HRA Approval process in Summary and Audit, Service Evaluation |

## SUMMARY

- Plan investigative projects of all types thoroughly and write appropriate protocols;
- Classify projects correctly by using this guidance;
- If you know your project is research, apply for permission via the R&D Unit (see www.northyorksresearch.nhs.uk). All research projects require Health Research Authority (HRA) Approval and most research projects also require a favourable opinion from an NHS Research Ethics Committee (NHS REC) and/or other approvals depending on the nature of the project. Advice can be sought from the R&D Unit.
- If you think your project is NOT research submit it for an opinion / registration as audit or service evaluation by contacting the Clinical Effectiveness Department.
- ALL investigative projects taking place in the Trust MUST be registered with either the R&D Unit or Clinical Effectiveness before they commence.


## Introduction

1. This document has been prepared to explain different types of investigative projects that are common in the NHS, and to give guidance on governance arrangements in York Teaching Hospital NHS Foundation Trust.

   These include:

   **Research** This is concerned with establishing what best practice should be. It is "… the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods." [1]

   **Audit** This 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"[2]. It is concerned with implementation of standards, treatment guidelines or acknowledged best practice.

   **Service evaluation or review** This is "a set of procedures to judge a service's merit by providing a systematic assessment of its aims, objectives, activities, outputs, outcomes and costs." [3]

   **Patient satisfaction surveys** These can take place in the context of projects that are basically audit, research or service evaluation.

   **Single case studies or reports** These describe individual patients with conditions or treatment responses that are considered interesting or unusual.

2. Routine monitoring of patients' notes by senior clinicians for purposes of staff

[1] Research Governance Framework, 2005

[2] Principles for Best Practice in Clinical Audit. National Institute for Clinical Excellence 2002

[3] NHS Executive, 1997 (Quoted in "An introduction to service evaluation", Royal College of Psychiatrists Research Unit, *www.focusproject.org.uk* )

supervision or personal reflective practice does not constitute carrying out an investigative project and this document does not apply.

## Audit, Service Evaluation and Research

3. It is important to be clear about these boundaries because if projects are misclassified this may:
   - lead to inappropriate claims being made from the data that have been collected with a potentially adverse impact on clinical practice
   - lead to research being conducted with neither HRA, NHS REC nor care organisation approval as required by the Research Governance Framework (RGF);
   - result in breaking the law in areas such as data protection and use of human tissue, where legislation contains more permissive arrangements for audit than for research;
   - result in breach of professional codes of conduct .[4]

   Both the individuals involved and the care organisations have responsibilities under the law and the RGF; the individuals have responsibilities under their professional codes of conduct. Therefore, to carry out a project that should be managed as research as though it were audit or service evaluation is a risk for both individuals and care organisation.

4. It is true that there may be grey areas and that distinguishing the type of project can sometimes be difficult. In most cases the position will be clear if this guidance is applied, but differences of opinion will arise and investigators need to have the position clarified before they start work. The Trust has made arrangements for decisions to be made on classification of projects while they are at the planning stage. Details of these arrangements are given in paragraph 13 below.

5. The most important thing in deciding whether a project is research is to be clear about its purpose. This means that audit, service evaluation or research questions need to be carefully formulated and explicit, and that project plans should be developed at the outset. Most methods of investigation, quantitative or qualitative, can be used in audit, service evaluation or research. The issue is not method but purpose.

   It is sometimes believed that if projects have one or more of these characteristics, that defines them as audit:
   - Retrospective methods are used;
   - Data are extracted from routine medical records;
   - The work is observational, with no changes to treatment being made;
   - There is no randomisation;
   - The only method of investigation is a questionnaire survey.

   This belief is incorrect. Retrospective methods can be used for audit, service evaluation or research; so can data that have already been collected for another purpose; so can questionnaire survey methods. Nor does the absence of randomisation or other features of experimental study take a project out of the scope of the Research Governance Framework. Observational methods are commonly used in research.

6. Service evaluation concerns evaluation of services, not of treatments or diagnostic tests. The key issue is generalisability. To evaluate a local service in terms of criteria such as effectiveness at reaching target patients, efficiency, patient satisfaction or value for money is very different from evaluating the effectiveness of a particular

[4] For example, doctors must be clear about the nature of the project they are undertaking in order to know whether they need to apply the GMC's "Good Practice in Research" (2010) http://www.gmc-uk.org/guidance/ethical_guidance/5992.asp

therapy for treating a medical condition or a test for diagnosing it. If the effectiveness of a therapy or test is the object of study the findings apply to patients outside the immediate organisation; such evaluations should be conducted as research, to appropriate scientific standards, and published.

Service evaluation can present particular classification challenges because it is often a hybrid exercise. A complex or large-scale service evaluation project may contain both audit and research elements. In such cases it is best for the whole project to be managed as research.

7. It is sometimes believed that research can never be carried out without specific individual participant consent. In fact there are circumstances such as some retrospective studies using pre-existing clinical data, where individual consent may not be required. However, if the data includes patient identifiable information being accessed outside the clinical care team the project may require an application to the Confidential Advisory Group at the Health Research Authority.

8. With the exception of large nationally-commissioned audits, audit and service evaluation projects are, generally, of local interest. The aim is to check on adherence to standards and / or improve local services, either within a single organisation, or in conjunction with local NHS partners. They should be presented at professional or multidisciplinary meetings and written up for use within the care organisation(s) involved. Occasionally it may be appropriate for such reports to be more widely published; however external publication in journals or books or by posters or presentations at research conferences is <u>usually</u> a hallmark of research. If an investigator is planning a project where the findings will be relevant for care or treatment of patients elsewhere and therefore considered to be publishable, s/he should consider the position very carefully and err on the side of caution. To publish a report of an investigative project that, having been carried out without the scientific and governance quality processes applicable to research, recommends adoption of a treatment or diagnostic test for patients generally, places the author at significant risk as well as causing potential damage to the reputation of the care organisation. Top quality professional journals will screen submissions and ask for details of the ethical opinion to be written into the paper; however this degree of rigour is not universal.

   Guidance on writing up audit and service evaluation projects is available from the R&D Unit website or from the Clinical Effectiveness Department.

## Governance arrangements

9. All investigative projects – including audit, research, service evaluation, patient satisfaction surveys and case studies - should be of good quality and managed to good clinical governance principles.

10. A single case study does not require any form of, organisational or ethical approval provided that:

    - The report relates to an individual patient;
    - The report is fully and carefully anonymised;
    - The patient's written informed consent to publication has been obtained.

    It should, however, be noted, that some journals do require ethical approval before submission of a case report; a prior check is advised.

11. All investigative projects other than single case studies should begin with written protocols containing:

    - a clear statement of questions to be addressed;

- background justification and appropriate literature review;
- details of the methods to be used for data collection, storage and analysis;
- details of the reporting and dissemination plan.

Protocols will vary in length and complexity according to the type of project involved. As a general guide, it may be possible to describe the plan for a straightforward audit project in about 2 sides of A4 paper; a protocol for a complex research project will be very much longer.

12. Where it is known that the project is research, applications for the necessary approvals must be made in advance. Different research projects may require different approvals and it is important to seek advice from the R&D Unit to ensure that the correct processes are followed. Information can also be found at www.northyorksresearch.nhs.uk

13. Where the project is thought to be audit or service evaluation, investigators should submit their protocols / registration form to the Trust's Clinical Effectiveness Department, who will confirm the correct classification, liaising with the Lead Clinician for Research and Development if the applicant wishes to publish or present the project externally, or if there is any uncertainty regarding the classification of project.

## Other useful information and sources of advice

The following document, available on the internet, contains useful information; the tables are particularly commended:

Healthcare Quality Improvement Partnership: A Guide for Clinical Audit, Research and Service Review – an educational toolkit designed to help staff differentiate between clinical audit, research and service review activities

The Health Research Authority website provides further information on the procedures they apply to their work www.hra.nhs.uk

Links to these external websites will be found on the R&D Unit website www.northyorksresearch.nhs.uk under *Advice & Information*.