DO CLINICAL AUDIT PROJECTS EVER NEED FORMAL ETHICS APPROVAL?

Medical research is important and the National Health Service (NHS) has a role in enabling such research to take place. While approval for a research project is a management decision, advice on ethical issues comes from a Local Research Ethics Committee (LREC).

The Tameside and Glossop LREC, based at Gateway House, Manchester operates within the framework of guidance from the Department of Health, the Royal College of Physicians and other professional bodies and principles contained in the Declaration of Helsinki.

REMIT OF THE LREC

The LREC must be consulted about any health related research within the area of Tameside and Glossop PCT, which involves:

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 or carers of patients and users of the NHS, as defined above
c. Access to data, organs or other bodily material of past and present NHS patients.
d. Foetal material and IVF involving NHS patients
e. The recently deceased on 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

Research Ethics Committee Approval – how to obtain ethics approval.

There are two application procedures 1) direct application to the LREC, or 2) obtaining local approval for a multi-centre research study, which has previously been approved by one of the Multi-Centre Research Ethics Committees (MRECs). If an application to the ethics committee is required it should be made by the “Chief investigator” – the person who is taking overall responsibility for the design, conduct and the report of the study.

The electronic application form is available from https://www.corecform.org.uk. Further COREC guidance can be found on www.corec.org.uk
All clinical audit needs to be conducted within an ethical framework. But what about specific ethics approval?

In principle the question “Does audit need ethical approval?” is an easy one to answer. The answer is ‘No’.

Clinical audit by definition does not involve anything being done to patients beyond their normal clinical management and therefore does not require formal ethical approval. It aims to improve patient care through systematic review of care against explicit criteria and the implementation of change.

However........

There are a few instances when an audit project may require ethics approval. These are considered under four headings:

- Is it really audit? Might you be doing research?
- Are you planning a patient survey?
- Are you planning to publish?
- Staff who are not bound by a duty of confidentiality

1. Is it really audit? Might you be doing research?

Healthcare professionals sometimes confuse clinical audit with research. This is easily done because the two disciplines have much in common. The similarities and differences between audit and research are outlined below.

"Research is concerned with discovering the right thing to do; audit with ensuring that it is done right”

Research is about creating new knowledge; knowledge about whether new treatments work and whether certain treatments work better than others. Research forms the basis of nationally agreed clinical guidelines and standards – it determines what best practice is.

Clinical Audit is a way of finding out whether we are doing what we should be doing. Are we following guidelines? Are we applying best practice?

So, for example, research might ask:

“What is the most effective way of treating pressure sores?”

Audit would then ask:

“How are we treating pressure sores and how does this compare with accepted best practice?”

1 Smith R. Audit & Research BMJ 1992: 305: 905-6
The piece of research would involve measuring outcomes as a way of finding out what the best treatment is.

The audit would measure process (are we doing the things we should do?) but might also look at outcomes, in this instance to monitor the success of a treatment, which is known to work, rather than to find out whether it works (a subtle but important difference).

‘A wider definition of clinical audit would include pre-audit work such as a description of an existing service, the stage prior to setting standards. This does not need ethical approval.’

The similarities:

- Audit and research involve answering a specific question relating to quality of care
- Both can be carried out either prospectively or retrospectively
- Both involve careful sampling, questionnaire design and analysis of findings
- Both activities should be professionally led
## Some of the differences

<table>
<thead>
<tr>
<th>Research</th>
<th>Clinical Audit</th>
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<tbody>
<tr>
<td>To determine best practice</td>
<td>Answers the question, “Are we following best practice?”</td>
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<tr>
<td>To gain new knowledge</td>
<td>Evaluates conformity with tested, proven knowledge</td>
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<tr>
<td>Is a systematic investigation which aims to increase the sum of knowledge</td>
<td>Is a systematic approach to the peer review of medical care, to identify opportunities for improvement and to provide a mechanism for bringing them about.</td>
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<tr>
<td>Aims to answer a research question, i.e. is based on a hypothesis</td>
<td>Measures against standards</td>
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<td>May involve patients receiving a completely new treatment</td>
<td>Never involves a completely new treatment</td>
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<tr>
<td>May involve extra disturbance of work beyond that required for normal clinical management</td>
<td>Never involves anything being done to patients beyond their normal clinical management²</td>
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<tr>
<td>May involve patients being allocated to different treatment groups</td>
<td>Never involves allocation of patients to different groups</td>
</tr>
<tr>
<td>Is based on a scientifically valid sample size (although this may not apply to pilot studies or qualitative studies)</td>
<td>Depending on circumstances, may be pragmatically based on a sample size, which is acceptable to senior clinicians.</td>
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<tr>
<td>Either uses a representative sample to make predictions and differences from one sample to another, or uses a purposive sample to gain information from key informants</td>
<td>The study is intended to measure the practice of the participating unit (or units) and is not intended to provide predictive models for other units. Thus sample size only needs to be representative of the time and place of data collection.</td>
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<td>Extensive analysis of data is routine</td>
<td>Some statistical analysis may be useful</td>
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<tr>
<td>Results are generalisable and hence publishable</td>
<td>Results are only relevant within local setting (although audit process may be of interest to wider audience and hence audits are also published).</td>
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<tr>
<td>Findings influence the activities of clinical practice as a whole</td>
<td>Findings influence activities of local clinicians and teams</td>
</tr>
<tr>
<td>Always requires ethics approval</td>
<td>Does not require ethics approval</td>
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² N.B. patient surveys can be construed as “doing something to patients beyond routine clinical management”. Surveys should be designed in such a manner as to cause minimum possible disruption to patients and may require specific ethics approval.
Grey Areas

Even with this guidance you may still find yourself struggling to decide whether your proposed project is audit or research. Indeed it is possible that larger projects may contain elements of both audit and research.

However, it is possible to get so bogged down in trying to categorise your project that you lose sight of your objectives. Use common sense and concentrate on three key questions and bear in mind that the subjects of your research could include staff, carers, users, etc.

1. Is the purpose of the proposed project to try to improve the quality of patient care in the local setting?
2. Will the project involve measuring practice against locally or nationally agreed standards?
3. Does the project involve anything being done to patients, which would not have been part of their normal routine management?

If you can answer ‘Yes’ to the first two questions and ‘No’ to the third, it is safe to say that your project conforms to the requirements of clinical audit. If it doesn’t, you’re probably doing research.

Decisions about whether ‘audit’ projects need ethics approval often hinge on the question of whether they really are audit, or whether they are actually research.

Research always requires ethical approval. Calling research by any other names does not remove this requirement.

In ‘hard-to-call’ cases, the decision about whether a project is audit or research is ultimately a matter for the Local Research Ethics Committee. If the conclusion is that you are undertaking research, you must formally submit the appropriate paperwork to LREC for ethics approval.

On other occasions, however, the boundaries between audit and research are genuinely blurred and a project may genuinely contain elements of both audit and research. You will need to obtain formal ethics approval for this project.

2. Are you planning a patient survey?

Again the first question to ask is whether the purpose of your survey is audit or research. Patient/User satisfaction surveys (about physical aspects of research) or which contain non-clinical information do not need ethical approval. The same would apply to focus groups. If the survey is audit, there are still a number of questions you should address which have an ethical dimension even though you may not require LREC approval. The concern here is with the patient’s right, dignity and time.
• Are the questions worth asking?
  Or is this wasting everyone’s time?

• Is the choice of a survey appropriate to the question?
  Should you be setting up a focus group instead, for example?

• How will patients be identified to participate?
  Have you taken reasonable steps to ensure that patients are alive?
  If there is good reason to suspect that patients may have died since the
time of their treatment, have you contacted their GP to confirm they are still
alive?

• How will you ensure patient confidentiality (and how will you communicate
this to the patients?)?
  It should be explained to the patient that their responses are confidential
  and will not influence their future treatment in any way. Data should be
  handled in accordance with GMC guidelines and Data Protection Act 1998.

Respondents need to be aware that their responses will be held on a database.
Although this database may not include patient-identifiable information, it may be
technically possible to link responses to individuals, and, if this is the case, this fact
needs to be made clear in accompanying information.

**Will the survey cause minimum disturbance?**

Is your survey addressing a sensitive topic? Are you asking questions that have
potential to cause emotional upset and distress? Is your questionnaire
unnecessarily long?

**Will the survey is any way interferes with the treatment of the patient?**

Is there any possibility that the survey will cause the patient to reflect negatively
upon their course of treatment, thereby jeopardising clinical outcomes?

Where questions are about clinical matters, there is greater potential for asking
inappropriate/insensitive questions and inadvertently doing harm.

It is worth noting that there is also an argument, which says that, by asking
patients’ questions about their treatment and care, we are doing something
different to them (see earlier definition of audit). If you are in any doubt about
whether you survey needs LREC approval, you are advised to write to:
ReGrouP Central Office,
C/o Salford PCT,
1st Floor, St James’s House,
Pendleton Way,
Salford, M6 5FW
Tel: 0161- 212 4946Fax 0161-212 4943
Email: Linda Dack????
Beverley.greenhalgh@salford-pct.nhs.uk
Also note that similar rules govern **Focus Groups** and other ways of consulting patients or the general public.

### 3. Are you Planning to Publish?

If the results of your project are generalisable beyond the local settings, you are probably doing research.

Clinical audits are sometimes published, but this is usually because the topic and/or methodology may be of interest to a wider audience – not because the results are generalisable. Intention is often a good guide – if it is solely to check that best practice is being followed, then it will be probably be audit, but if it is to compare two or more practices, it is likely to be research.

Editors of some journals will not publish articles about audit projects unless ethics approval has been sought. Anyone undertaking an audit which they may want to publish should obtain a letter from the LREC which states that it does not require ethical approval.

### 4. Staff who are not bound by a duty of confidentiality

It is possible that some of the work for your audit project may be done by someone who is not an employee of the Trust (e.g. might be a university student or patient).

A potential problem exists when people working on audit projects are volunteers or not paid by the Trust. You must consider providing an honorary contract for such people if they are to have access to patients’ notes and a member of the Trust staff must take responsibility for how and where clinical information is accessed.

Once again, if in doubt, it is recommended that you write to the Chair of the R+D Task Group (Dr Kate Wooff), or the ReGrouP Central Office for advice or speak to the Caldicott Guardian for the PCT (Dr Kailish Chand).

**Research Governance**

**What is Research Governance?**

Research makes an important contribution to health and social care but it can involve an element of risk regarding both the return on investment and the safety and well being of those participating. The Department of Health has published a Research Governance Framework, which provides the necessary guidance to everyone involved in research.

The framework brings together all current legislation such as the Data Protection Act and Health and Safety and seeks to promote improvements in research quality to ensure that research is conducted to the highest scientific and ethical standards.
The Research Governance Framework applies to all research in health and social care settings and details standards for the conduct of research, responsibilities and accountabilities for individuals (regardless of how junior or senior they are) and organisations who might be involved. This includes research subjects, professionals who care for patients in studies, research managers, organisations who host research, fund research and carry out research.

**What approval do you need to carry out research in the NHS?**

The PCT must implement research governance, which means that before you start a research project you must first:

1. Gain approval from your line/service manager (if you work in one of the PCT’s directly managed services)
2. Gain ethical approval from a Local Research Ethics Committee (LREC)
3. Register the project with the ReGrouP Central Office.

If you are planning to carry out a commercially funded study you should contact the R+D Lead as early as possible during the negotiations to ensure that the correct management agreements are in place.

Further suggested reading:

1. Confidentiality: Protecting and Providing Information, General Medical Council (also see [www.gmc-uk.org](http://www.gmc-uk.org))
2. Personal Information in Medical Research, Medical Research Council, October 2000 (see [www.mrc.ac.uk](http://www.mrc.ac.uk))
5. Human Rights Act
   - [www.nhsia.nhs.uk/caldicott/pages/default.asp](http://www.nhsia.nhs.uk/caldicott/pages/default.asp)
7. Research in the NHS: [www.doh.gov.uk/research](http://www.doh.gov.uk/research)
8. Research Ethics Committees: [www.corec.org.uk](http://www.corec.org.uk)

**Acknowledgement**

With thanks to Gloucester Primary Care Audit Group for permission to adapt some of these ideas.