GUIDANCE ON ETHICAL CONSIDERATIONS FOR CLAHRC IMPLEMENTATION ACTIVITY

A draft for discussion

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September 2009

This discussion document gives the background to the development of the ethical considerations for non-research activity and indication of the purpose of the guidance. It then gives details of a process by which activity identified as non-research can be considered in terms of ethics. The paper is intended for discussion at the CLAHRC Directors meeting on 23rd September 2009 and subsequently.

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Tables

1) Background

The issue of whether implementation activity within CLAHRC requires formal ethical approval, using established NHS research governance processes, has been raised at several meetings of the CLAHRC Directors. Discussions have identified that one of the key issues is the decision about what constitutes 'research'. Although there are guidelines issued by IRAS these were no felt to be as comprehensive as required for some implementation activity.
The team from the South Yorkshire CLAHRC circulated a document (the 'Simple Rules Toolkit') they had produced for use within Sheffield Teaching Hospitals intended to help staff there to understand the nature of their project and the processes that were then required for appropriate governance approval. It has subsequently been updated to be more generalisable, using funding from the Healthcare Quality Improvement Partnership (HQIP). It was agreed that Kate Gerrish (Implementation lead, South Yorkshire CLAHRC) and Ruth Boaden (Implementation lead, Greater Manchester CLAHRC) would organize a meeting to develop this generalisable toolkit into something that could be used by CLAHRCs for projects within CLAHRCs that are not 'research' but for which some ethical guidance would be helpful.

a) Process

All CLAHRCs were invited to send a representative to a meeting in Sheffield on 21 Aug 09 to discuss this issue and to come up with a draft proposal for consideration by the CLAHRC Directors meeting. SDO agreed to underwrite the costs of this meeting.

Attendees:

- ***Ruth Boaden*** – Greater Manchester CLAHRC (Deputy Director, lead for implementation)
- ***Kate Gerrish*** – South Yorks CLAHRC (Translating Knowledge into Action Lead)
- ***Paul Sinfield*** – Leicestershire, Northamptonshire & Rutland CLAHRC (Implementation Theme Manager)
- ***Michael Spence*** – Greater Manchester CLAHRC (Knowledge Transfer Associate Chronic Heart Disease Implementation Theme)

This document is the outcome of this meeting. Due to time constraints it was not possible to circulate for wider comment prior to being tabled at the CLAHRC Directors meeting, but it is hoped that this will start a process of discussion amongst a wider community which will result in a final version by the end of 2009 at the latest.

b) Why is this guidance needed?

An informal review of literature, focused on quality improvement and ethics, and the knowledge and experience of the participants in the meeting concluded that guidance is needed because:

- Professional frameworks are not enough – and not all staff carrying out implementation activity will have a clinical professional background
- Lack of clarity about what requires formal review
- Inconsistent treatment of projects between and even within organisations
- Lack of clarity about who is responsible for governance of implementation
- Assumption that quality improvement/implementation is without risk (Flaming, Barrett-Smith, Brown, & Corocan, 2009)
- Recent publicity about patient safety and ethical approval (Kass et al., 2008)
- Easy access to patients and populations

Although these are common issues, it was felt that a common approach for CLAHRCs to use if they wished too would demonstrate effective use of resources as well as sharing of learning. Perhaps the biggest and most influential component of CLAHRC is collaboration; we need to work together in partnership with the NHS to create a shared way of thinking.

c) What is the purpose of this document?

This is a guidance document, intended to support a systematic approach to the ethical issues to be considering when undertaking implementation projects.

At present it has not been considered by any national body and is intended to support the work of CLAHRCs. Individual organisations will need to develop their own processes to support the use of this guidance (see page 13).

d) Sources of information

The main sources of information used at the meeting were:

- *Alberta Research Ethics Community Consensus Initiative (*ARECCI*)*[1]
- *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 'Sheffield Tool')*
- *National Research Ethics Service (NRES) guidance on research, service evaluation and clinical audit*
- *A small number of academic papers on quality improvement and ethics (see Appendix 2)*

After some discussion it was decided that the CLAHRC approach would be based on the ARECCI tool because:

- It flagged up certain issues which projects need to take into account and which were not highlighted clearly in other approaches
- The filter process it used was found to be helpful and relatively simple
- On the whole the questions were good, however it was felt that some part of it were a little too bureaucratic
- The language used was set at the right level for healthcare staff, not only those already involved in research and used to the language that is involved (e.g. 'peer review')
- There was explicit consideration of the risk of projects that are not research which was lacking in other approaches

The current guidelines that are in place within the NHS (Appendix 1) from then National Research Ethics Service (NRES) do not provide sufficient guidance regarding the 'grey areas' of quality/service improvement that appears to constitute much of the CLAHRC implementation work. They only distinguish between service evaluation/ clinical audit and research. They have however been used as a cross-check for the process outlined here to ensure that it is consistent with the NRES guidance.

[1] http://www.ahfmr.ab.ca/arecci/tool/

e) Who is this guidance for?

This guidance is intended to be used by those within CLAHRCs responsible for implementation activity. Such staff will have a range of professional backgrounds, including doctors, nurses, managers and academic researchers and may be employed either within the NHS, within a university, or jointly.
It does not prescribe the details of how such a process might be managed within organisations, since this will differ with the context, but it does outline the principles and the processes required.

2) Distinguishing between research and non-research activity

From the literature reviewed it was noticeable that there were a number of different uses of language to describe what appears to be the same activity. There is a huge range of terminology used for projects that are not, or may not be, considered to be 'research'. This document is not intended to serve as a discussion on this topic (although Appendix 2 does give some further information for those interested, drawing on the literature on quality improvement and ethics) but the following points are important here:
Projects that are not 'research' come under a large number of headings (see Table 1). For this purposes of this document it does not matter which of these terms are used – the process is the same.

Table 1: Terms used to describe non-research activity

1. Clinical Audit
2. Practice Development
3. Service Evaluation
4. Quality/Service Improvement
5. Action Research
6. Service Design and Development
7. Case study
8. Satisfaction surveys

The key areas of debate concerned with whether something can be defined as research appear to centre on the issues shown in Table 2:

Table 2: Areas of debate concerning the definition of research activity

Issue	Explanation	Research or not?
Data	What is being collected, where it is being collected, who is collecting it how it will is be used, accessed, stored etc.	More rigorous processes for storage, access, anonymity etc are needed for research but basic ethical principles should still be followed for other types of work.
Generalisability[2]	Is there an intention that the results will/can be generalized?	The issue is with 'intention' – the results of non-research activity may/can be generalized but this is not the main objective of the work
Conduct[3]	How the project is carried out, who will be spoken to, does it make demands on individuals beyond 'normal' treatment or data collection (for patients) or expectations of work (for staff)	Projects that make additional demands might be regarded as research. Non-research activity may change what is demanded e.g. where adherence to established best practice is being improved but this is to bring treatment to 'normal' standards.

[2] See NRES guidance section (a)

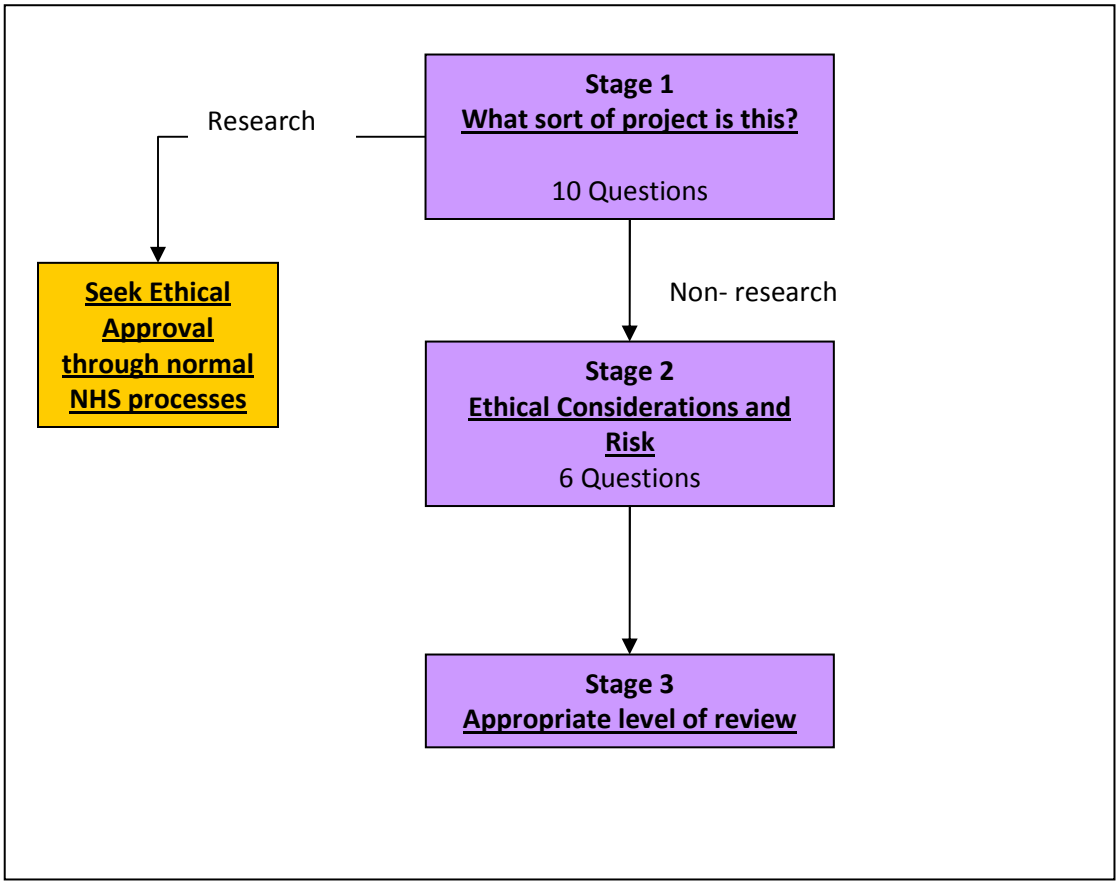
Project plans	How fixed are the plans? Will changes to the plans require referral back to an approving body?	Research will have a process defined before the work commences, with any variations from plan requiring reports to/approval from the approving body. Implementation is more dynamic; it cannot be structured in advance in the same way (although some form of project plan is required); projects evolve and change in nature as time progresses. Any approving body would need to understand at what point a change was significant. This would probably involve the assessment of risk.
Publication	Will the results be published in journals that publish research results?	It is not true that formal ethical approval is required for the publication of results – there are an increasing number of journals (with excellent reputations and citation counts) that will publish the results of improvement and implementation work. The issue here is whether the work is regarded as research or not.
Patient Involvement and payment	Are patients being paid to participate?	Normally patients would not be paid to take part in implementation, since this is 'normal' care, but they often would for research

[3] See NRES guidance section (d)

3) Guidance on ethical consideration for non-research projects

This guidance follows the process shown in Figure 1

Figure 1



Stage 1: About Your Project

The answer to the questions in Table 3 will provide guidance about the likelihood as to whether the project is research or non-research.

Table 3: determining whether a project is likely to be research or not

	If 'Yes' then project is …			
	Probably research	Possibly research	Possibly not research	Probably not research
1. Is this project primarily designed to test a specific hypothesis or answer a specific quantitative or qualitative question? Yes/No	*			

[4] adapted from http://www.ahfmr.ab.ca/arecci/tool/

The intent here is to assess the project in terms of its fit with quantitative and qualitative research designs: a) Quantitative projects typically involve formulation of a specific hypothesis or research question which informs its scientific design including analysis methods, and b) Qualitative research projects typically involve formulation of a research question and application of a specific qualitative theory that underlies and guides the methodology used in the design of the study including the analysis. Other types of project may have less clear hypotheses/research questions linked to the design of the project.				
2. Does the project involve a comparison of multiple sites and/or control groups? Yes/No		*		
The intent here is to assess the project in terms of its fit with quantitative research design where control for extraneous factors can be an important part of the rigor of the project in studying the primary variables of interest. However, it is possible to carry out non-research projects that compare sites and/or use control groups.				
3. Is the project designed to support generalisations that go beyond the particular population the sample is being drawn from? Yes/No	*			
This item assesses the current project in terms of its fit with the aim of research to produces results that are intended to be generalisable to the population of interest through rigorous sampling and analysis techniques. In general, this implies future application to that whole population.				
4. Does the project impose any additional burdens on participants beyond what would be normally expected or normally experienced during the course of care, program participation or role expectations? Yes/No	*			
The intent here is to assess the project in terms of its fit with research, where participation is voluntary and the activities participants will be involved with are in addition to routine care, program provision, or role performance. A closer definition of 'normal' expectations and experience may be needed here.				
5. Is the primary purpose of the project to produce the kind of results that could be published in a research journal? Yes/No		*		
This item is referring to a project whose PRIMARY purpose is to obtain results that could be accepted for publication in a peer reviewed journal that publishes research findings. It is recognized that in addition to journals that focus on publishing research results, there are a growing number of journals devoted to sharing and developing knowledge generating activities in the fields of Evaluation and Quality Improvement through publishing results from these types of projects.				
6. Will project participants be among those who might potentially benefit from the result of the project as it proceeds? Yes/No			*	
Quality improvement projects usually provide timely and specific feedback to the aspect of the organization they are focusing on, therefore participants in these projects may be more likely to benefit from any findings that are produced. Participants in research projects might, in some cases, benefit but this is not the primary purpose of the research.				
7. Is the project intended to develop a better practice within your organisation or setting? Yes /No				*

The intent here is to assess the current project in terms of the **primary** focus of quality improvement or evaluation projects on producing findings about a specific program and/or process to improve practice within a specific organization. Projects might also implement what is known best practice consistently e.g. NICE guidelines				
8. Would this project still be done at your site even if the results might not be applicable anywhere else? Yes /No				*
The intent here is to capture the site specific/local nature of non-research projects as opposed to research projects where the site does not matter in terms of specific locales but only in more general terms such as rural vs. urban.				
9. Does the language used in the project description refer explicitly to a particular programme, organisation, or locality, rather than using more general terminology such as rural vs. urban populations? Yes /No				*
The intent here is to differentiate the language used in project descriptions as another cut on how to distinguish between research and non-research. By and large research projects use more general terminology to reflect their intent to be generalisable, while non-research projects usually refer to specific programmes and services in specific locales.				
10. Is the current project part of a continuous or 'normal' process of gathering or monitoring data within an organisation? Yes /No				*
The intent here is to assess the project in terms of its fit with the primary focus of quality improvement.				

Using the analysis

- 'Yes' answers to any of questions 1, 3, 4 mean that the project is probably research. Further advice should be sought from R&D departments and/or the NRES central advisory service[5].
- 'Yes' answers to questions 2 and 5 mean that the project may be research, but not certainly. Further advice should be sought from R&D departments and/or the NRES central advisory service.
- A 'Yes' answer to question 6 means that the project is probably not research.
- 'Yes' answers to questions 7,8,9,10 mean that the project is almost certainly not research and users should proceed to stage 2.

Stage 2: Ethical considerations

For projects identified in stage 1 as non-research projects, the questions in Table 4 ***can*** be used in order to ensure that all ethical considerations are covered. It is for individual organisations to determine:

A. Whether all considerations in Table 4 should be addressed or whether it is best to carry out the risk analysis first (Table 5) which will then determine the nature of the information required.

[5] http://www.nres.npsa.nhs.uk/applications/apply/is-your-project-research/

B. The level of detail required in response to the questions in Table 4
C. The exact process employed for the level of approval required (which is the result of the risk assessment in Table 5)

Those completing the table should check with the clinical governance office for the relevant NHS organisation what other review arrangements or sources of advice might apply to the project. For example, there may be standard guidelines on the conduct of clinical audit. The Caldicott Guardian will be a source of advice on the use of patient data.

Table 4: Ethical considerations for non-research projects

1. *What is the purpose of the project?* 1.1. Why are you doing it? • Have you looked at the evidence? • Did the stakeholders request the project? 1.2. Who will benefit? 1.3. How will the information generated be disseminated and used?
2. *How will you carry out this project?* 2.1. What is your approach, method or strategy? 2.2. Why is the approach, method or strategy appropriate? 2.3. How will you know when to end the project? • How will you know when you have obtained enough information for your project? • What is the capacity for further work? • Will the outcomes be sustainable?
3. *How will you ensure that the process used to select people and organisations is appropriate?* 3.1. Why will you approach certain people and organisations rather than others? 3.2. How will you approach people and/or organisations to participate?
4. *How will you respect the rights of people and organisations?* 4.1. How will you ensure that the data collected is necessary for the project? 4.2. How will you obtain and store information? 4.3. How will you ensure, where necessary, that data is anonymised?
5. *Which people and organisations do you need to obtain formal agreement from?* 5.1. What do you need before the project starts? 5.2. If agreement is needed describe how you will obtain it? 5.3. Will people and organisations be able to withdraw, and if so, how?
6. *What have you done to Identify and minimise risks?* A drop down list of the questions outlined in Table 5 :

Table 5: Risk Analysis

Does your project involve...?

[6] adapted from http://www.ahfmr.ab.ca/arecci/tool/

1. Likelihood that a breach of confidentiality could place participants at risk of legal liability, denial of insurance or other damage to financial standing, employability, or reputation?

There is widespread agreement about the rights of individuals to privacy and the corresponding duty of investigators to treat private information in a respectful and confidential manner. This item assesses whether the current project is higher risk with respect to the protection of privacy and the consequences for the participant should confidentiality of that private information be breached.

While the best protection of the confidentiality of personal information and records is through anonymity, when that is not possible project leaders should indicate the extent of the confidentiality that can be promised to participants and the countermeasures that are put in place to mitigate/ease the response should it occur. These should be clearly outlined on the consent form and during the consent process, including a plan to limit access to and provide secure storage of the private information for a specified period of time and with a specific plan for its destruction at the end of that timeframe as appropriate.

2. Questions or procedures that might cause participants psychological distress discomfort or anxiety beyond what might be expected in day to day interactions with others?

For example, questions that raise painful memories or unresolved emotional issues or procedures that involve manipulation in some manner may be anticipated to potentially cause discomfort, anxiety or distress in participants. Project leaders should anticipate all potential reactions that may be triggered by such questions or procedures, and include counter measures designed to reduce the magnitude of the potential response or ease the response should it occur. Having appropriately trained personnel administer the questions or procedures and providing appropriate support and resource contact information are but a few of such countermeasures. The need for informed consent should be considered and potential risks need to be identified to participants with a description of how these risks will be reduced or eased.

3. Questions that involve sensitive issues such as sexual orientation or practices, illegal behaviour, stigmatizing conditions or diagnoses, religious or cultural beliefs or practices?

Questions that touch on these and other sensitive issues may be anticipated to potentially cause participants to be cautious in how they respond. This private information once collected may have consequences beyond the project that need to be anticipated in advance. Countermeasures to protect privacy and confidentiality which minimize (reduce or curtail the magnitude of the potential response) or mitigate (ease the response should it occur) any potential negative impacts on participants should be built into the plan. How to handle consent needs to be carefully thought out in the context of the specific project. Appropriately trained personnel collecting the information and linkage to appropriate support resources are examples of countermeasures.

4. A power relationship between the investigator and participants (e.g., manager/employee, therapist/client, teacher/student)?

If in the institutional context in which the project will be carried out, undue influence is present by virtue of the trust and dependency that exists in power relationships, participants may feel restricted in how free they are to participate or withdraw from participation. Relationships such as manager/ employee, health provider/patient and teacher/student are particularly fraught with power imbalances and these need to be considered carefully in the design of the project to ensure confidentiality of private information and protection from any potential retribution. These should also include consideration of potential perceptions by the participant that may affect their responses. The design ought to include countermeasures that reduce any form of coercion over participants. In the case of the manager/employee situation, suggestions include having someone else as project lead and data collector with all data collected anonymised to the respective manager of the employees. All risks and the plan to counter them should be clearly outlined in the informed consent process.

5. A real or potential conflict of interest between an investigator and the sponsor of the investigation?

Any conflict of interest of this nature needs to be declared upfront and measures put in place to counteract any real or potential undue influence on any aspect of the project including data collection, analysis and reporting of findings.

6. Therapeutic and / or non-therapeutic risks or burdens for participants which are beyond what would be experienced in routine care or beyond what a reasonable person might expect in day to day interactions?

Examples of risks for participants include physical, psychological, spiritual, and social harm or distress. Examples of burdens over and above routine care or expectations in day to day interactions may include intrusiveness, discomfort, or embarrassment.

7. A person who does not normally have access to participant records for clinical care; whose use of records is for a secondary purpose?

This item assesses the current project in relation to this higher risk situation: someone outside of the usual providers of programming, care or service has access to personally identifying information. Further to that, this individual(s) is collecting this data for purposes other than the original intent of its collection in routine care, programming or service. It is important to ensure that safeguards are in place to protect against any breach of the privacy and confidentiality of personal information. Consult the appropriate articles in the Health Information Act or other legislation in your province. Consider doing a privacy impact assessment and an ethics consultation to ensure appropriate protections.

8. Risks of breaching the confidentiality of any individual's personal information beyond that experienced in the provision of routine care or day-to-day life?

For example, a letter, fax or e-mail to a participant that includes sensitive information. The risk here is that using these methods to transmit private information about participants may have the potential to breach their confidentiality. Consider the need for informed consent to be transparent about the risks involved and to inform participants how you will safeguard the privacy of their information.

9. Special populations or any individuals or groups in a socially vulnerable position?

Special populations include but are not limited to pregnant women, children, frail elderly, prisoners, refugee claimants, students, and staff. Examples of individual behaviours that may contribute to vulnerability include but are not limited to perception, cognition, motivation, identity, language, communication, social behaviour and cultural beliefs or practices. Ethical obligations to vulnerable individuals and populations often require special procedures to protect their interests.

10. Issues relating to items highlighted in the Caldicott principles, personally identifiable data, documents, records or specimens originally collected solely for purposes not related to the current study?

Projects that propose to use such data originally collected for purposes not related to the current study (e.g., chart reviews) need to include safeguards to protect against any breach of the privacy and confidentiality of these individuals. As well, there may be consent issues with respect to the individuals from whom the data was originally collected and to be respectful, informed consent ought to be part of the project plan. See also the appropriate articles in the respective Health Information Act of your province, if the information collected is health related.

11. Personally identifiable data, documents, records or specimens originally collected solely for purposes not related to the current study?

Projects that propose to use such data originally collected for purposes not related to the current study (e.g., chart reviews) need to include safeguards to protect against any breach of the privacy and confidentiality of these individuals. As well, there may be consent issues with respect to the individuals from whom the data was originally collected and to be respectful, informed consent ought to be part of the project plan.

12. Collection of data from voice, video, digital or image recordings? The risk here is that using these methods to collect private information from participants may have the potential to breach their confidentiality by revealing their personally identifying information. Consider the need for informed consent to be transparent about the risks involved and to inform participants how you will be protecting the privacy of their information. Who has access and secure storage of the private data are also important considerations in the project plan.
13. The use of tests, survey procedures, interview procedures, oral history, focus groups or observation of public behaviour where the participants can be identified directly or indirectly through the information recorded? Tests can include but are not limited to cognitive, diagnostic, achievement, and aptitude. The risk here is that using these methods to collect private information from participants may have the potential to breach their confidentiality by revealing personal information. Consider the need for informed consent to be transparent with participants about the risks of their involvement and to inform them how you will be protecting their privacy. Appropriately trained personnel to collect the information and appropriate plans for access and secure storage of the private data are also important components of the plan.
14. Collection of data through non-invasive procedures routinely employed in clinical or other settings? Examples of non-invasive procedures routinely used in clinical care include In BP, Ht, Wt, TPR and ECG readings.
15. Student projects? There may be potential for greater risk in projects where students are involved because students can sometimes lack the experience or skills needed to carry out projects and may potentially in some cases not have the supervision needed to overcome these lacks which can increase the risk to participants.

Stage 3: Resultant action

	You should …	Details
"Yes" answers to any of questions 1-8 in Table 5 indicate that the project is relatively high risk	Carry out a review consistent with local policies	"Review" means independent ethics scrutiny by a group or individual(s) who are removed from the project, but who understand its context[7]. The data generated from the responses to the questions in Table 4 should be provided to the reviewer(s). The specific setting determines how full review will be operationalised.
"Yes" answers to either question 11 or 12 in Table 5 indicate that the project is somewhat more than minimal risk	Take advice consistent with local policies	"Advice" here relates to the specific issues raised by the responses to questions 11 and 12. I t may be obtained from an independent person in the organisation.
"Yes" answers to any of questions 13-15 in Table 5 indicate that the project is minimal risk.	Use the ethical considerations (Table 4) to ensure that all aspects have been considered	This level of risk requires only self-assessment, unless local policies dictate otherwise.

[7] It is expected that this person would be from the same organisation or health economy, since they would be the most likely to understand the context of the project. They do not have to be experienced in research.

References

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Appendix 1: Differentiating Research, Clinical Audit and Service Evaluation[8]

	RESEARCH	CLINICAL AUDIT	SERVICE EVALUATION
a.	The attempt to derive generalisable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them.	Designed and conducted to produce information to inform delivery of best care.	Designed and conducted solely to define or judge current care.
b.	Quantitative research – designed to test a hypothesis. Qualitative research – identifies/explores themes following established methodology.	Designed to answer the question: "Does this service reach a predetermined standard?"	Designed to answer the question: "What standard does this service achieve?"
c.	Addresses clearly defined questions, aims and objectives.	Measures against a standard.	Measures current service without reference to a standard.
d.	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.)
e.	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 simple interview or questionnaire.	Usually involves analysis of existing data but may include administration of simple interview or questionnaire.
f.	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 groups: the health care professional and patient have chosen intervention before clinical audit.	No allocation to intervention groups: the health care professional and patient have chosen intervention before service evaluation
h.	May involve randomisation	No randomisation	No randomisation
	ALTHOUGH ANY OF THESE THREE MAY RAISE ETHICAL ISSUES, UNDER CURRENT GUIDANCE:-		
	RESEARCH REQUIRES RESEARCH ETHICS COMMITTEE REVIEW	AUDIT DOES NOT REQUIRE RESEARCH ETHICS COMMITTEE REVIEW	SERVICE EVALUATION DOES NOT REQUIRE RESEARCH ETHICS COMMITTEE REVIEW

[8] http://www.nres.npsa.nhs.uk/applications/apply/is-your-project-research/

Appendix 2: Ethics and quality improvement

There is a small but well developed body of knowledge on QI and ethics which continues to develop following high-profile cases (Kass et al., 2008). This questions whether existing ethical approval mechanisms, "designed largely with medical research in mind" (Kass et al., 2008, p.351) are appropriate for QI research (Baily, Bottrell, Lynn, & Jennings, 2006; Lynn et al., 2007).

A paper discussing the differences between QI and research, and the implications for ethical approval processes (Baily et al., 2006, p.s12) makes it clear that:

- It is possible to carry out research on QI without doing QI – this would clearly be defined as research e.g. retrospective study of QI in a variety of organisations. Such research helps to answer questions such as "*what are the principles of change?", "How do these principles work within different organisational contexts?"*
- It is also possible to combine research and QI into a single activity/project. "*For example, a health care organization with multiple delivery sites could conduct an activity in which the sites are divided into two groups, a different strategy is used in each group to introduce a new practice, and the results of the strategies are compared, with elements included in the activity's design to facilitate generalization of the results to other organizations.*" (Baily et al., 2006, p.S13).
- However, the most complex activity is something that is both QI AND research: "*systematic, data-guided activities designed to bring about immediate local change are also investigations designed to develop or contribute to generalisable knowledge*" (Baily et al., 2006, p.S12).

Projects that are both QI and research might have some of the following characteristics

- Randomisation of patients into different intervention groups
- Testing of issues beyond current science/experience e.g. new treatments
- Involvement in projects of researchers with no ongoing commitment to the improvement of the local care situation
- Delayed or ineffective feedback of data from monitoring the implementation of changes
- Funding from an outside organisation with a commercial interest in the use of the results

These would have to be regarded as 'research' for the purposes of ethical approval.