Whilst this article was originally written for the written submission as part of the old summative assessment exam for general practice, it is still relevant for projects/audits submitted under Naturally Occuring Evidence (NOE) for nMRCGP

Ethics And The Written Submission: Recommendations

There is an important conceptual difference between whether a piece of "research" formally requires ethical review (which is a regulatory issue) and whether there are significant ethical issues which need to be considered (which is a "good practice" issue).

It is recommended that all GPRs planning to submit written work for summative assessment should write a brief but formal protocol at an early stage which includes identification of the ethical issues, and to discuss this with colleagues - and perhaps the local LREC chair. This is to ensure that the rights, safety, dignity and well-being of the subjects of an audit or NPMS project are protected. Steps to ensure that there is no coercion of subjects to participate, no burden placed on them, and no risk to confidentiality, should be described in this protocol.

LREC approval is **not required** for:

1) A straight-forward audit that contains no patient-identifiable data, and has a methodology that does not involve going back to the patient for additional interviews or questionnaires
2) Questionnaire studies in which participants are randomly invited to participate on an "opt-in" basis, and the questions do not involve confidential information, then REC approval is not required (eg leaving questionnaires in the waiting room about such issues as access, use of nurse practitioners etc)

LREC approval **is required** for:

1) Questionnaire studies in which participants are selected and approached on the basis of confidentially held information (e.g. they have a particular diagnosis).
2) Research projects

If there is doubt about whether a particular piece of work requires ethical approval then the GPR should contact the chair of the LREC, or COREC for a decision. The result of this enquiry should be included in the written report. Neither Deanery staff nor the National Office of Summative Assessment are competent to make this judgement.

Suggested Text for NOSA website

Ethics and the written submission

All forms of written submission, whether COGPED audit or NPMS, may relate to or contain confidential patient data. From the ethical point of view there are two separate considerations that need to be made.

1) One is the question of good practice: i.e. what steps have been taken to protect the confidentiality of participant, and does the audit or project pose any threat to the rights, safety, dignity and well-being of the subjects?

   It is recommended that all GPRs planning to submit written work for summative assessment should write a brief but formal protocol at an early stage which includes identification of the ethical issues, and to discuss this with colleagues - and perhaps the local LREC chair. This is to ensure that the rights, safety, dignity and well-being of the subjects of an audit or NPMS project are protected. A sample protocol is provided [LINK]

2) The other is whether ethical approval should be obtained before the audit or project is undertaken.

   LREC approval is **not required** for:

   - A straight-forward audit that contains no patient-identifiable data, and has a methodology that does not involve going back to the patient for additional interviews or questionnaires
   - Questionnaire studies in which participants are randomly invited to participate on an "opt-in" basis, and the questions do not involve confidential information, then REC approval is not required (e.g. leaving questionnaires in the waiting room about such issues as access, use of nurse practitioners etc)

   LREC approval **is required** for:

   - Questionnaire studies in which participants are selected and approached on the basis of confidentially held information (e.g. they have a particular diagnosis).
   - Research projects

   If there is doubt about whether a particular piece of work requires ethical approval then the GPR should contact the chair of the LREC, or COREC for a decision. The result of this enquiry should be included in the written report. Neither Deanery staff nor the National Office of Summative Assessment are competent to make this judgement.

Suggested protocol

1) Does your audit or project involve the collection and description of data from individual patients?

Yes ☐ No ☐

If you answered "Yes" describe what steps you have taken to ensure that patient confidentiality is protected.

2) Does your audit or project use a methodology that involves approaching patients for interviews or completion of questionnaires?

Yes ☐ No ☐

If you answered "Yes" then proceed to question 3

If you answered "No" then proceed to question 4

3) Are patients to be approached on the basis of confidential information, such as a diagnosis?

Yes ☐ No ☐

If you answered "Yes" to questions 2 and 3 then ethical approval from your Local Research Ethics Committee is required.

4) Is your written work in the form of an audit, discussion paper, plan for new service, notes review, clinical case study, or literature review?

Yes ☐ No ☐

If you answered "Yes" then ethical approval from your Local Research Ethics Committee is **NOT** required.

5) If you are planning a questionnaire study in which participants are randomly invited to participate on an "opt-in" basis, and the questions do not involve confidential information, then REC approval is not required (e.g. leaving questionnaires in the waiting room about such issues as access, use of nurse practitioners etc)

6) If you are planning a research project ethical approval will normally be required.

7) If you are unsure about whether ethical approval is required, contact the chair of you LREC or alternatively contact the Central Office of Research Ethics Committees http://www.corec.org.uk/