

School of Medicine Ethics Committee Miscellaneous Policies:

Requirements for School of Medicine Ethics Committee approval for educational studies involving School students or staff

Quality Assurance and Evaluation vs. Medical Education Research

This guidance has been produced by the School of Medicine Ethics Committee in response to the uncertainty regarding the need for ethics committee approval for projects which are concerned with aspects of the teaching, learning, educational activities or attitudes of School of Medicine students.

1. **Curriculum evaluation.** Evaluation is a core requirement of all university courses. All medical courses are required by the GMC to undertake course evaluation. In the case of the Keele undergraduate medical course, students, on entry to the course, sign the medical students' charter (<http://www.bma.org.uk/ap.nsf/Content/medschcharter>), which includes a statement "the student undertakes to provide feedback on the usefulness, significance and effectiveness of all aspects of the course, including teaching".

Evaluation and research activities within the School are performed within an ethical framework informed by the Research Ethics Frameworks (REF) of the Department of [Health's](#) National Research Ethics Service:

(<http://www.nres.npsa.nhs.uk/>)

the funding Councils (e.g. that published by the Economic and Social Research Council:

(http://www.esrcsocietytoday.ac.uk/ESRCInfoCentre/opportunities/research_ethics_framework/).

and the professional bodies (e.g. that published by the BMA):

<http://www.bma.org.uk/ap.nsf/Content/HubProfessionalIssuesandEthics>

Appendix I summarises key aspects of this framework.

Where a project is an evaluation of an aspect of the curriculum which is a routine part of quality assurance, no ethics committee approval is required. Examples would include student questionnaire evaluation of aspects of the

curriculum or of curriculum changes. Where the evaluation includes additional student inputs, such as student interviews or focus groups, participation by the students must be voluntary and students must give consent to participate according to SoM ethics Committee guidelines.

2. If data arising from the activities described in (1) above are submitted for publication in journals or presentation at meetings, formal ethics committee approval is not required, with the following provisos:
 - a. In the case of questionnaires, the questionnaire must contain a sentence to the effect that data arising from the questionnaire may be used for research and submitted for publication. The Chair of the SoM Ethics Committee will make sure that this guidance on consent on use of data from questionnaires is also included in the student handbook.
 - b. All published student data must be made anonymous – that is, not traceable to individual students. This must be stated within the rider described in 2a, above.
 - c. In the case of interviews or focus groups, the consent form must include information as in 2a and 2b, above.
 - d. If data arising from an evaluation is to be published, it must be sent to the chairman of the School of Medicine Ethic Committee for confirmation that the study meets the criteria for evaluation, not research, prior to submission for publication.
If these provisos are met, when submitted for publication, the article may include a sentence: “The procedures for securing the participation and safeguarding the well-being of student / staff who took part in this evaluation study fulfilled the requirements of the Keele School of Medicine Ethics Committee, and written confirmation of this has been provided by the chairman of that committee”

3. **Educational research.** Where a proposed project involves a study of any aspect of student learning or teaching which is not part of the normal quality assurance activity of the School, formal School of Medicine Ethics Committee approval is required. Examples of such projects include research into a new educational intervention not incorporated as part of the curriculum, any intervention in which it is proposed to randomise students, observation or assessment of student learning which is not a normal part of QA e.g.

additional questionnaires or focus groups or observation or videotaping of tutorials. Where there is any doubt, the School of Medicine Ethic Committee can advise.

4. Monitoring the extent and scope of evaluation activity

The Director of Undergraduate Programmes is responsible for overseeing evaluation activity and associated plans across the school. S/he is also responsible for ensuring a standard code of practice is in place, which sets out clearly how the scope and extent of evaluation activity is set across the School, and clarifies the process for being given permission to carry out evaluations or access data from evaluations.

5. Appendix I

The six key principles of ethical research that the ESRC expects to be addressed, whenever applicable:

1. Research should be designed, reviewed and undertaken to ensure integrity and quality.
 2. Research staff and subjects must be informed fully about the purpose, methods and intended possible uses. Of the research, what their participation in the research entails and what risks, if any, are involved.
 3. The confidentiality of information supplied by research subjects and the anonymity of respondents must be respected.
 4. Research participants must participate in a voluntary way, free from any coercion.
 5. Harm to research participants must be avoided.
 6. The independence of research must be clear, and any conflicts of interest or partiality must be explicit.
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- The responsibility for conduct of the research in line with relevant principles rests with the principal investigator.
 - The responsibility for ensuring that research is subject to appropriate ethical review, approval and mentoring lies with the institution which should have clear, transparent, appropriate and effective procedures in place for ethical approval whenever it is necessary.

Adapted from Research Ethics Framework, Economic and Social Research Council
http://www.esrcsocietytoday.ac.uk/ESRCInfoCentre/opportunities/research_ethics_framework/.

Guidelines for informed consent procedures for students or staff who participate in Medical Education Research projects

There are similar ethical concerns around the recruitment of students and staff for research projects in medical education. The principal risks for a volunteer in such a research study include perceived, or actual, coercion to participate, unreasonable demands on time and breaches of data confidentiality.

All studies that require direct participation by research volunteers require valid consent to be obtained. For consent to be valid the decision to participate must be based on an informed judgement, be free of coercion and the participant must be free to withdraw at any time.

Information given to volunteers (including those who volunteer only for their data to be used for research purposes, in addition to Quality Assurance / evaluation purposes) should include clear statements that address the following points:

- What happens if I agree to take part?
 - It should be clear to the participant which activities, if any, are a normal part of any ongoing course evaluation and which activities are conducted as part of the research project.
- What happens if I choose not to take part?
 - This should include a clear statement that, for students, their education and training will be unaffected and, for staff, their employment and working will be unaffected if they choose not to take part.
- What happens to my data?
 - Ideally, researchers should include details of how research findings may be fed back to research participants
- What happens if I withdraw from the study?
- Who should I contact for further information?
 - To include the researcher's contact details and, in the case of any concerns the Chair of the School of Medicine Ethics Committee as a contact point

Written consent is required for any face-to face interviews, focus group activities or observations of small group teaching sessions. For questionnaire-based research, implicit consent, based on completing the questionnaire, would normally be sufficient. Observation of large group activities (e.g. lectures) may not require individual consent – subject to ethical approval.

Separate consent is not required for research based around ongoing teaching activities & evaluations or for retrospective data analysis. Ethics project approval will still be required for such studies. Note that some forms of teaching evaluation may still require explicit consent.

Guidelines for informed consent procedures for course evaluation

Course evaluation is recognised as a necessary and important part of the School of Medicine's activities – both in undergraduate and post graduate studies. It is part of the contract between the School and the student that they will participate in the evaluation of the course. However, all course evaluation must be conducted in line with the School of Medicine guidelines (see separate document); in particular, all evaluations must be conducted in consultation with the relevant module leaders and with the consent of the appropriate Programme Director.

Ethical issues for course evaluation are similar to those raised by education research studies. Evaluations should avoid perceived, or actual, coercion to participate, unreasonable demands on time or breaches of data confidentiality.

As evaluations form a routine part of student activities, any information given to students on the purpose of the evaluation is likely to be brief but should include an invitation, rather than an obligation to complete the assessment.

For questionnaire-based evaluation, implicit consent, based on completing the questionnaire, would normally be sufficient. Written consent may be required for some face-to face interviews or focus group activities and this should be considered by the evaluators and by the Programme Director. For questionnaire-based evaluations, implicit consent, based on completing the questionnaire, would normally be sufficient. Observation of large group activities (e.g. lectures) would not require individual consent.

Accessing staff or students as participants in research in respect of their professional capacity.

This guidance refers to requests from within the School, Faculty and University or outside bodies to engage staff or students as subjects of research because of their particular role. The Medical School has a duty of care to its staff and students, which will be exercised by the School Ethics Committee for research projects which wish to recruit staff or students because of their professional role.

Normally there is no problem agreeing these provided certain conditions are met:

1. The School of Medicine Ethics Committee must approve all such projects
2. Projects have the relevant and documented ethical approval of the sponsoring organisation
3. Access to staff and students is focussed, non-disruptive and follows best practice guidelines (see below)
4. There is no element of coercion to participate
5. Appropriate consent measures are in place
6. As a matter of courtesy, participants are given feedback on project outcomes and are appropriately recognised in dissemination of the project
7. An undertaking is given to provide the School with a report on the research findings at the end of the project
8. There is minimal dependence on Medical School resources; limited administrative support may be available but cannot be guaranteed

Guidelines for accessing staff or students (see point 3 above):

- a. Opportunities may exist to discuss the study with the relevant group publicly (eg in the Lecture Theatre, before or after teaching sessions). Such approaches must not disrupt teaching sessions.
- b. Email and other approaches should be targeted to relevant groups.
- c. All data will be treated confidentially and, where possible, responses will be anonymous to the researcher.
- d. Any identifiable data should be anonymised by the researcher within a reasonable timescale, in line with Data Protection and confidentiality guidelines
- e. Posters should be displayed in agreed locations and will have an expiry date – after which they should be removed.
- f. Requests to participate will be distributed at the start of the project. Typically, there will be an opportunity to remind participants to return their response after two weeks; a further, email reminder may be sent after four weeks. Feedback on response rate will be required

- g. The relevant participants may be approached in a variety of media (e.g. face-to-face, at the beginning or end of teaching sessions, and with the agreement of the module leader; via email; via internal post).