Guidance for Schools on the Ethical Review of Research

About this guidance.

Ethical review (and approval) is required for all projects where the research involves participation of human subjects, their data and/or their tissue (even where the applicant indicates that there is only minimal risk). This document outlines the minimum expectations for Schools/Departments/Faculties for the composition of School, Department or Faculty Research Ethics Committees (hereafter referred to as RECs to encompass School, Department or Faculty Committees as appropriate) and associated processes.

Wording in **bold** indicates a minimum requirement by School/Faculty Research Ethics Committees. Writing not in bold recommends good practice. Writing in *italics* represents guidance on interpretation based on discussions at the Working Group, University REC and directly with Economic and Social Sciences Research Council (ESRC).

### Composition

- **RECs must be multidisciplinary and comprised of both men and women.** *Within small groups/Departments or Schools this may be hard to achieve – in this case it is recommended that groups join with others in the same Faculty to enable appropriate multidisciplinary mix to be achieved.*

- **RECs should include at least one lay member who is not a member of the School, Department or Faculty and is not a member of teaching or research staff.** Examples of appropriate lay members might include professional persons, individuals from funding agencies or charities, community leaders. *Some Committees may have School/Department/Faculty associated lay members already – e.g. from project advisors, Industrial Academic Boards etc. Other potential lay members may be non-teaching/research members of University staff external to the School/Dept/Faculty. Ideally lay members may already have an appreciation of research requirements or goals, but should not have a personal interest in the research itself. A typical term of office for a lay person would be three years, but this is up to individual Committees to decide as appropriate.*

- **RECs should have a minimum of seven people. This includes a Chair (appointed by the Head of School/Department or Dean if at Faculty level), a layperson, a representative from another Department, School or Faculty, and at least four research active members of the Department, School or Faculty. Overall the REC must have broad experience of and expertise in the areas of research regularly reviewed by the REC.** The members of the REC will ideally be taken from a range of seniorities and levels of expertise amongst staff. It is expected that RECs will be provided with the appropriate level of administrative support. *For smaller Schools, a Committee of seven may be difficult to establish, in this case it may be appropriate to refer to a Faculty Committee. The expertise of the members of the Committee will vary depending on the background and discipline- in some disciplines it is...*
reasonable to expect that most or all teaching and research staff will have had formal training in ethical review processes and issues, whereas in others this is less likely to be the case. If formal training or experience of ethics has not been received by Committee members then it is expected that they should undergo some form of training on ethical review process and issues – the Working Group is considering training provision for ethical review in association with the Graduate School.

**Frequency and format of meetings**

- **Committees are expected to meet face to face at least once a year.** Committees that are regularly reviewing research submissions that are more than a minimal risk may meet more regularly to share expertise and develop good practice. *In practice, most review is likely to take place via electronic communication, particularly in areas where there is a need for fast turnaround on large volumes of applications, and where there are standard protocols for dealing with routine challenges, such as working with children (in the School of Education) or storage of data.*

Good practice tip: The School of Education has transformed their existing procedures into a paperless electronic system. A link to their documentation for ethical review can be found [here](#).

**Process of review**

- **Ethical review (and approval) is required for all projects where the research involves participation of human subjects, their data and/or their tissue (even where the applicant indicates that there is only minimal risk).** For more detail refer to the University of Nottingham *Code of Research Ethics and Research Conduct* (pg. 7).

- **Minimal risk is defined as per the ESRC’s guidance (section 1.2.3, pg. 8 of ESRC’s Framework for Research Ethics 2010).** All applicants should identify if they consider their projects to involve minimal risk or more than minimal risk. This level of risk may be indicated via a checklist of some form as part of an ethical review submission. Examples of these checklists are provided on the Research Innovation Services (RIS) Research Ethics web pages and can be accessed [here](#).

- **The level and type of ethical review may vary, with the principal determinant for the type of review being the risks associated with the project.**

  1. In the case of Undergraduate and Postgraduate Taught course projects, it is acknowledged that many student project programmes may involve large numbers of projects of minimal risk. If the REC deems it appropriate, a supervisor or module convenor may approve Undergraduate and Postgraduate taught project work where they are confident that the project is of minimal risk. In these cases, the supervisor or module convenor is responsible for ensuring that the project follows standard procedures that adhere to requirements of the ethics committee. If such standard procedures are not available, even if the project is of minimal risk, the proposal must be submitted for approval to the REC. The forms associated with all Undergraduate and Postgraduate Taught course project ethical approval (including those approved by a supervisor) must still be submitted via the normal REC process for purposes of audit and to allow confirmation that a correct judgement of minimal risk has been made. It is expected that ethical approval given to standard project procedures should be reviewed by the REC every three years as a minimum.
Policy for Ethical Review Process

2. For projects that are not Undergraduate or Postgraduate Taught projects, where an applicant has indicated that the research activity is of minimal risk this judgment must be confirmed by the REC (not the supervisor or the Principal Investigator of the project). This will normally be by ‘light touch’ review, by a minimum of two members of the REC.

3. Where a research activity has been judged to be of more than minimal risk, it must be reviewed by a REC. It is up to individual RECs to determine how a routine full review takes place – a minimum of two reviewers must consider each application. Some Committees may wish all, or particularly challenging, reviews to be viewed by all members of the REC. If a case is identified as raising particularly challenging or difficult issues then it is the Chair of the Committee’s responsibility to ensure that an appropriate level of review takes place – it is likely that such a proposal will require full review.

4. The Chair of the Committee is responsible for the appropriate selection of reviewers. All ethical review applications and decisions, including supervisor or module convenor approvals should be recorded. This could take the form of meeting minutes or an overview spreadsheet that summarises all decisions made, with any key issues highlighted. This is intended to support the process of completing the Annual Monitoring process and develop good practice throughout the University.

Good practice tip: In the School of English, all staff and students who are engaged in research involving human participants are required to follow the School protocol. In cases where students are collecting data as part of a taught module or student project, as long as the students are following the same protocol, the convenor may submit a protocol for the entire module. However, each individual student must submit the proper paperwork with their assessment, namely informed consent forms signed by each participant, to verify that the protocol has been followed. Failure to do so is considered a violation of the School protocol which results in the student failing the piece of coursework, and thus not receive a mark higher than 40.

Good practice tip: In the Faculty of Engineering, for the module "Human Computer Systems”, MM4HCI, students are provided with a series of “good practice tips” to support their coursework where they are required to evaluate a technology in use. The coursework specification itself has also been approved by the Faculty of Engineering Ethics committee, and students are able to view an electronic copy of the ethical approval documentation.

Good practice tip: The School of Psychology has designed a rota system for allocating reviewers to submissions in order to ensure that ethical review is completed quickly and equitably. A link to the School of Psychology’s guidance can be found [here](#).

Requirements of the ethics submission

- For undergraduate and postgraduate (both taught and research) student applications, the applicant’s research ethics review submission should be signed by the applicant’s supervisor in addition to the student themselves. For staff research projects, the Principal Investigator of the project must sign the research ethics submission. All applications must be submitted to the REC. If appropriate signatures are not included on an application form (submissions via University email can substitute for paper signatures) then an application should not be considered by a Committee and approval should not be granted.

- Forms may be submitted electronically, and submission/reply from a University of Nottingham email address can be used in place of a paper-based signature.
Good practice tip: The Medical School Research Ethics Committee has a useful material accessible via the RIS webpages that contains structured submission documents and guidelines to help individuals to write their ethics proposals. The guidelines, in particular, highlight issues that need to be considered regarding major risk factors associated with clinical research, and what is required of the experimenter to address these.

Good practice tip: Comprehensive guidance for ethical review from the School of Sociology and Social Policy, as well as a copy of their detailed review documentation can be found here.

Location of Committees

All Schools/Departments/Faculties have access to a Committee (or Committees) to which they submit their proposals. The University of Nottingham in the UK does not have a central Committee that reviews ethics applications (in particular, the Graduate School does not have an ethics Committee). For the China and Malaysia campuses, central cross-faculty Committees are being set up. If you are unsure of the appropriate Committee for your submission, please consult your local School Research Ethics Officer, details of which can be found here, or alternatively contact Claire O’Callaghan in RIS (mailto:Claire.Ocallaghan@nottingham.ac.uk or telephone 0115 8466197).

Good practice tip: The Centre for Advanced Studies (CAS) has specific guidance for researchers preparing research proposals to the AHRC and ESRC which is accessible here.

These guidelines were produced by a Working Group appointed by the University’s Research Ethics Committee:

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