Ethical review of student research

Guidance for students, supervisors and Research Ethics Committees
# Ethical review of student research: guidance for students, supervisors and research ethics committees

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Ethical review of student research: guidance for students, supervisors and Research Ethics Committees

Introduction

1. Much research in health and social care settings is undertaken wholly or partly for educational purposes, either for the award of a doctorate or as part of the requirements for an undergraduate or post-graduate qualification below doctoral level.

2. The requirements for ethical review of health and social care research set out in the Governance Arrangements for Research Ethics Committees (GAfREC)\(^1\) do not distinguish between student research\(^2\) and research undertaken for other purposes. Student research involving human participants or their tissue or data may raise the same kinds of ethical consideration as any other research. Where student research is within the categories of research requiring ethical review either under the policy of the UK Health Departments or legislation, application is required to a Research Ethics Committee.

3. REC review must ensure that the same protections for the safety, rights, dignity and well-being of participants are in place whoever undertakes a particular research project. However, the Research Ethics Service recognises that student research:

   - Has significant educational value, including the training it provides for those who will go on to become the professional researchers of the future
   - May be undertaken to tight academic deadlines and requires support if these are to be met
   - May not necessarily be of the same scientific quality or importance as other professional research, though it may still contribute to knowledge or indicate areas for further study.

4. This document provides detailed guidance for students and their supervisors on applications for ethical review, and describes how RECs review student research to enable it to be undertaken safely and with due consideration for participants. It has been endorsed by the National Research Ethics Advisers’ Panel.

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\(^2\) The term “student research” is used in this document to mean any research undertaken wholly or partly for educational purposes. It is recognised that some such research is led by professional researchers and will have other aims.
Applications for ethical review

5. Applications for ethical review by RECs are made using the Integrated Research Application System (IRAS) at www.myresearchproject.org.uk. IRAS can also be used to generate other applications that may be required, in particular for permission from NHS care organisations (“R&D approval”). An integrated dataset has been developed between NRES, NHS R&D offices and other review bodies to simplify the preparation of applications and avoid unnecessary form-filling.

6. For applicants with no previous experience of IRAS, it is strongly recommended that they begin by looking at the free e-learning module available from the IRAS home page. This provides an accessible introduction to the design of IRAS and a step-by-step guide to creating an IRAS account and getting started.

7. Further guidance is available within IRAS either by clicking on the information icons next to each question (“question-specific guidance”) or from the Help page.

Getting help with applications

8. Before starting to complete an application, student researchers should identify a lead R&D office for their study and seek their advice on the approvals and permissions required. This may be the R&D office at the NHS care organisation where the research will mainly be conducted, or the research governance office for their educational institution.

9. Where applicants experience technical difficulties using IRAS, they should contact the IT Helpdesk by emailing helpdesk@infonetica.net or calling 0207 099 2015.

10. Other general queries or feedback about the design, content or use of IRAS may be sent to iras@nres.npsa.nhs.uk.

11. Specific queries about applications to particular review bodies should be directed to the review body concerned using the contact details at https://www.myresearchproject.org.uk/Help/Contact.aspx. Queries relating to the REC application form or the process of ethical review can be raised either with the REC office to which the application will be submitted or sent to the NRES Queries Line at queries@nres.npsa.nhs.uk.

12. Detailed guidance on information sheets and consent forms for study participants is available on the NRES website at http://www.nres.npsa.nhs.uk/applications/guidance/consent-guidance-and-forms/. Student applicants should take careful note of this guidance when preparing study documentation for submission.
Completing the IRAS Project Filter

13. The Project Filter in IRAS asks a series of questions about the project in order to generate the appropriate application forms and questions in the integrated dataset. Correct completion of the Filter is essential for the preparation of valid applications and applicants are recommended to consult the question-specific guidance carefully.

14. One of the questions in the Filter asks whether the project, or any part of the project, is being undertaken for educational purposes. Answering Yes to this question ensures that the integrated dataset includes relevant details of the student, course and supervisor for the information of the REC and other review bodies. Other than these details, answering Yes does not affect the integrated dataset. The forms and questions generated in IRAS will depend on the type of research being undertaken and the procedures involved rather than the purpose for which it is being conducted.

15. It is important to note that the Filter question should still be answered Yes where the educational component is only one aspect of a project being conducted by a professional research team.

Appointing the Chief Investigator

16. Under paragraph 3.6.1 of the Research Governance Framework for Health and Social Care (RGF)\(^3\), the sponsor of a research study is responsible for ensuring that an appropriate senior individual is designated as the Chief Investigator (CI) for any research undertaken in or through the NHS or social care services, or using participants’ organs, tissue or data. The CI normally takes responsibility for the conduct of single-site research or for co-ordinating research undertaken at more than one site. Paragraphs 3.6.3 of the RGF set out in full the responsibilities of Chief Investigators.

17. Particular considerations apply to the appointment of the CI for a student research project as the student may not have the experience and expertise required to undertake this role. The sponsor and host organisation will be responsible for agreeing the most appropriate arrangements in each case. The REC will normally follow the advice from the R&D office(s) involved.

Studies not undertaken solely for educational purposes

18. It is recognized that students may participate as research team members in studies that are not purely educational. In this case, the CI will be another experienced researcher such as a health or social care professional or academic researcher.

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Studies undertaken for doctoral awards

19. Where the primary purpose of a study is to fulfil the requirements of a doctoral award, the student may have sufficient experience to be able to take full responsibility for the design and conduct of the research. If the sponsor, who will normally be the higher educational institution, appoints the student as Chief Investigator, this should be supported by the REC provided that appropriate supervision arrangements are in place. However, appointment of the CI remains a matter for the sponsor, taking into account factors such as the student’s experience, the type of supervision arrangements in place, the nature of the study and any risks involved. In some cases, the sponsor may consider it more appropriate for the academic supervisor to take on the role.

Projects undertaken for awards below doctoral level

20. Where projects are undertaken by a student in fulfilment of educational awards below doctoral level, it is normally expected by the Research Ethics Service and R&D offices that the academic supervisor will take on the role of Chief Investigator.

21. Exceptionally, a non-doctoral project may be undertaken by an experienced researcher working towards a further degree. In this case, it would be appropriate for the student to be named as the CI.

Role of clinical supervisors

22. For many student projects, the person appointed as Chief Investigator will also be named in the Site-Specific Information (SSI) Form in IRAS as the local Principal Investigator responsible for the conduct of the research at the research site. The SSI Form is submitted to the NHS R&D office as part of the application for management permission to undertake research at NHS sites.

23. However, where a study is undertaken as part of a clinical placement, the student should seek advice from the NHS R&D office on the role of the student’s clinical supervisor within the study, and this may need to be discussed between the care organisation and the sponsor. Where the project is a clinical trial or investigation involving novel interventions, the R&D office for the NHS care organisation may advise that it would be more appropriate for the clinical supervisor to be appointed as the local Principal Investigator, and in some cases even as the Chief Investigator. Alternatively, it may be appropriate for some of the responsibilities of Chief/Principal Investigator to be delegated from the academic supervisor (while remaining formally the CI/PI) to the clinical supervisor. Arrangements for delegation should be recorded in the SSI Form.

Responsibility for preparing the REC application

24. Where a project is mainly undertaken for educational purposes but the student is not named as the Chief Investigator, the student may still complete the REC application form.
on behalf of the CI as part of their training. If a favourable opinion is given, it is expected the student will undertake the research under supervision by the CI.

Supporting information

25. REC applications should include details of the student, educational course and academic supervisor at Question A2-1 in IRAS. Exceptionally, an application may be submitted without the details of the student being available.

26. A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted to the REC and R&D office(s) with all applications for student research. A standard CV template is available in IRAS under My Account. Where more than one student is involved in the project, additional students may be named as key collaborators at A63 in IRAS and CVs should be provided. Further information may be provided in a covering letter if necessary.

27. Exceptionally, it may be necessary for a supervisor to submit an application in advance, prior to allocating the project to particular student(s), so that the outcome of the ethical review is available by the time the project must start. In these circumstances, it is acceptable for the application not to provide details of the student(s) concerned, on the understanding that these will be notified to the REC before the research starts. The REC may make this a condition of a favourable opinion for the research.

28. All applications to RECs should enclose a research protocol or equivalent document. This is a self-contained document describing the objectives, design, methodology, statistical considerations (or other methods of data analysis) and organisation of a research study. In the case of student research, a copy of the project proposal or assignment may be an appropriate document. It should carry a date and version number in case it is necessary to make changes following review or during the project.

Insurance and indemnity arrangements

29. The sponsor of a research study is responsible for ensuring that adequate insurance and indemnity arrangements are in place to meet the potential liabilities of all parties involved in the management, design and conduct of the study. It is essential that these arrangements are clearly described in the REC application form. Detailed guidance is available in the question-specific guidance within IRAS.

30. In the case of student research undertaken primarily for educational purposes, the sponsor will normally be the Higher Educational Institution (HEI). Student applicants should seek early advice from their research governance office on the institution’s employers’ liability insurance or other existing insurance and whether this would provide cover for the proposed study. (Employers’ liability would apply to the student’s academic supervisor who is employed by the HEI.) For some studies, particularly interventional trials, the HEI may need to take out additional insurance cover. The applicant should
indicate in answer to the questions in IRAS which liabilities will be covered by the HEI, what type of policy will apply (whether employers’ liability or trial-specific insurance) and the financial limit of the cover. A copy of the insurance certificate should be provided with the REC application if at all possible. Exceptionally, the REC office may accept the application without the certificate; if so, it will require that the certificate is provided before the study starts as a condition of its favourable opinion.

31. Where the research team includes NHS staff, e.g. clinical supervisors, the HEI research governance office and the NHS R&D office may need to discuss how responsibilities for insurance and indemnity will be assigned. NHS Indemnity for clinical negligence may apply to some of the potential liabilities in the study and if so this should be made clear in the application form. No evidence of NHS Indemnity needs to be provided to the REC as this will be confirmed when NHS permission for the study is given by the NHS R&D office.

32. It is not necessary to provide any evidence of insurance or indemnity in the case of a study limited to processing of non-identifiable tissue or data, since the risk of harm to participants in such cases is considered negligible.

Responsibilities of academic supervisors

33. Under the Research Governance Framework, academic institutions sponsoring research within the NHS are responsible for ensuring that students are properly supported and supervised in the conduct of research.

34. Before a student submits any application for REC or other approval, the academic supervisor should assess the level of experience of the student, taking into account the scale of the research and the potential for harm to participants. A level of support should be provided reflecting this.

35. The academic supervisor should sign the declaration in Part D3 of IRAS for all projects undertaken wholly or partly in fulfilment of educational qualifications, and a copy of their CV should be included with all applications. The declaration provides assurance of:

- The scientific and ethical quality of the research proposal and the safety and well-being of participants.
- The ability of the applicant to conduct the proposed research.
- The availability of time and resources to achieve the proposed research objectives.
- Active and effective arrangements to monitor and assess the progress of the research (in liaison with clinical supervisors and others where appropriate).
- Appropriate arrangements to disseminate the findings of the research.
36. Where the academic supervisor also has the role of Chief Investigator, they should sign both the CI and academic supervisor declarations for the REC and R&D applications in IRAS. They should also sign the Principal Investigator declaration on the Site-Specific Information Form which forms part of the R&D application at each NHS site.

Attending the REC meeting

37. The REC normally invites the Chief Investigator to attend the meeting at which a research study is to be reviewed. The purpose of this is to be available to respond directly to requests from the Committee for further information, clarification or reassurance. In this way, many issues of concern to the Committee may be resolved at the meeting.

38. **In the case of any study undertaken mainly for educational purposes, it is highly desirable that both the supervisor and the student should attend the REC meeting wherever possible, whether or not the student is the named CI on the application.** Experience of attending REC meetings and discussing the ethical issues with REC members contributes to the training benefits of student research. The REC will take the student’s level of experience into account when asking questions about the purpose and design of the study and the arrangements for conducting it.

39. NRES considers the attendance of the supervisor at the REC meeting to be an important part of their responsibility both to support the student and to be available to discuss arrangements for supervision.

Proportionate review

40. NRES is currently piloting arrangements for proportionate review of research raising no material ethical issues. The proportionate review service (PRS) allows for studies meeting the criteria to be reviewed by a sub-committee of a REC, either at a meeting or in correspondence, and an opinion given within 10 working days. Further information is available at [http://www.nres.npsa.nhs.uk/applications/submitting-your-application/](http://www.nres.npsa.nhs.uk/applications/submitting-your-application/)

41. The criteria for PRS are related to the procedures involved in a particular research study and the risks involved, rather than who will be undertaking it. Student research is not in itself a criterion. However, many student research projects are likely to meet the published criteria and if so may benefit from the shorter timelines, enabling the research to start more quickly and be completed within academic deadlines. Student applicants are encouraged to consider whether their research would be suitable for PRS and if necessary to seek advice from the REC offices involved in the pilot.

42. Where research is submitted through PRS, the CI/student will not normally be invited to attend the REC meeting in the same way as for applications reviewed at full committee. However, the lead reviewer on the sub-committee may contact the CI/student informally to seek clarification about aspects of the application.
Considerations for ethical review of student research

43. Some student projects may not conform to the high scientific standards expected of health and social care research designed by trained professionals. However, the National Research Ethics Service recognises that the educational value of student research is an important and worthwhile goal in itself aside from any scientific value or other benefits to be derived from such research. The students of today will become the practitioners and professional researchers of tomorrow. The opportunity to undertake research is an important part of their training, providing an insight into the importance of evidence based practice and the methodologies of empirical research.

44. Therefore, even student research with little scientific value, or that which repeats research conducted previously, may still be considered to be ethical provided that the potential educational benefit is not outweighed by the risks, burdens or intrusions to the research participants.

45. However, the educational value to be gained from the conduct of student research needs to be “real” and thus student research must be carefully and rigorously designed in order to assure the REC that the intended educational goals are well-conceived and achievable. The academic supervisor should take full responsibility for this.

46. All research involving human participants may involve a measure of potential risk, burden, inconvenience or intrusion into privacy. The rights, safety, dignity and well-being of participants are as important in student research as in any other health or social care research, and the REC will expect the same standards of protection to be in place, such as the need for fair recruitment procedures, informed consent and adequate protection for personal data. As well as the need to minimise any potential risk or inconvenience, it is also important to avoid any loss of trust by patients and service users in the educational processes associated with health and social care, and the damage this could cause to future professional training.

47. When reviewing the participant information sheet, the REC will wish to ensure that the participants are informed about the educational goals of the research and understand that any benefit from the research, either for themselves or for science or the care of future patients and service users, may be limited. (Student researchers should consult NRES guidance on participant information sheets and consent forms - see paragraph 12.)

48. The consideration of the ethical issues involved in their research, which is required of students by the REC application process, may itself have an educational and training benefit for the student. The REC can help to realise this benefit by approaching the review in a facilitative and proportionate way, recognising the limited experience of the applicant and seeking to guide their understanding of what is expected.