Research Guide: research governance and ethics

Introduction

Ethics review and approval are fundamental components of research activity. Identifying the most appropriate process to obtain ethical approval for your study is not always straightforward and is influenced by the characteristics of the participants and where the research is taking place. The individual nature of most research projects means that there is no simple 'one size fits all' recommendation. This guide offers general guidance, rather than definitive advice, and signposting to resources where more detailed information can be found on ethics review and approval.

Key areas covered:

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1. Ethical principles

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research in the UK. These principles protect and promote the interests of people who access services and the public in health and social care research. It describes ethical conduct and proportionate management of health and social care research, to support and facilitate high-quality research in the UK.

The policy framework is for organisations and individuals that have responsibilities for health and social care research. This includes funders, sponsors, researchers and their employers, research sites and care providers. Failing to meet ethical, legal and professional obligations amounts to research misconduct and in some cases is unlawful (for example, when involving adults who lack capacity to give consent).

For further information on research and ethical issues we recommend the UK Research Integrity Office's (UKRIO) Code of Practice for Research - Promoting good practice and preventing misconduct . This reference tool supports researchers and research organisations to conduct high quality research. The Code provides principles and standards for researchers and research organisations to follow. The Recommended Checklist for Researchers provides a one-page checklist of the key points of good practice in research.

2. Research Governance in the United Kingdom

The UK Policy Framework for Health and Social Care Research has replaced the separate research Governance Frameworks in each UK country with a single set of principles for the whole UK – The Integrated Research Application System (IRAS). IRAS is a single system for applying for the permissions and approvals for health and social care/community care research in the UK. IRAS is aligned with the new UK Policy Framework for Health and Social Care Research. IRAS supports a single electronic submission regardless of which UK nation the lead R&D office is in. This change is part of the Four Nations NHS/HSC Compatibility Programme that aims to make the researcher experience of setting up a study the same across the UK.

All applications to conduct UK research in or through NHS/HSC organisations must use the IRAS system. The process for submission is the same regardless of which UK nation the research is led from, and whether NHS/HSC Research Ethics Committee (REC) review is required. However, as not all research conducted within the UK requires approval from an NHS REC; the Health Research Authority has produced a decision tool Do I need NHS Ethics approval? to help you to determine if your study requires this type of approval.

The decision regarding which ethics approvals are necessary for your proposed research activity is something that you as the researcher must determine in collaboration with your research supervisors and/or research team. In addition to an independent ethics review, you will need to consider other permissions that might be needed to enable you to carry out your research within specific organisations or locations. It is the responsibility of researchers, and sponsors of research, to decide which type of ethical review and approval is needed to meet statutory requirements.

It is crucial that you allow adequate time in the project timescale for obtaining ethics approval before your project can begin.

If your research involves doing the research on the premises of an NHS/HSC organisation, with NHS/HSC patients or with NHS/HSC staff, then you should always contact the local NHS/HSC research & development office as early as possible to discuss your research plans.

Step by step support is provided on the IRAS Website and their e-learning online guide on how to prepare and submit your IRAS application and REC review.

3. University ethics approval

If your proposed research is being undertaken in part fulfilment of an academic award (for example, BSc, MSc or PhD), the university that you are registered at will, in most cases, act as the research sponsor. This is also usually the case for research being carried out by university employees. University research governance processes are normally hosted by a central research office within each university, but individual faculties, schools, or research institutes may have their own ethics approval committee. Normally, where the proposal involves carrying out the research on the premises of an NHS/HSC organisation, with NHS/HSC patients or in some cases with NHS/HSC staff, the university will signpost you directly to the IRAS system. Once you have IRAS approval, evidence of this is then provided to your University Committee. We recommend that you find out about the process you will need to follow well in advance. Information about a university's procedures, forms/online submission requirements, and committee dates should be available from a research supervisor or the university website.

4. Health and social care research ethics approval

4.1 Health Research Authority (HRA) and NHS Research Ethics Committees

The purpose of the Health Research Authority is to protect and promote the interests of people who access services and the public in health and social care research. HRA approval brings together the assessment of governance and legal compliance, with an independent ethical opinion by a Research Ethics Committee (REC) so that you only need to submit one application. It applies across the UK where the NHS organisation has a duty of care to participants, either as people who access services or as NHS staff/volunteers. The HRA website provides the latest guidance on applying for ethical approval.

There are more than 80 NHS RECs across the UK. Their purpose is to safeguard the rights, safety, dignity and wellbeing of research participants. RECs consist of up to 15 members, a third of whom are 'lay' people. RECs review research proposals and give an opinion about whether the research is ethical. They also look at issues such as the participant involvement in the research.

A Central Booking Service is in place which covers all bookings for a review by NHS RECs in the UK. After preparing your application, contact the Online Booking Service - Health Research Authority to book onto a REC meeting.

Ethics reviews should be proportionate to the scale and complexity of the research proposed. Therefore, if your research does not present any material ethical issues, it may have a proportionate review by a sub-committee of a REC. Details on what constitutes ‘no material ethical issues’ and how proportionate approval can be requested are available on the HRA website.

Governance Arrangements for Research Ethics Committees (GafREC) is a policy document of the Devolved Administrations, the Health Research Authority and the UK Ethics Committee Authority. It describes what is expected from the research ethics committees that review research proposals relating to areas of responsibility of the Devolved Administrations and the Health Research Authority. It also explains when review by these committees is required. Further information about when a review by an NHS/HSC Research Ethics Committee is needed can be found here.

4.2 Research passports

A research passport is needed for non-NHS staff to obtain an Honorary Research Contract or Letter of Access (LOA) to enable them to carry out research in the NHS. The research passport system provides:

- one set of checks on a researcher conducting research in the NHS
- one standard form completed by the researcher and his/her employer and validated by an NHS organisation
- a completed Research Passport which is presented to all the relevant NHS organisations
- faster study start-up.

Application for a research passport is also made through the IRAS system and further information can be found in the IRAS HR Good Practice Resource Pack .

4.3 Social Care research approval

The HRA took over responsibility for research in adult social care in January 2015. Some RECs can review social care research, intergenerational studies involving adults and children or families and some proposals for social science studies situated in the NHS. Further details of the remit of social care RECs can be found here. Applications to RECs able to review social care research are also booked through the Central Booking Service as above.

Social care research does not require review by a social care flagged REC if it is reviewed by another committee abiding by the UKRI Economic and Social Research Council's (ESRC) Framework for Research Ethics, unless the research involves NHS patients, people who access services or people who lack capacity as research participants. Student research within the field of social care should normally be reviewed by a university REC (UREC).

4.4 Local approvals or permissions for research

Individual organisations may also have a process for giving approval and/or permission for research to take place. Any organisation where a researcher wishes to carry out their research can apply their own qualifying conditions, and it remains their choice to withhold access (for example, if they think the research is too disruptive or will not deliver benefits).

5. Research involving health or social care staff

Employers have a duty of care to their employees. RECs are not expected to assume employers' responsibilities or liabilities, or to act as a substitute for employers' proper management of health and safety in the workplace. It is for employers to ensure that they are fulfilling their duties as employers when their employees take part in research.

Governance Arrangements for Research Ethics Committees (GAfREC) (section 2.3.14) states that research involving staff, who are recruited by virtue of their professional role, does not require REC review except where it would otherwise require REC review under this document (for example, because there is a legal requirement for REC review, or because the research also involves patients or service users as research participants).

This means that REC approval isn't needed for researchers who only wish to recruit occupational therapists or health/social care professionals as participants. However, research only involving staff as participants still needs to have permission from the relevant health/social care organisation to take place and should still undergo some form of independent ethical review. A university ethics approval process will in many cases be the way in which this requirement is met, or through an ethics review panel set up by an individual organisation/institution. It is essential that you are familiar with the research governance and ethics approval process for the relevant organisation.

6. Research outside of statutory services

Research done outside of statutory health and social care organisations (for example, with a charity, in schools or in independent practice) must also have an independent ethics review. You must check with individual organisations what their requirements are before planning your research activity.

The ethics approval process may seem less clear where the research involves people receiving a service from a charity or voluntary sector organisation; via a social enterprise; third or independent sector service. GAfREC (section 2.3.5) states that REC review is required if a specific research project involves any of the following:

a. potential research participants identified in the context of, or in connection with, their past or present use of NHS or social care services (including services provided under contract with the private or voluntary sectors and participants recruited through these services as healthy controls). It excludes research where participants have been identified because they have a condition that was diagnosed by the NHS in the past but where the research is being conducted independently of the NHS for example, people with cancer which may have been diagnosed by the NHS but are identified from a cancer charity's contact list to be participants in a research project that is independent of the NHS.
b. potential research participants identified because of their status as relatives or carers of past or present users of these services.

If the service is not being provided through a relevant country Health Department, it is still important for a research project to have an independent review. This could be via a university ethics committee or individual organisational arrangement. If you are working in non-statutory or independent sector organisation you may have more difficulty finding an appropriate forum to undertake a review and you should ask your employer for advice.

If you are self-employed or an independent practitioner, other options might include:

- Obtaining advice from the HRA, for example, if there are substantial ethical issues and no access is possible to other review systems.
- Making enquiries with the organisation that you wish to recruit participants from (for example, charity, third sector organisation).
- Buying in consultancy expertise for an independent review.

6.1 Market Research

Market research may be undertaken by professional market researchers for public health research or on behalf of pharmaceutical or medical device companies. Where this research is conducted by professional market researchers and follows the principles set out in the Market Research Society Code of Conduct or with the Legal and Ethical Guidelines issued by the British Healthcare Business Intelligence Association (BHBIA), it does not require REC review, except where otherwise required by law, for example, if it requires approval under the Mental Capacity Acts (GAfREC section 2.3.15). However, other local organisational/institutional approvals may still be needed for permission to carry out the research.

Tips for applying for ethics approval:

- Allow plenty of time for the ethics approval process and any clarifications and/or revisions to your proposal that might be required before your project can start.
- There is a wealth of information on websites, such as the IRAS and HRA: explore and read all the guidance available before starting your application.
- Talk to a colleague who has been successful in making an application to an ethics committee and ask their advice.
- Ask your Trust or organisational R&D Department for advice.
- Keep records of any advice you receive about approvals and permissions required or not

required. This could be valuable in providing evidence in circumstances when REC approval is not required, but when information is necessary to support local permission requests or any future submission for journal publication and/or an abstract for a scientific conference.

References

Health Research Authority (2022) *UK Policy Framework for Health and Social Care Research.* London: HRA. Available at: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/uk-policy-framework-health-and-social-care-research/

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