Research ethics and approval process: A guide for new GP researchers

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Background

The underlying moral principles and values, and the virtues held as desirable for a researcher, should be reflected upon and embedded in the research. The foundation step is to download the National Health and Medical Research Council's (NHMRC's) *National Statement on Ethical Conduct in Human Research* and the NHMRC's *Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* to use as references.

Objective

This paper draws on the experience of The Royal Australian College of General Practitioners' (RACGP's) National Research and Evaluation Ethics Committee to provide an eight-step approach to the research ethics process.

Discussion

The researcher should use the research ethics process as an opportunity to foster and guide the development and conduct of ethical research.

Why have research ethics?

Researchers endeavour to gain, develop, generate, construct and improve upon ideas, knowledge and understanding.[1] Human research is 'conducted with or about people, or their data or tissue'.[1] The impact of the research on the lives of participants can raise ethical questions.

Scenario

'My registrar is conducting a project on general practice care plans. She plans to use data from my medical records, and interview patients and practice staff. I am interested and want to extend it as a whole-of-practice quality improvement and publish the findings. How do we start? Do we need ethics approval? Is this even research?'

How do I start?

General practice research can be immensely rewarding. For the new researcher, the initial steps can seem like stepping into another country – with a new language, different expectations and, importantly, research ethics. We suggest the following eight steps as a guide to the research ethics process. The foundation step is to download the National Health and Medical Research Council's (NHMRC's) *National Statement on Ethical Conduct in Human Research*[1] and the NHMRC's *Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*[2] as references on research in multicultural Australia.

1. Open a dialogue with your local vocational/university medical education staff

Seeking help and guidance at the beginning of the project is highly recommended. An ongoing relationship with experienced GP researchers from a local university, vocational training provider, or Medicare Local will help you to brainstorm research and ethical questions and troubleshoot problems. This support is essential to avoid any major flaws in your study. Wasting participants' time in a flawed study is inherently unethical.

2. Decide on your research question(s)

Research questions need to be clear, focused and answerable. It can be difficult to narrow down an exciting 'big idea' into a question that can be meaningfully researched. In this scenario, care plans and quality improvement are worthy goals, but not answerable questions. We need to consider the following:

- What aspect of care planning requires study?

- Are there gaps that require an intervention?
- What are the key concepts?
- How are these meaningfully measured?

Research questions determine the choice of measurement, methodology and analysis. For instance, the overall research question might be: 'What is the accuracy of the information in GP care plans?' This question immediately raises several issues that must be addressed, including the definition of 'GP care plan' and how these will be identified, and how 'information accuracy' will be measured.

3. Engage deeply with the ethical dimension of your project

Start by reflecting on the four traditional bioethics principles – respect for autonomy, non-maleficence, beneficence and justice.[3] Some questions to ask include:

- Who are the participants of the study and are there any who may be particularly vulnerable (eg employees of the researcher)?
- Is the research just and beneficial (eg fairness of the burden placed on the participants)?
- What are the local contexts and risks (eg a small rural setting or an Aboriginal community where participating patients and practice staff may be easily identified)?
- How will the biopsychosocial risks to participants and their families be minimised?
- Does the project engage the participants respectfully (eg respect their autonomy, privacy, confidentiality, values, cultural sensitivities and their communities)?
- Are there likely to be benefits to the community, especially vulnerable communities (eg will it build capacity in the Aboriginal and Torres Straits Islander community or workforce)?

Allow adequate time to prepare the research plan, including sufficient discussion of ethical issues among the research team, and with peers and academic colleagues. Human Research Ethics Committees (HRECs) can be approached for advice informally. This will guide the ethics review application.

4. Do I need ethics approval?

As a rule, all 'research' will need some form of ethics review. Routine clinical audits and quality assurance activities are not usually considered research[1] and may not require research ethics approval. However, the intent to publish findings in the scenario takes the study beyond 'routine' quality assurance practice. Seek advice when in doubt about the boundary between quality assurance and research.

> 'Quality assurance, evaluation and research exist on a continuum of activity … irrespective of whether an activity is quality assurance, evaluation or research, the activity must be conducted in a way that is ethical.'[4]

Exemptions from ethical review can be granted for research that carries negligible risk – where the only foreseeable risk from the research is no more than inconvenience (eg time spent filling out a survey).[1] Anything more than this (eg risk of discomfort) is not considered negligible risk.[1]

Table 1. Some practical issues from the NREEC

Waivers for participant consent
Waivers are usually indicated only in exceptional circumstances (eg when very significant public good is pitched against a difficult consent process, such as unfeasibly time-consuming).[1] Generally, researchers should consider offering participants the ability to opt-out, such as putting a notice in the waiting room of the practice.
Content of participant information and consent forms
A good participant information document is explicit and succinct. Simplified documents written to a 6th or 7th grade reading level have been demonstrated to improve participant understanding.[5] These documents should include: • title of the research study • list of the investigators • description of the study and intervention with a structured discussion of the risks and benefits • a list of the tasks associated with participation, including inducements • a statement that non-participation or withdrawal will not jeopardise any future or ongoing relationship with the research team specifically, or the organisation more broadly. The NMHRC provides standardised participant information and consent forms[6] as a guide at its online Human Research Ethics Portal (available at http://hrep.nhmrc.gov.au).
Protection of confidentiality
Anonymising participant data might not protect privacy if the individual can be identified by context. For instance, if the participants in the care plan research include the clinicians who created them, their privacy may not be protected if their clinician is the only practitioner in a particular location. This is also particularly relevant in the handling of genetic data.[1,7] The reporting of results from small datasets must be done with care.
Payment of participants
So long as the reimbursement for participants' time and costs is fair and proportionate (see *Section 2.2.10* of the *NHMRC's National Statement on Ethical Conduct in Human Research*),[1] most HRECs will not question the payment (eg $150 voucher for participation in a focus group). Ethical problems arise when payments are disproportionate, seen as coercive, encourage risky behaviour or are culturally inappropriate.[8]

Submitting ethics applications

5. Which committee do I submit to?

The Royal Australian College of General Practitioners' (RACGP's) National Research and Evaluation Ethics Committee (NREEC) is the only general practice-specific HREC in Australia. Research to be conducted in, with or

about general practice and primary care (eg study about GP care plans relating to the scenario) should have ethics approval from the NREEC.

GP researchers who are affiliated with a medical school (eg if the registrar has an academic supervisor or GPs who are conjoint or adjunct academics) can seek ethics approval from their university's HREC. This can sometimes be an advantage as research proposals considered low risk, where the only foreseeable risk from research is no more than discomfort (eg blood pressure measure, or the slight anxiety from an interview),[1] can undergo a simpler review process that does not involve the full HREC.

Research to be conducted in public health organisations such as hospitals also requires a formal site-specific risk assessment. Aboriginal health research will need approval from an Aboriginal and Torres Strait Islander-specific HREC.

6. Completing ethics application forms

Research proposals are usually submitted through the National Ethics Application Form (NEAF) (available at www.neaf.gov.au). This online structured questionnaire seeks detailed and comprehensive information regarding the research proposal. The application must be thorough as incomplete applications with missing required attachments will not be approved. The following needs to be clearly described:

- Information that will be provided to participants and the process for doing so. These must be adequate to constitute informed consent (eg drafts of participant information sheets, consent forms, recruitment advertisements).
- Mechanisms that will be put in place to protect the privacy and confidentiality of participants at all phases of the research (eg research protocol).
- Data collection mechanisms. These must be accurate and appropriate (eg drafts of survey instruments and interview schedules).
- Data storage and management systems. These must be secure and reliable.
- Plan for analysing, sharing and disposing of data. These must be appropriate.
- Plan to provide feedback to participants on the outcomes of the research.

Table 1 highlights some practical issues (and guidance) from the NREEC database.

Working together with HRECs

7. Responding to HREC comments

The NREEC, like other HRECs, reviews applications to ensure robust processes are in place to address ethical issues. Following discussions in the committee, projects are either approved or not, usually after clarifications or amendments. Some applications, especially from new researchers with no links to more experienced researchers, usually require substantial amendments. Final approval can be given 'out of session' if the issues were relatively straightforward and have been addressed appropriately.

When responding to an ethics review, address all the identified issues comprehensively. Clarify with the HREC if the feedback is unclear. Ensure submitted documents are clearly written, understandable, labelled and organised. This avoids delay due to reviewer misunderstanding. Include revised documents in both 'tracked changes' and 'changes accepted' formats. The cover letter must summarise the responses to each issue raised.

Note: Because many HREC members are usually experienced researchers, they may comment on the research methods, particularly if they are flawed. While this is an opportunity for an additional independent review of the study protocol, it must be remembered HRECs primarily provide ethical (not methodological) review. New researchers are strongly encouraged to seek help and guidance from local experienced researchers before submitting an ethics application.

8. Approved! What next?

HREC approvals are typically valid for 5 years. Data storage, which must be secure for all research materials (eg consent forms, data collection forms, computer files), is usually maintained for no less than 5 years. Researchers are required to inform the HREC of any study protocol deviation and adverse events experienced by participants. An annual progress report is also required.

Universities and research and public health organisations have research governance policies and procedures parallel to the HREC process, which is an advantage when conducting research within these institutions. In the case of this scenario, it may be reasonable to conduct the research project within the governance of the general practice. If you do, ensure practice and medical indemnity insurance covers research activities. It is also important to maintain relationships with more experienced researchers to anticipate any problems.

Remember the big picture in research ethics!

Compliance and standards prescribed in the NEAF are important. However, it is only a small part of becoming and being an ethical researcher. What underlies these procedures – moral principles and values, and the virtues held as desirable for a researcher – should be regularly reflected upon and embedded in the research methods, content and context. Use the research ethics process as an opportunity to foster and guide the development and conduct of ethical research.

> '… ethics guidelines are not simply a set of rules. Their application should not be mechanical. It always requires, from each individual, deliberation on the values and principles, exercise of judgement, and an appreciation of context.'[1]

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