RACGP Standards for general practices

Frequently Asked Questions for Criterion C3.6 — Research

What has changed in Criterion C3.6 – Research in the RACGP *Standards for general practices* (5th edition) (the Standards)?

Background

Changes to Indicator C3.6 ►A - Research in the RACGP's Standards have been made effective from 1 January 2020. A new Indicator has been developed in response to feedback from stakeholders to better describe appropriate indemnity for research that is based on the level of risk.

The new Indicator is supported by explanatory materials that clarify the intent of the Indicator. Changes have been made to C3.6 ►A and C3.6 ►B under 'Meeting each Indicator'. The glossary has also been updated to define indemnity.

Standards for general practices (5th edition) wording	
Old wording	C3.6 ►A Our practice has all research approved by an ethics committee and indemnified.
Updated Indicator wording	C3.6 ►A Our practice has all research approved by an ethics committee.
New Indicator	C3.6 ►B Our practice confirms that the appropriate indemnity is in place for research, based on the level of risk.
New to 'Meeting each Indicator'	You must: • maintain records of appropriate indemnity for your practice and general practitioners based on research activity level of risk. You could: • have a process addressing practice communication with external researchers and their risk requirements • contact your indemnity insurer to confirm you have the appropriate level of cover for the research being undertaken where it is not explicit in your policy.
New to glossary	Medical indemnity provides security or protection against a loss or other financial burden. Medical indemnity insurance is a compulsory condition of registration for all medical practitioners in Australia.

What is the difference between research and a quality improvement activity?

In general, the purpose of quality improvement or clinical audit activities is to improve the delivery of a particular treatment or service. Before transferring health information to a third party, you need to seek specific consent from patients.

The RACGP has developed Guiding principles for managing requests for the secondary use of de-identified general practice data to support practices to make informed decisions about releasing practice data. The use of de-identified data does not require specific or express consent.

The RACGP recommends that patients be made aware of the practice's approach to the collection and security of healthcare information for primary and secondary purposes, and whether it provides de-identified data to third parties. This information should be displayed publicly; for example, as part of a practice privacy policy in the waiting room and/or on the practice website.

The RACGP encourages practices to include information about quality improvement activities and clinical audits in the practice's policy that addresses the management of health information.

You must make patients aware that declining to participate in research or quality improvement/clinical audit activities will not affect the care they receive at the practice.

Ethics approval is not required for quality improvement activities when the primary purpose is to monitor, evaluate or improve the quality of healthcare delivered by the practice. However, as many scientific journals require evidence of ethical approval or exemption prior to publication, if there is an intention to publish the findings of a clinical audit or quality improvement activity, ethical approval should be sought prior to commencing.

If the purpose of an activity is to add new knowledge or test innovations beyond usual care, then it is likely to be considered research and will require ethics approval. The National Health and Medical Research Council provides a list of triggers for consideration of ethical review. These include:

- when the activity potentially infringes on the privacy or professional reputation of participants, providers or organisations
- secondary use of data – using data or analysis from quality assurance or evaluation activities for another purpose
- gathering information about the participant beyond that collected routinely; information may include bio specimens or additional investigations
- testing of non-standard (innovative) protocols or equipment
- comparison of cohorts
- randomisation or the use of control groups or placebos
- targeted analysis of data involving minority/vulnerable groups whose data are to be separated out of that data collected or analysed as part of the main quality assurance/evaluation activity.

Supporting resources:

- Guiding principles for managing requests for the secondary use of de-identified general practice data
- Ethical Considerations in Quality Assurance and Evaluation Activities
- General practitioner and patient participation in research projects and clinical trials in general practice
- RACGP Research Policy

If I am approached by a researcher, what information should I request from them?

It is important to understand the potential risks that individual research activities may have for your practice and patients. Researchers must obtain ethics approval prior to implementing their research project. In the ethics application, the researchers must address numerous questions relating to how they will carry out their project ethically and the potential risks the project may have on potential participants.

In designing a research project, researchers have an obligation to minimise the risks to participants. Researchers are required to inform potential participants (ie the general practice or the patients in the general practice) of any potential risks, how the risks will be minimised during the research, and identify potential benefits of the research and who will benefit from the research.

It is common practice for researchers to have an information sheet and consent form that they provide the practice outlining the potential risks that the research activities may have for the practice and/or patients. The information sheet also provides contact details of the research team so that you can further clarify the research requirements.

Practices should ensure they have a clear understanding and agreement on the role of the researchers and how they will interact with patients.

Some other potential considerations:

- What practice-staff training may be required for the project?
- Who will pay for staff training for a project, if required?
- How much of existing practice staff's time will be required to conduct research activities?
- What are the activities required of existing practice staff? And, if relevant, who will pay for this?
- What practice space is required for the project?
- How long will the practice space be required for the project?
- Who will be using the practice space during the project?

Supporting resources:

- Secondary use of de-identified data: A checklist for general practice
- RACGP Research Policy

Further information

For further information, contact standards@racgp.org.au