The Royal Australian College of General Practitioners

Research Ethics Workshop

A practical workshop on how to complete a human research ethics application

Professor Nick Zwar
Fairfield Hospital, NSW

The Royal Australian College of General Practitioners

Workshop Program

- Introduction and reflections on experiences of ethics applications
- Research definition and scope of human research ethics committees
- Writing a participant information sheet – group exercise
- Tips for ethics applications
- Beyond Approval
- Discussion

The Royal Australian College of General Practitioners

RACGP and Research

Mission

"To benefit our communities by ensuring high quality clinical practice, education and research for Australian General Practice and supporting our current and future members in their pursuit of clinical excellence."

The Royal Australian College of General Practitioners

Historical Context

Tuskegee Study

1930: Examination of the natural history of untreated syphilis
400 black men with syphilis, 200 controls

Recruitment without informed consent & misinformation re treatment, eg spinal taps = “special free treatment”

1936: Complications: infected men > controls,
Study continued

1940: Penicillin found effective for syphilis,
Study participants were not treated with antibiotic

1972: Exposition of study in US press

The Royal Australian College of General Practitioners

Human Research Ethics Committees (HREC)

- Research projects involving humans must be reviewed and approved by an HREC which is established by and advises an institution or organisation regarding ethical approval for research projects.

- The primary role of an HREC is to protect the welfare and rights of participants in research.

The Royal Australian College of General Practitioners

When is Ethics Approval Required?

- For conduct of research involving or impacting upon humans.
- Research "investigative work undertaken on a systematic and rigorous basis using quantitative and qualitative methods to generate new knowledge that seeks to impact on human physical, social and psychological wellbeing."
- Defining involvement – use or collection of personal, collective or cultural data; testing of responses to conditions devised by the researchers or testing of new chemical therapies.

The Royal Australian College of General Practitioners

Ethical Principles

- Integrity

  Guiding value is integrity, expressed in a commitment to search for knowledge, to recognise principles of research conduct and in dissemination of results.

- Respect for persons

  Regard for the welfare, rights, beliefs, perceptions, customs and cultural heritage of participants.

- Beneficence

  Responsibility to maximise benefits and minimise risks of harm or discomfort to participants.

- Justice

  Burden and benefits of research should be shared in a just and equitable manner.

The Royal Australian College of General Practitioners

Ethics and Law in Research

- Research needs to be legal as well as ethical.
- Examples of legal issues
  - Commonwealth laws on registration.
  - Certain research on pharmaceutical drugs and medical devices.
- Examples of state laws
  - Access to and use of health information.
  - Consumer protection.

The Royal Australian College of General Practitioners

RACGP National Research & Evaluation Ethics Committee

- Committee is supported by an Executive Officer who also supports the RACGP National Standing Committee-Research (NSC-R).

- Composition of Committee:
  - Chair
  - Medical graduate with research experience
  - Lay people, one woman and one man, not associated with the institution
  - Minister of religion
  - Lawyer
  - Fellow of the RACGP in active General Practice
  - Observer, Registrar Research And Development Officer (RRADO)

The Royal Australian College of General Practitioners

Operation

- In carrying out its functions the Committee will:
  - Conform with the NHMRC *National Statement on Ethical Conduct in Research Involving Humans.*
  - While promoting the advance of knowledge by research, ensure that the rights of participants take precedence over the expected benefits to human knowledge.
  - Ensure that the consent of the participants must be obtained in all research projects involving humans.
  - Ensure that no member of the committee adjudicates on projects in which they may be personally involved.
  - Ensure that projects consider local cultural and social attitudes.
  - Give its own consideration to projects that involve research in more than one institution.
  - Require the principal investigator to disclose any previous decisions by another HREC in relation to the project and if the study his being reviewed by another HREC.
  - Determine a method of monitoring appropriate to each project.

The Royal Australian College of General Practitioners

Jurisdiction of RACGP National Research & Evaluation Ethics Committee

- Research and evaluation projects being conducted in general practice or related primary care settings.
- Ranges from clinical trials through to research projects being conducted by academic general practitioners, divisions of general practitioners or individual researchers.

The Royal Australian College of General Practitioners

Jurisdiction Issues

- The Committee will accept applications for ethical review from both RACGP members and non members.
- Projects from GP registrars.
- Increasingly research projects are submitted by Divisions of General Practice.
- The Committee will also accept applications for ethical review from other primary care research projects related to general practice eg. pharmacist projects which also have GP involvement.

The Royal Australian College of General Practitioners

Informed Consent

- Information
  - Research procedure, purpose, risks and benefits.
  - Right to withdraw at any time.
  - Who will present the information, when where, how?
- Comprehension
  - Adapt presentation to subjects' capabilities.
  - How to assess participants' understanding?
- Voluntariness
  - No threat or excessive, unwarranted, inappropriate, improper reward.

The Royal Australian College of General Practitioners

Privacy and Confidentiality

- Privacy
  - Having control over the extent, timing, circumstances of participation.
  - Freedom from unwanted intrusion.

- Confidentiality
  - Non-disclosure of individual information to third parties.
  - Substitute codes for identifiers.
  - Limiting access to data.
  - Storing data in locked cabinets or with electronic security code.

The Royal Australian College of General Practitioners

Scenario

You have received funding to evaluate a primary care based smoking cessation service. The service model involves the GP identifying smokers interested in quitting and referring them to the practice nurse who will have received training in smoking cessation counselling. The nurse will also be able to provide subsidised nicotine patches for eight weeks.

Evaluation involves baseline, four week and six month measures of smoking status (including validation with expired CO monitor), stage of change, use and value of quit support services.

The Royal Australian College of General Practitioners

Elements for Participant Information Sheet

- Study title
- Investigators names and contact details
- Introduction
- Purpose of study
- Study procedures including what participants will be asked to do and the time commitment
- Eligibility to participate
- Risks and any debriefing arrangements as required
- Other treatments
- Clause regarding voluntary participation and non-involvement in the project will not affect ongoing management or treatment of existing patients
- Clause regarding stopping the study if events indicate
- Treatment and compensation for injury
- Possible benefits of participation
- Details of data collection, storage, use and disposal
- Informing participants of access to research findings
- Proposed reporting of findings (thesis, publication, reports given to participants, sponsors etc.);
- Provide the details of the Ethics Approval.

The Royal Australian College of General Practitioners

Questions an ethics committee may consider.

- Will this project contribute to new knowledge?
- Is there any undue pressure to participate?
- Will the participant be fully informed?
- What will the participant be required to do – new medication, time, any costs associated?
- What happens if there is an 'adverse event' – how are the participants notified, who looks after them, who pays for their care?
- Privacy of data – what will be used, how and by whom?
- Who will see the study results (whether positive or negative) – will others be able to use the new knowledge?
- What happens to the participants at the end of the research – has provision been made for their ongoing care?

The Royal Australian College of General Practitioners

Ethical Issues of Importance in General Practice Research

Close relationship between patient and doctor

- Can raise risk of coercion.
- freedom to choose whether or not to participate needs to be very clear and explicit and that this will not damage future doctor/patient relationship.

- Recruitment is frequently done by the GP rather than a research nurse or other person in the practice
  - Risk that patient will find it difficult to say no.

The Royal Australian College of General Practitioners

Fitting the Approval Process into Research Project Management

- Murphy's Law of research.
- Ask yourself what will the HREC need to see to give approval and make sure those documents are all present in your application.
- Ask yourself, who are the participants?
- Common issues
  - Study objectives and benefits are not clearly articulated
  - Information sheets are incomplete or difficult to comprehend
  - Explanation of risks - balance of disclosure versus comprehension
  - Data security
  - Compensation issues
  - Publication policy

The Royal Australian College of General Practitioners

Tips for Completing Ethics Application Forms

- Allow sufficient time.
- Make sure all relevant questions have been answered.
- Make sure all documents are provided.
- Avoid rough cut and paste.
- Proof read the application thoroughly.
- Ask a lay person to proof read the lay statement, patient information sheet and consent form.
- Discuss with relevant health professionals.
- Engage relevant community groups.
- Specify plans for publication.
- Include the number of copies required for submission.

The Royal Australian College of General Practitioners

Beyond Approval

- HRECs have a monitoring role
- Progress and final reports of completed research are required
- HRECs require that researchers immediately report
  - Ethical issues
  - Serious or adverse events
  - Proposed changes in protocol

  (Approval is not automatic)
- Fulfil obligations to participants as stated in protocol
- Publication is important

The Royal Australian College of General Practitioners

Issues facing HRECs including the RACGP National Research and Evaluation Ethics Committee

- Workload and increasing complexity of issues to be considered.
- Resourcing to support role including monitoring role.
- Efficiency in time taken to review and respond to applications.
- Incomplete or poor quality applications that do not provide all the information needed for the Committee to complete its review.

The Royal Australian College of General Practitioners

Resources

- General Information about Research including ethics application form and meeting dates at http://www.racgp.org.au/research or email ethics@racgp.org.au
- Enquiries about ethics to the Executive Officer
- NHMRC National Statement on *Ethical Conduct in Research Involving Humans* at www.nhmrc.gov.au/ethics
- US National Cancer Institute ethics tutorial

  http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp
- Belmont Report

  http://ohsr.od.nih.gov/guidelines/belmont.html
- Mulligan EA et al. Application of the privacy principles in general practice. AFP 2002, 30 (2): 189-191.