Committee for Examinations
Objective Structured Clinical Examination

Station 5
Perth April 2017

The Royal Australian & New Zealand College of Psychiatrists

1.0 Descriptive summary of station:

In this station the candidate is expected to describe the differences between clinical audit and a research study, and then explain considerations, including the role of ethics committees, when undertaking research. The candidate is also expected to discuss the ethical principles related to an observational research project.

1.1 The main assessment aims are:

- To explain the key differences between clinical audit and research.
- To describe the main considerations, including cultural issues, when planning an observational study.
- To discuss the ethical principles related to observational research.

1.2 The candidate MUST demonstrate the following to achieve the required standard:

- Explain that research is generally designed to test a hypothesis while clinical audit is aimed to measure performance against a standard.
- Identify that ethics committees review research proposals to protect participant rights.
- Include cultural consideration and consultation in the planning stage of this research.
- Specify the importance of the ethical principles of autonomy and informed consent in research.

1.3 Station covers the:

- **RANZCP OSCE Curriculum Blueprint Primary Descriptor Category**: Other Skills (research)
- **Area of Practice:** Adult Psychiatry
- **CanMEDS Domains**: Scholar, Professional
- **RANZCP 2012 Fellowship Program Learning Outcomes:** Scholar (Research), Professional (Ethics)

References:

- Australian Code for the Responsible Conduct of Research (the Code) 2007 NHMRC.
- Gillon, R (1994). "Medical ethics: four principles plus attention to scope". British Medical Journal 309 (184). doi:10.1136/bmj.309.6948.184.
- National Health and Medical Research Council Act 1992, Australian Government.
- National Statement on Ethical Conduct in Human Research (2007) (updated 2013) (the National Statement) issued by NHMRC.
- National Safety and Quality Health Service standards September 2012: Australian Commission on Safety and Quality in Health Care (ACSQHC) (September 2011), National Safety and Quality Health Service Standards, ACSQHC, Sydney. 978-1-921983-04-7.
- COREC (2005), Differentiating Audit, Service Evaluation and Research. www.corec.org.uk/recs/guidance/guidance.htm.
- National Ethics Advisory Committee. 2012. Ethical Guidelines for Observational Studies: Observational research, audits and related activities. Revised edition. Wellington: Ministry of Health.

1.4 Station requirements:

- Standard consulting room; no physical examination facilities required.
- Three chairs (examiner x 1, candidate x 1, observer x 1).
- Laminated copy of 'Instructions to Candidate'.
- Pen for candidate.
- Nametag for examiner "Dr Robertson"
- Timer and batteries for examiner.

2.0 Instructions to Candidate

You have **eight (8) minutes** to complete this station after **two (2) minutes** of reading time.

This is a **VIVA** station. **There is no role player in this station.**

In this **VIVA,** You are working as a junior consultant psychiatrist in a community mental health centre.

You recently completed a clinical audit on how the metabolic syndrome is being monitored in patients with schizophrenia in your centre. You noted many of the indigenous people with schizophrenia have hyperglycaemia.

Your registrar, Dr Robertson, approaches you to be his scholarly project supervisor. Dr Robertson wants to test the hypothesis that indigenous people with schizophrenia have a higher rate of hyperglycaemia than non-indigenous people with schizophrenia. He is planning to observe the routinely collected laboratory data prospectively as part of the metabolic syndrome monitoring programme in your centre. He also hopes to publish the findings in a peer-reviewed journal primarily focussing on the indigenous aspect.

Your tasks are to:

- Explain to Dr Robertson the key differences between clinical audit and research study.
- Describe the main considerations when planning and preparing for this research study.
- Apply the key ethical principles related to this research study.

The examiner will play the role of Dr Robertson.

You <u>are not</u> required to describe the process for getting College approval for scholarly project.

You will not receive any time prompts.

Station 5 - Operation Summary

Prior to examination:

- Check the arrangement of the room, including seating and other specifics to your scenario.
- On the desk, in clear view of the candidate, place:
  - A copy of 'Instructions to Candidate' and any other candidate material specific to the station.
  - Pens.
  - Water and tissues are available for candidate use.

During examination:

- Please ensure mark sheets and other station information, are out of candidate's view.
- At the **first bell**, take your places.
- At the **second bell**, start your timer, check candidate ID number on entry.
- TAKE NOTE there are **no** cues and **no** time prompts in this station.
- If the candidate asks you for information or clarification say:

  'Your information is in front of you – you are to do the best you can'.
- At **eight (8) minutes**, as indicated by the timer, the final bell will ring. Finish the examination immediately.

At conclusion of examination:

- Retrieve all station material from the candidate.
- Complete marking and place your mark sheet in an envelope by / under the door for collection (**do not seal envelope**).
- Ensure room is set up again for next candidate. (See 'Prior to examination' above.)

If a candidate elects to finish early after the <u>final task</u>:

- You are to state the following:

  'Are you satisfied you have completed the task(s)?
  If so, you <u>must</u> remain in the room and <u>NOT</u> proceed to the next station until the bell rings.'

- If the candidate asks if you think they should finish or have done enough etc., refer them back to their instructions and ask them to decide whether they believe they have completed the task(s).

3.0 Instructions to Examiner

3.1 In this VIVA station, your role is to:

Observe and listen to the responses provided to the station tasks and judge it according to the station assessment aims and defined tasks as outlined in 1.1 and 1.2.

When the candidate enters the room briefly check ID number.

There is no opening statement or any prompts.

Specifically, the tasks that the candidate has been asked to perform are described below:

The FIRST TASK is:

Explain to Dr Robertson the key differences between clinical audit and research study.

The SECOND TASK is:

Describe the main considerations when planning and preparing for this research study.

The THIRD TASK is:

Apply the ethical principles related to this research study.

3.2 Background information for examiners

The aims of this station are to describe the differences between clinical audit and research study. The candidate is also expected to discuss the ethical principles related to observational research.

In order to achieve this station the candidate **MUST**:

- Explain that research is designed to test a hypothesis while clinical audit is aimed to measure performance against a standard.
- Identify that ethics committees review research proposals to protect participant rights.
- Include cultural consideration and consultation in the planning stage of this research.
- Specify the importance of the ethical principles of autonomy and informed consent in research.

A surpassing candidate may consider the role of researchers in a study where an adverse outcome such as hyperglycaemia is likely to be encountered in the observation period, relationship with clinicians to address the adverse outcome, obtaining informed consent from people with schizophrenia who are vulnerable and their capacity may be compromised due to the presence of cognitive symptoms, and seeking mentoring and / or support from a senior colleague with research experience.

Research versus Clinical Audit

The candidate should be able to describe some of the key differences between research and clinical audit within the context of this station.

RESEARCH	CLINICAL AUDIT
The attempt to derive generalisable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them.	Designed and conducted to produce information to inform delivery of best care.
Quantitative research – designed to test a hypothesis.	Designed to answer the question: “Does this service reach a predetermined standard?”
Addresses clearly defined questions, aims and objectives.	Measures against a standard.
Needs a statistically valid sample size.	Does not necessarily need a statistically valid sample size.
Extensive statistical analysis is required.	Basic statistical analysis usually suffices.
Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care.	Usually involves analysis of existing data but may include administration of simple interview or questionnaire.

No built-in mechanism to require action on findings.	Clear responsibility to act on findings through development of an action plan.
Findings can have a wide influence on clinical practice.	Findings usually only influence practice within the area evaluated.
Always requires ethics committee approval.	Does not usually require ethics approval.
Expectation that research findings are published.	Without ethics approval, audit results are not generally eligible for publication.

Important aspects of research planning

When considering their research plan, the candidate can discuss the type of study design, management of research bias, study power, timeframes to obtain ethics approval, publication goals (e.g. journal to submit to, mentioning publication in the ethics application and informed consent), rights and authorship (e.g. order of authors, substantial participation in the project), governance, leadership, support, having access to resources (e.g. time, data, and quality managers / statisticians), any opportunity costs, and utilisation / dissemination of the findings.

Research application and governance

Human research is described as research conducted with or about people, their data or tissues. Although there is no generally agreed definition, human research can generally be understood to include the involvement of people through:

- participation in surveys, interviews or focus groups
- undergoing psychological, physiological or medical testing or treatment
- being observed by researchers
- access to people's personal documents or other material by researchers
- the collection and use of individuals' body organs, tissues, fluids, etc.
- access to people's information, in individually identifiable, re-identifiable or non-identifiable form, as part of an existing published or unpublished source or database.

All human research activities involving patients and / or staff must undergo ethical review and monitoring by a Human Research Ethics Committee (HREC). This review and monitoring is conducted in accordance with the relevant national human research legislation (e.g. The National Statement on Ethical Conduct in Human Research (2007) in Australia; Human Research Council in New Zealand).

Ethics Committees

Ethics committees review research proposals to ensure that they are ethically acceptable and undertaken in accordance with relevant standards and guidelines. The underlying goals of ethics committees are to:

- protect patient rights;
- encourage shared decision making between patients (or substitute decision maker) and clinicians;
- promote fair policies and procedures that optimise the likelihood of achieving good, patient-centred outcomes;
- enhance the ethical environment for health professionals within healthcare organisations.

Ethics committees have become increasingly interested in protecting the rights of participants who may not be patients; e.g. carers / support persons, staff, other key stakeholders.

Some ethics committees, particularly those affiliated with academic institutions and large healthcare systems, have expanded their traditional functions to address both clinical and organisational ethical issues. Ethics programs may include:

- integrating ethics throughout the healthcare organisation from the bedside to the executive level;
- ensuring that systems and processes contribute to, and do not interfere with ethical practice;
- promoting ethical leadership behaviours: explaining values that underlie decisions, stressing the importance of ethics and promoting transparency in decision making.

Ethics committee members can also assist in resolving ethical conflicts and answering ethical questions through the provision of advice and consultation.

The requirement for ethical review of human research can be determined by the level of risk to participants and the category of research. All research considered to be greater than 'low risk' or including vulnerable participants or sensitive issues should have a formal and comprehensive review by a fully constituted Human Research Ethics Committee (HREC).

Researchers must be aware of the effects research activities may have on participants and whether their participation in the project may lead to any harm, discomfort and / or inconvenience:

- 'Harm' to research participants may include physical harms (injury, illness, pain); psychological harms (feelings of worthlessness, distress, guilt, anger or fear related, for example, to disclosure of sensitive or embarrassing information, or learning about a genetic possibility of developing an untreatable disease); devaluation of personal worth (being humiliated, manipulated or in other ways treated disrespectfully or unjustly); social harms (damage to social networks or relationships with others; discrimination in access to benefits, services, employment or insurance; social stigmatisation; and findings of previously unknown paternity status); economic harms (discovery and prosecution of criminal conduct).
- 'Low risk research' describes research where the only foreseeable risk to participants is not more than one of 'discomfort', which can include minor side-effects of medication, the discomforts related to measuring blood pressure or doing exercise, or anxiety introduced by being interviewed. 'Inconvenience' may include such activities as filling in a form or participating in a street or phone survey, or simply giving up time to participate in research.
- Research into human genetics, pregnant women / human foetus, human stem cells, people highly dependent on medical care, people with intellectual or cognitive disability or severe mental illness usually require review by a full committee.

Cultural aspects of research planning

The Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS) has created the Guidelines for Ethical Research in Australian Indigenous Studies (GERAIS) to ensure that research with and about Aboriginal and Torres Strait Islander peoples follows a process of meaningful engagement and reciprocity between the researcher and the individuals and / or communities involved in the research. The GERAIS has 14 principles:

- Principle 1 - Recognition of the diversity and uniqueness of peoples, as well as of individuals, is essential.
- Principle 2 - The rights of Indigenous peoples to self‑determination must be recognised.
- Principle 3 - The rights of Indigenous peoples to their intangible heritage must be recognised.
- Principle 4 - Rights in the traditional knowledge and traditional cultural expressions of Indigenous peoples must be respected, protected and maintained.
- Principle 5 - Indigenous knowledge, practices and innovations must be respected, protected and maintained.
- Principle 6 - Consultation, negotiation and free, prior and informed consent are the foundations for research with or about Indigenous peoples.
- Principle 7 - Responsibility for consultation and negotiation is ongoing.
- Principle 8 - Consultation and negotiation should achieve mutual understanding about the proposed research.
- Principle 9 - Negotiation should result in a formal agreement for the conduct of a research project.
- Principle 10 - Indigenous people have the right to full participation appropriate to their skills and experiences in research projects and processes.
- Principle 11 - Indigenous people involved in research, or who may be affected by research, should benefit from, and not be disadvantaged by, the research project.
- Principle 12 - Research outcomes should include specific results that respond to the needs and interests of Indigenous people.
- Principle 13 - Plans should be agreed for managing use of, and access to, research results.
- Principle 14 - Research projects should include appropriate mechanisms and procedures for reporting on ethical aspects of the research and complying with these guidelines.

Consultation with Māori is an integral part of research planning and ethics application when involving indigenous people in New Zealand. There should be due recognition of Māori as the tāngata whenua and indigenous people of Aotearoa New Zealand. He Korowai Oranga: Māori Health Strategy specifies that 'The Government is committed to fulfilling the special relationship between iwi and the Crown under the Treaty of Waitangi' (Minister of Health and Associate Minister of Health 2002, p 2). This commitment should be respected by all researchers and, when applicable, should be reflected in the design and conduct of observational studies. Relevant principles that apply include:

- Partnership: working together with iwi, hapū, whānau and Māori communities to ensure Māori individual and collective rights are respected and protected in order to achieve health gain
- Participation: involving Māori in the design, governance, management, implementation and analysis of research, particularly research involving Māori
- Protection: actively protecting Māori individual and collective rights, and Māori data, cultural concepts, norms, practices and language in the research process.

Issues relating to Māori cultural and ethical values should be addressed in discussion with Māori concerned, including appropriate whānau, hapū or iwi. He Korowai Oranga states: 'Comprehensive, high-quality Māori health research and information is necessary to inform the Government and to assist whānau, hapū and iwi to determine and provide for their own health priorities' (Minister of Health and Associate Minister of Health 2002, p 23).

Ethical Principles for Consideration

When considering research, there are basic medical ethical principles underlying any decision that the candidate should demonstrate knowledge of. Tom Beauchamp and James Childress proposed a framework incorporating the "four principles" approach in their textbook (Principles of biomedical ethics):

- Respect for autonomy - the patient has the right to refuse or choose their treatment (Voluntas aegroti suprema lex).
- Beneficence - a practitioner should act in the best interest of the patient (Salus aegroti suprema lex).
- Non-maleficence - "first, do no harm" (primum non nocere).
- Justice - the distribution of scarce health resources, and the decision of who gets what treatment (fairness and equality) (Iustitia).

The following considerations are important to the ethics of observational studies. The application and weighting of these considerations will vary depending on the nature and specific circumstances of the observational study in question.

- Respect for people, and for their rights, incorporates at least two fundamental principles:
  - Autonomy, which requires that people who are capable of deliberation about their personal goals should be treated with respect for their capacity for self-determination.
  - Protection of people with impaired or diminished autonomy, which requires that people who are dependent or vulnerable be afforded security against harm.
- Informed consent
  - Researchers should obtain the prior informed consent of study participants. Informed consent has two basic components:

    a) The decision is informed by adequate understanding of any information that is relevant to that decision.

    b) The decision is voluntary, and is therefore free from undue influence such as manipulation or coercion.
  - Information about the purpose of the study should be as specific as possible without compromising the validity of the study.
  - When specific information cannot be provided at the outset, the researcher should offer to provide results to participants.
  - When researchers collect information directly from individuals, or seek their consent to access records, they should inform them that supplying information is voluntary.
  - The right of any person to decline to take part in a study or to withdraw from the study at any time must always be explained and respected. This includes the right to decline to answer all or any questions in a questionnaire.

- Justice
  - Justice requires that, within a population, there is a fair distribution of the benefits and burdens of participation in a study, and for any participant, a balance of burdens and benefits.
  - Accordingly, a researcher must:
    a) avoid imposing on particular groups an unfair burden of participation in research; for example, vulnerable members of communities should not bear disproportionate burdens of studies from which other members of the community are intended to benefit
    b) design studies so the inclusion and exclusion conditions for participants are fair
    c) not discriminate in the selection and recruitment of participants by including or excluding them on the grounds of ethnicity, age, sex, disability or religious or spiritual beliefs, except when such exclusion or inclusion is essential to the purpose of the study.
- Beneficence and non-maleficence
  - The risks of a study should be reasonable in the light of the expected benefits.
  - Researchers should consider the features of a proposed study in the light of ethical considerations, and satisfactorily resolve ethical issues raised by the study. Not all ethical considerations weigh equally. A study may be assessed as ethically justifiable even if a usual ethical expectation, such as confidentiality of data, has not been comprehensively met, provided the potential benefits clearly outweigh the risks and the researchers can minimise the risks.
  - A proportionate approach should be taken: the greater the risk of harm from the study, the greater should be the care in addressing the ethical issues raised.
  - Above the threshold of minimal risk, a study warrants greater provision for the protection of participants. A study is within the range of minimal risk if potential participants can reasonably be expected to regard the probability and magnitude of possible harms from participation in the study as no greater than those encountered in those aspects of everyday life that relate to the study (for example, a clinical consultation with a health care provider).

The potential harms associated with observational studies are generally less than with experimental studies, as no intrusive intervention takes place and participants are less likely to be in a dependent relationship with the researcher. Depending on the method used (whether previously collected information is used or new information is collected) potential harms in observational studies could include breaches of confidentiality.

- Integrity

  A researcher's commitment to the advancement of knowledge implies a duty to conduct honest and thoughtful inquiry and rigorous analysis, and to be accountable for her or his activities.

- Conflict of interest

  Researchers should identify to co-researchers, sponsors, employers, participants and, where applicable, ethics committees any perceived, potential or actual conflict of interest he or she might have in relation to any others who are involved with the study. Such conflicts of interest can compromise the design or conduct of a study or the reliability of its results, thereby exposing study participants or others to needless risk or inconvenience.

  As appropriate to the circumstances, any conflict of interest should be minimised.

3.3 The Standard Required

Surpasses the Standard – the candidate demonstrates competence above the level of a junior consultant psychiatrist in several of the domains described below.

Achieves the Standard – the candidate demonstrates competence expected of a junior consultant psychiatrist. That is the candidate is able to demonstrate, *taking their performance in the examination overall*, that

i. they have competence as a ***medical expert*** who can apply psychiatric knowledge including medicolegal expertise, clinical skills and professional attitudes in the care of patients (such attitudes may include an ability to tolerate uncertainty, balance, open-mindedness, curiosity, 'common sense' and a scientific approach).

ii. they can act as a ***communicator*** who effectively facilitates the doctor patient relationship.

iii. they can ***collaborate*** effectively within a healthcare team to optimise patient care.

iv. they can act as ***managers*** in healthcare organisations who contribute to the effectiveness of the healthcare system, organise sustainable practices and make decisions about allocating resources.

v. they can act as ***health advocates*** to advance the health and well-being of individual patients, communities and populations.

vi. they can act as ***scholars*** who demonstrate a life-long commitment to learning as well as the creation, dissemination, application and translation of medical knowledge.

vii. they can act as ***professionals*** who are committed to ethical practice and high personal standards of behaviour.

Below the Standard – the candidate demonstrates significant defects in several of the domains listed above.

Does Not Achieve the Standard – the candidate demonstrates significant defects in most of the domains listed above or the candidate demonstrates significant defects in the first domain of being a medical expert.

STATION 5 – MARKING DOMAINS

The main assessment aims are:

- To explain the key differences between clinical audit and research.
- To describe the main considerations, including cultural issues, when planning an observational study.
- To discuss the ethical principles related to observational research.

Level of Observed Competence:

6.0 SCHOLAR

6.2 Did the candidate appropriately demonstrate understanding of the key differences between clinical audit and research study? (Proportionate value – 30%)

Surpasses the Standard (scores 5) if:
demonstrates a sophisticated understanding of the differences between clinical audit and research; incorporates the concept of compliance and monitoring versus generation of novel information.

Achieves the Standard by:
demonstrating the capacity to differentiate between clinical audit and research; generalisability of findings, sample size, statistical analysis, use of existing data, act on findings, influence on clinical practice.

To achieve the standard ***(scores 3)*** the candidate **MUST:**

a. Explain that research is generally designed to test a hypothesis while clinical audit is aimed to measure performance against a standard.

A score of 4 may be awarded depending on the depth and breadth of additional factors covered; if the candidate includes most or all correct elements.

Below the Standard (scores 2 or 1):
scores 2 if the candidate does not meet (a) above, or has omissions that would detract from the overall quality response; significant omissions affecting quality scores 1.

Does Not Achieve the Standard (scores 0) if:
demonstrates limited understanding of uniqueness of research; unable to adequately explain differences between research practice and audit.

6.2. Category: RESEARCH	Surpasses Standard	Achieves Standard		Below the Standard		Standard Not Achieved
ENTER GRADE (X) IN ONE BOX ONLY	5 ☐	4 ☐	3 ☐	2 ☐	1 ☐	0 ☐

6.2 Did the candidate appropriately demonstrate understanding of the main considerations when planning a research study? (Proportionate value – 30%)

Surpasses the Standard (scores 5) if:
comprehensively considers all aspects of research planning; seeking mentoring from senior colleague to allow reflective practice; reflecting on the role of researchers in a study where an adverse outcome such as hyperglycaemia is likely to be encountered in the observation period and relationship with clinicians to address the adverse outcome.

Achieves the Standard by:
demonstrating the capacity to: identify key requirements governing human and health services research; type of study design, management of research bias, study power; timeframes to obtain ethics approval; publication goals, rights and authorship; governance, leadership, support; having access to resources (e.g. time, data, and quality managers / statisticians); any opportunity costs; utilisation / dissemination of the findings.

To achieve the standard ***(scores 3)*** the candidate **MUST:**

a. Identify that ethics committees review research proposals to protect participant rights
b. Include cultural consideration and consultation in the planning stage of this research.

A score of 4 may be awarded depending on the depth and breadth of additional factors covered; if the candidate includes most or all correct elements.

Below the Standard (scores 2 or 1):
scores 2 if the candidate does not meet (a) or (b) above, or has omissions that would detract from the overall quality response; significant omissions affecting quality scores 1.

Does Not Achieve the Standard (scores 0) if:
limited understanding of factors related to research good clinical practice; unable to adequately explain ethical research practice and governance.

6.2. Category: RESEARCH	Surpasses Standard	Achieves Standard		Below the Standard		Standard Not Achieved
ENTER GRADE (X) IN ONE BOX ONLY	5 ☐	4 ☐	3 ☐	2 ☐	1 ☐	0 ☐

7.0 PROFESSIONAL

7.1 Did the candidate appropriately discuss the ethical principles associated with research? (Proportionate value – 40%)

Surpasses the Standard (scores 5) if:
able to provide a sophisticated argument for or against research activities based on sound ethical principles; incorporates relevant ethical theories; understands intellectual property aspects of research;

Achieves the Standard by:
demonstrating the capacity to articulate: beneficence, non-maleficence, justice, discrimination, integrity, conflict of interest, potential harm of breaches of confidentiality, protection of people with impaired or diminished autonomy; obtaining informed consent from vulnerable people who may have compromised capacity in the presence of cognitive symptoms.

To achieve the standard ***(scores 3)*** the candidate **MUST:**
a. Specify the importance of the ethical principles of autonomy and informed consent in research.

A score of 4 may be awarded depending on the depth and breadth of additional factors covered; if the candidate includes most or all correct elements.

Below the Standard (scores 2 or 1):
scores 2 if the candidate does not meet (a) above, or has omissions that would detract from the overall quality response; significant omissions affecting quality scores 1.

Does Not Achieve the Standard (scores 0) if:
does not appear to be aware of or adhere to accepted medical ethical principles.

7.1. Category: ETHICS	**Surpasses Standard**	**Achieves Standard**		**Below the Standard**		**Standard Not Achieved**
ENTER GRADE (X) IN ONE BOX ONLY	**5** ☐	**4** ☐	**3** ☐	**2** ☐	**1** ☐	**0** ☐

GLOBAL PROFICIENCY RATING

Did the candidate demonstrate adequate overall knowledge and performance at the defined tasks?

Circle One Grade to Score	**Definite Pass**	**Marginal Performance**	**Definite Fail**