Human Research Ethics Policy

1. Purpose

The primary purpose of the Human Research Ethics Policy is to protect the welfare and the rights of participants in research. The primary responsibility of those making decisions on research proposals is to decide whether the conduct of the proposal will protect participants.

2. Scope

The policy applies to all research projects undertaken in the name of KOI (including student projects).

3. Ethics Statement

KOI is dedicated to maintaining a learning environment committed to equitable opportunities, free intellectual enquiry and a culture of scholarship which is aligned to the goals of higher education in Australia. Members of the KOI community are committed to ethical values and behaviour:

- Acting responsibly, honestly and with integrity
- Pursuing scholarship courageously and creatively
- Making decisions in a just and compassionate way
- Working with others in a nurturing and cooperative way
- Generating a community of trust, respecting the dignity of others and fostering equality of opportunity
- Avoiding actions that could be harmful to others.

The Student and Staff Codes of Conduct set out the general standards and ethical conduct expected of those who work and study at KOI.

4. Human Research Ethics

There are additional considerations governing the ethical framework for research in order to comply with regulatory requirements. The Australian Code for the Responsible Conduct of Research (2018) guides institutions and researchers in responsible research practice and promotes integrity in research. The NHMRC National Statement on Ethical Conduct in Human Research (2018) sets out the national standards of ethical conduct for research involving humans and should be used by researchers when developing their projects.

The essential values that guide ethical research are the values of respect for human beings. Research merit and integrity, justice and beneficence guide the design and conduct of human research and help shape a relationship of trust, mutual responsibility and ethical equality between researchers and research participants.

The basis for approving a research project is the set of guidelines in the National Statement on Ethical Conduct in Human Research (NHMRC, 2018). Researchers should design their projects in accordance with these guidelines. The purpose of the Statement is to promote ethically good research that accords participants with the respect and protection that is due to them, and is of benefit to the wider community. The Statement clarifies the responsibilities of researchers in the ethical design, conduct and dissemination of results of human research.

'Human research' has a broad definition and includes research conducted with or about people, or their data or tissue. Ethics approval is required for certain research activities involving humans. Research projects requiring ethics approval include, but are not restricted to, gathering information about human beings (and organisations) through interviewing, surveying, questionnaires, observation of human behaviour, audio/video taping, administering tests or stimuli, collecting or using human tissue/bone/blood or other body fluids, clinical trials, using archived data in which individuals are identifiable, and study or research in illegal activities. Ethics approval may not be required where the project has an educational, or practical experience focus.

Researchers undertaking 'human research' may not commence their research until they have written advice that their project has ethics approval. Student should discuss their projects with their supervisors who will help to develop the project and give due consideration to the ethical issues involved.

The issues considered in examining a request for ethics approval include the aim of the research, methodology, experience and training of the researchers, the participants and their vulnerability, risk versus benefit, risk management and unexpected outcomes, recruitment of participants, dependent relationships, cultural sensitivities, confidentiality, informed consent, publication of the research, funding, conflict of interest and payment to participants.

The Research and Scholarship Committee has the responsibility for considering applications for approval of research involving human subjects of the kind described above. Applicants should use the attached form for the approval for their research projects.

Further information on the work of the Committee may be obtained by contacting the Vice-President (Academic).

The Vice-President (Academic) is responsible for arranging periodic briefings on research ethics for its staff, monitoring ongoing research and obtaining reports on projects.

Note: It is not envisaged that KOI staff and students will undertake research involving animal subjects.

Useful websites

Australian Code for the Responsible Conduct of Research
http://www.nhmrc.gov.au/publications/synopses/r39syn.htm

National Statement on Ethical Conduct in Human Research (2007)
http://www.nhmrc.gov.au/publications/synopses/e72syn.htm

Human Research Ethics Handbook - Commentary on the National Statement (2000)
http://www.nhmrc.gov.au/publications/synopses/e42syn.htm

Values and Ethics - Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2003) http://www.nhmrc.gov.au/publications/synopses/e52syn.htm

5. Human Research Ethics Policy

This policy is based on the National Statement on Ethical Conduct in Human Research (Commonwealth of Australia, 2007 and amended 2009).

Research and Scholarship Committee

The Research and Scholarship Committee has the responsibility for applying the Human Research Ethics Policy, determining procedures and approving applications for human ethics clearance by staff and students in accordance with the Human Research and Ethics Policy and handling complaints.

Relevant considerations for assessing applications

The Research and Scholarship Committee or its delegate must be satisfied that the research design can produce valid results and can protect the welfare and rights of research participants. It may seek or receive advice from an internal or external expert who has specific expertise in the particular type of research.

As a guide, the following matters will usually require consideration.

- *The project*
  - Is there a clear hypothesis?
  - Is the research question useful? Is the research worthwhile?
  - Is the research likely to yield new information, enhance understanding or clarify existing uncertainty?
  - Has this, or similar, research been carried out before in the same, or similar, contexts?
  - Can the research proposal be supported by a systematic review of the literature that would demonstrate the importance of the research question and that it builds upon the results of previous research?
  - If indicated, have perspectives of potential participant groups, the wider community, or other disciplines been incorporated into the research proposal?
  - Are the aims of the proposal clear?
  - Does the value of the project appear to be adequate to justify its conduct with humans?
- *The researchers*

  - Do the researchers have necessary qualifications, competence and experience?
  - Are there adequate arrangements to ensure that members of the research team are aware of relevant ethical and legal obligations?
- *The funding*
  - What is the relationship between the source of funding and the aims of the project?
  - Does that relationship have any implications for the ethical conduct of the project, especially the recruitment of participants, the character of information sought or the freedom to publish the results?
- *Research methodology*
  - Are all aspects of the research methodology clearly described?
  - Is the Research and Scholarship Committee satisfied that the methodology is appropriate to the achievement of the aims of the project?
- *Recruitment of participants*
  - Is it clear how participants will be recruited? The location of the fieldwork should also be described and explained in relation to the purpose of the research.
  - Do the recruitment methods respect participants' rights to the confidentiality of their affairs?
  - Is it clear how many participants of the various categories will be interviewed? Are the proposed participants appropriate in number and kind? If there are likely to be any cultural concerns experienced by the participants, explain how they will be addressed.
- *Burdens of research*
  - Are the burdens and risks of research to participants clearly identified and have appropriate measures been taken to minimise these?
  - Is the balance between the burdens and risks to participants and the aims and benefits of the project such as to warrant approval?
- *Incentives for participation*
  - Are financial or other rewards proposed to be given to participants?
  - Are these of such a size or value that they may unduly influence the freedom of participants to withdraw or otherwise protect themselves from risks?
- *Consent*
  - Explain how the consent of participants will be obtained. Are the ways in which participants will be approached clearly described?
  - Is the information to be provided to potential participants adequate in content and appropriate in form?
  - Do the proposed methods of securing consent to participate provide a) sufficient time to consider the decision; b) evidence that participants understood their choices, and c) sufficient opportunities to ask questions and re-consider?
- *Interview Question Sheet*
  - Provide a list of questions which will be used in the interviews. The questions may not be changed without the approval of the committee or a delegated person. Note that the question sheet may need to be translated into any appropriate languages so that maximum understanding can occur by the participants.
- *Discontinuing participation*
  - Are the ways in which participants are advised of their freedom to withdraw sufficient in content and frequency?
- *Information protection*
  - Is it clear who will (and who will not) have access to information collected during the project?
  - Are the proposed storage and security measures adequate?
  - Are participants clearly informed that information they provide will be used only for the project?
  - What measures are proposed to protect the confidentiality of information in the course of the project and are these adequate to give the degree of protection promised to participants?
  - Are the manner and form in which results will be published clearly described, and do they adequately protect the confidentiality of information and privacy of participants?
- *Clearances*
  - Have appropriate clearances for the project been obtained from participating institutions? Is there a clear process for obtaining any additional clearances.
- *Legal issues*.
  - Does the project involve subject matter or conduct which may give rise to legal vulnerability of participants or researchers? Are adequate precautions to be taken?

In addition to these recurrent issues, some research requires particular additional attention, either because of the vulnerability of the intended participants or the type of research. Research with vulnerable participants that needs additional consideration includes:

- research involving children (see National Statement on Ethical Conduct in Human Research 4.1–4.4)
- research involving participants with intellectual or mental impairment, including temporary impairment, for example as a result of alcohol or drug-induced intoxication (see National Statement on Ethical Conduct in Human Research 5.1–5.4)
- research involving persons in highly dependent medical care situations
- research involving persons in dependent or unequal relationships (see National Statement on Ethical Conduct in Human Research 7.1–7.3)
- research involving collectivities
- research involving Aboriginal or Torres Strait Islander communities.

Types of research requiring additional attention include:

- research involving significant issues of privacy (e.g., access to medical records)
- research involving ionising radiation and/or MRI
- research involving assisted reproductive technology
- clinical trials
- epidemiological research
- research using human tissue samples
- human genetic research
- research involving deception.

Expedited review for minimal risk research

There are procedures for expedited review for applications deemed to pose a low risk to participants.

Research undertaken as a learning activity within a subject

For research undertaken as a learning activity within a subject, the Subject Coordinator will submit the proposed activity to the Vice-President (Academic) for approval. Individual student projects will then be approved by the Subject Coordinator.

The research must be deemed low risk research (see below). Data collection must be primarily for teaching purposes. Students may use the data for an assignment to be submitted to the subject lecturer, but there is no intention by students or staff to publish the data. Otherwise, the activity will usually require presentation by the full Research and Scholarship Committee for clearance.

Note. Approval is not required for regular class projects in which students act as participants with results being collated as part of a class activity, unless this involves disclosure of potentially sensitive information.

Low risk research

If a research project is deemed low risk, it may be approved by the Chair of Research and Scholarship Committee. In the absence of the Chair of Research and Scholarship Committee, it could be approved by the Vice-President (Academic). The justification for this type of review is that the research involves minimal risk to participants, not that speedy approval is needed.

Although circumstances may vary, examples of situations in which expedited review might be permitted include:

- anonymous questionnaires where there is no coercion to participate
- social science questionnaires on non-controversial, non-personal issues
- observational studies in public situations which focus on non-sensitive issues
- studies of existing de-identified data, documents, records, pathological or diagnostic specimens
- studies that do not involve an intervention that could result in significant harm to participants
- collection of certain biological specimens, including hair, nail clippings or saliva
- certain projects involving discarded tissue
- applications for approval of amendments to previously approved research protocols

- studies that are substantially similar to another study already approved.

Research with potential for physical or psychological harm should generally not be considered for expedited review. This includes drug trials, research involving invasive physical procedures and research exploring sensitive personal or cultural issues.

Other situations where review would not normally be expedited include where vulnerable populations are involved or where conflicts of interest may arise, such as those between the roles of clinician and researcher, or teacher and student. Expedited review is never justifiable solely on the grounds of a researcher's claim to the need for urgent review of their project.

Medium and high risk research

Please note, KOI does not currently consider medium to high- risk research, and this position will be reviewed as administrative research resources grow as a direct result of growth in KOI research.

Document control

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********** END OF POLICY **********