



## Human Research Ethics Policy

### Purpose and Scope

The purpose of this policy is to:

- outline King Own Institute (KOI)'s commitment to ensure that all human research undertaken under its auspices is ethical and responsible;
- protect the welfare and rights of participants in research;
- prescribe KOI's framework for the ethical review, approval, monitoring and review of human research;
- ensure KOI complies with the [National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research 2023](#) ('the National Statement') and the [Australian Code for the Responsible Conduct of Research, 2018](#) ('the Code').

This Policy applies to:

- all human research conducted under the auspices of KOI,
- all staff, students, visiting academics, volunteers and other personnel involved in the conduct of human research under the affiliation of, or in collaboration with, KOI; and
- all staff and committees of KOI involved in the ethics review of proposed research and related protocols.

### Related Documents

This Policy is to be read in conjunction with KOI's:

- Responsible Conduct of Research Policy
- Research Breaches Procedure
- Research Authorship Procedure
- [Conflict of Interest Policy](#)
- [Conflict of Interest Procedures](#)
- [Conflict of Interest Guidelines](#)
- [Documents and Records Control Policy](#)
- [Staff Code of Conduct](#)
- [Student Code of Conduct](#)

### Definitions

**Allegation** means "a claim or assertion arising from a preliminary assessment that there are reasonable grounds to believe a breach of the Code has occurred. May refer to a single allegation or multiple allegations" (the Code).

[Australian Code for the Responsible Conduct of Research, 2018](#) ('the Code') means the code developed by the National Health and Medical Research Council and Universities Australia.

**Breach** means "a failure to meet the principles and responsibilities of the Code and may refer to a single breach or multiple breaches" (the Code).

**Complainant** means "a person who has made an Allegation about the conduct of research"



(the Code).

**Conflict of Interest** is “a situation where an independent observer might reasonably conclude that the professional actions of a person are or may be unduly influenced by other interests. This refers to a financial or non-financial interest which may be a perceived, potential or actual conflict of interest” (the Code).

**Co-researcher** means “One or more participants (or a particular sub-group of participants) who make(s) a significant contribution to the planning, design, implementation or outputs of a research project, including the collection, analysis or interpretation of data. Examples of co-researcher contributions include where participants contribute expertise, such as their cultural knowledge of mores and local practices, or their personal insights into local conditions, special interests (e.g. gaming), or social identities or contexts (e.g. young people living in out-of-home care, community activists or people who identify as LGBTIQ+)” (the National Statement).

**Data** “refers to bits of information in their raw form. Data can refer to raw data, cleaned data, transformed data, summary data and metadata (data about data). It can also refer to research outputs and outcomes” (the National Statement).

**Ethics review** means “Review of research by a Human Research Ethics Committee (HREC) or other body” (the National Statement).

**Higher risk research** means “Research in which there is a risk of harm and in which there may also be a foreseeable burden. The risk of harm in higher risk research may or may not be a risk of significant harm and may be harm to the individual, group, community, societal or global level” (the National Statement).

**Human Research:** Human research is conducted with or about people, or their data or biospecimens. Human participation in research is therefore to be understood broadly to include the involvement of human beings through: taking part in surveys, interviews or focus groups; undergoing psychological, physiological or medical testing or treatment; being observed by researchers; researchers having access to their personal documents or other materials; the collection and use of their biological material as defined in Chapter 3.2 of the National Statement; access to their individual information in identifiable or potentially re-identifiable form as included in an unpublished source or database that is used for human research.

**National Statement on Ethical Conduct in Human Research 2025** (the National Statement) is a statement released by the Australian Research Council and National Health and Medical Research Council.

**Limited disclosure** means “Not disclosing to research participants all of the aims and/or methods of the research” (the National Statement).

**Lower risk research** means “Research in which there is no risk of harm, but in which there is a risk of discomfort and in which there may also be a foreseeable burden (low risk research) OR research in which there is no risk of harm or discomfort, but which includes a potential for minor burden or inconvenience (minimal risk research)” (the National Statement).

**Research** “is the creation of new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies, inventions and understandings. This could include synthesis and analysis of previous research to the extent that it is new and creative” (the Code; and the National Statement)

**Research Misconduct** means “a serious breach of the Code which is also intentional or reckless or negligent” (the Code).



**Researcher** is “a person (or persons) who conducts, or assists with the conduct of, research” (the Code).

**Sponsor means** “An individual, company, institution or organisation that takes responsibility for the initiation, management and/or financing of research” (the National Statement).

#### **4. Policy**

KOI will establish systems and processes to ensure compliance with the National Statement, the Code and KOI’s internal governance documents for research and research training.

KOI is committed to conducting research in an ethical and accountable way to facilitate a pervasive ethical research culture.

KOI recognizes that:

- “The relationship between researchers and research participants is the ground on which human research is conducted”; and
- the values of “respect for human beings, research merit and integrity, justice, and beneficence help to shape that relationship as one of trust, respect, mutual responsibility and equity” (the National Statement).

#### **5. Principles**

1. KOI is committed to ethical research and an ethical research culture.

2. KOI is committed to complying with the Code and the National Statement.

3. Researchers, all those involved in ethics review processes and all those involved in research management and governance must be aware of the ethical values and principles in the National Statement and the Code.

4. All research at KOI must be underpinned by the following values and principles of ethical conduct of the National Statement, which 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:

- Respect for human beings;
- Research merit and integrity;
- Justice;
- Beneficence.

5. KOI will promote ethical research that protects and respects research participants and researchers, and that extends benefit to the community.

6. KOI will ensure that individual research proposals comply with all relevant policies and legislation.

7. KOI will establish and maintain procedures for the ethical review of human research, according to the degree of risk involved in the research.

8. 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.

9. 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.

### **Human Research Ethics Review Process**

The Code guides institutions and researchers in responsible research practice and promotes integrity in research.

The National Statement sets out the national standards of ethical conduct for research involving humans and must be used by KOI researchers when developing their projects.

All human research at KOI must undergo ethics review in accordance with the requirements of the National Statement. In addition to ethics approval, human research must also be authorised by KOI before it can proceed.

A chief-investigator must be either a full-time or part-time academic staff member. All ethics applications must identify at least one chief investigator.

In authorising research, KOI will consider, but not re-review, any issues raised during the ethics review of the research proposal. For this reason, all staff research projects must first be discussed with the Vice President Academic. All research ethics applications must be endorsed by the Vice-President Academic and submitted to the Chair of the Research and Scholarship Committee and its Secretary using the [Human Research Ethics Form](#).

The Vice President Academic will desk-reject an ethics application if:

- it is incomplete and/or supporting documents are missing; or
- it does not sufficiently address reviewer feedback and/or lacks research merit and integrity; or
- the project involves greater than lower risk.

Only ethics applications with research merit and integrity that involve lower risk will be submitted to the RSC.

Lower risk research is peer reviewed prior to submission to the Research and Scholarship Committee. Peer review is coordinated by the Vice President Academic.

Students must discuss their projects with their supervisors who will help to develop the project and give due consideration to the ethical issues involved.

Researchers must design their projects in accordance with the National Statement, the Code and the requirements prescribed by KOI, including the requirements of this Policy.

Two themes must always be considered in human research: the risks and benefits of research; and participants' consent.

The basis for approving a research project is the set of guidelines in the National Statement.

Risk in research exists on a continuum with the risk profile of an individual research project falling somewhere along this continuum. In order to determine the proportionate level of review and oversight for each project, the use of risk categories is useful. These categories are described in Figure 1.



Figure 1: Risk profiles of research

Lower risk		Higher risk (Individual, group, community, societal or global)	
Minimal	Low	Greater than low	High
No risk of harm or discomfort; potential for minor burden or inconvenience*	No risk of harm; risk of discomfort (+/- foreseeable burden)	Risk of harm (+/- foreseeable burden)	Risk of significant harm (+/- foreseeable burden)

If a research project is assessed as having more than low risk, the project must be reviewed by an established HREC.

In establishing non-HREC pathways for ethics review of lower risk research, KOI has the resources and capacity to carry out such review competently and professionally.

**Process for Human Research Ethics Applications**

KOI's Research and Scholarship Committee (RSC) is responsible for ethics review of lower risk research.

The RSC is comprised of people who are familiar with the National Statement and have an understanding of:

- the ethical issues that can arise in the research under review;
- issues associated with the collection, use and management of data and information in research (see Chapter 3.1, Element 4 of the National Statement);
- the privacy guidelines that may apply to the research under review;
- other legal standards that may apply to the research under review.

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

Ethics review is informed by guidance provided by the National Statement.

The RSC will assess the level of risk for research projects for which it is responsible. It will make this assessment in accordance with the guidance on risk provided in Chapter 2.1 of the National Statement.

Lower risk (minimal risk) research may be eligible for an exemption from ethics review under paragraphs 5.1.15 – 17 in the National Statement (see Exemptions below). Researchers involved in this type of research can apply for an exemption by submitting a Human Research Ethics Review Exemption Form for review and approval by the RSC.

If ethics approval by a HREC registered in Australia has been established for a research project, additional ethics approval from KOI is not required. However, researchers are required to submit a Human Research Ethics Declaration Form to the Vice President Academic for recordkeeping.

If ethics approval with an overseas international review board/ethics committee has been established, additional ethics approval from KOI is not required if:



- participants within Australia will not be recruited;
- KOI will not be responsible for the conduct of the research at an Australian site; and
- the researcher employed by KOI will not be responsible for fieldwork, recruitment or data collection overseas.

However, researchers from KOI are required to register the external approval with the Vice President Academic for recordkeeping.

All research involving greater than low risk must be reviewed and approved by an HREC registered in Australia in accordance with the National Statement.

A modification request for research approved by KOI's Research and Scholarship Committee is to be submitted to the Chair and Secretary of the Research and Scholarship Committee on the approved form if revisions are to be made to an approved research project.

Researchers undertaking 'human research' may not commence their research until they have written advice that their project has ethics approval. Retrospective ethics approval of research is not supported by KOI as required by the National Statement.

### **Monitoring and review**

The Chief Investigator(s) of all approved projects are required to submit an annual progress report and a final report upon project completion for consideration by the Research and Scholarship Committee. This is to ensure compliance with the approved research protocol and that any complaints or issues occurred have been appropriately addressed and rectified.

### **Recordkeeping and legal protection**

All ethics proposals and scholarly records are electronically recorded and maintained in a secure folder in accordance with the KOI's Research Records Management Policy.

KOI provides an assurance of legal protection to all those involved in the ethical review of research for liabilities that may arise in the course of the bona fide conduct of their duties as advised in the National Statement (Chapter 5.1). Protection is afforded to the Vice President Academic, members of the RSC and ethics reviewers, including peer reviewers.

### **Exemptions**

Some research may be eligible for exemption from ethics review.

Research that involves the use of personal information without consent will not be granted an exemption from ethics review because, to conduct such research, a waiver of the requirement for consent would need to be granted by an appropriate ethics review body.

Research that may be eligible for exemption from ethics review includes research that carries a lower risk (minimal risk) to participants or the community and satisfies one or more of the conditions in (a) to (d), below:

(a) the research involves the use of collections of information or data from which all personal identifiers have been removed prior to being received by the researchers and where researchers explicitly agree:

(i) not to attempt to re-identify those with whom the information or data is associated

(ii) to take all reasonable steps to prevent re-identification of the information or data for unauthorised purposes or access to the information or data by those who are not authorised



(iii) that any sharing of any research data during or after the project will not create any additional risks of re-identification of the information or data;

(b) the research is restricted to surveys and observation of public behaviour using information that was or will be collected and recorded without personal identifiers and is highly unlikely to cause distress to anyone associated with the information or the outcomes of the research;

(c) the research is conducted as part of an educational training program in which the research activity is for training purposes only and where any outcomes or documentation are for program use only;

(d) the research uses only information that is publicly available through a mechanism set out by legislation or regulation and that is protected by law, such as mandatory reporting information, information obtained from registries of births and deaths, coronial investigations or reports of the Australian Bureau of Statistics.

KOI will keep a record of any decision to grant exemption from ethics review.

### **Expedited Review for Lower Risk Research Undertaken as a Learning Activity**

For research undertaken as a learning activity within a subject delivered by KOI, 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 lower risk research. Data collection must be for teaching purposes only.

Students may only use the data for an assignment to be submitted to the subject lecturer. Permission is not granted to publish the data. Otherwise, the activity will require presentation to the Research and Scholarship Committee for approval and undergo peer review as required.

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.

### **Roles and responsibilities**

#### KOI

KOI will:

- maintain, review and evaluate a comprehensive framework to review research proposals, including higher degree research, and teaching related research projects involving human participants;
- ensure that any risks to participants, researchers and the University are identified and managed appropriately;
- establish procedures for monitoring approved research to ensure that all research projects conform with the National Statement and external regulatory requirements.

#### Research and Scholarship Committee (RSC)

The RSC will:

- ensure researchers receive regular advice on ethical matters to ensure that research at KOI conforms with the Code and the National Statement;
- review, evaluate and approve lower risk research proposals by staff in compliance with the National Statement and the Code; and



- provide regular reports on all matters relating to human research ethics processes and outcomes, including compliance with the National Statement and the Code.

#### Academic Board

The Academic Board will:

- monitor the effectiveness of this policy;
- ensure KOI is compliant with the National Statement and the Code and has the resources and capacity to carry out lower risk research competently and professionally; and
- ensure KOI has effective systems and processes in place for reviewing, evaluating and monitoring research of academic staff.

#### Vice President Academic

The VPA is responsible for

- ensuring appropriate support and resources for students and academic staff undertaking research at the Institution;
- arranging periodic briefings on research ethics for its staff, monitoring ongoing research and obtaining reports on projects.

#### Research and Scholarship Committee

The Research and Scholarship Committee is responsible for:

- evaluating the suitability of ethics applications;
- coordinating the lower risk ethics peer-review process;
- administration and record keeping of ethics applications, outcomes and reports on ethics related matters;
- record keeping of declarations of research at KOI with ethics approval obtained from a registered HREC;
- ensuring appropriate storage arrangements for research data and information in accordance with the National Statement; and
- reporting and advising on ethical issues in research projects to the Academic Board.

#### Researchers

Researchers have significant responsibilities for the ethical conduct of research.

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

Each researcher is responsible and accountable to KOI, sponsors and funders of the research, participants and, in some research, to regulators or other entities who have a formal role in the oversight of the research.

Researchers must engage appropriately with communities and/or consumers that are relevant to their research and to positively engage with ethics review, governance and monitoring processes.

Each research proposal must demonstrate that the research has merit and integrity, and



reflects the values of justice, beneficence and respect for human beings.

Researchers must familiarise themselves with the guidance in all relevant sections of the National Statement and understand how their responsibilities relate to the responsibilities of institutions and ethics review bodies, as described in Section 5 of the National Statement.

KOI encourages staff undertaking research to read the Voluntary AI Safety Standard (2025) and to follow its recommendations for the responsible use of artificial intelligence should it be of relevance to their program of research.

Researchers must adhere to the applicable requirements, standards and good practice guidance in the relevant profession and area of research.

Research proposals must be clear and comprehensive, and written in language that is easily understood by ethics review bodies. Researchers should be aware that the submission of poor-quality proposals for review may delay the review, ethical approval and/or institutional authorisation process, with consequent impact on potential participants in the research or the community.

Researchers must present information about the research to participants in ways that help them make informed choices about their participation and support them in those decisions and in their participation. Researchers should then consider:

- (a) whether the information about the research is best communicated to participants through speech, writing, visually or in some other way, or a combination of these;
- (b) the need for accurate and reliable translation (written and/or oral) of the information into a participant's first language or dialect;
- (c) the participant's cultural background and its potential effects on the communication process;
- (d) the participant's educational background and level of literacy, numeracy and understanding of scientific and academic concepts, if known;
- (e) the participant's age and level of maturity;
- (f) any visual, hearing or communication impairment with which the participant is living.

Each researcher must disclose to the review body and, where appropriate, the participants, the amount and sources or potential sources of funding for the research. This information may include financial support, in-kind support, per capita payments or other payments or incentives provided by any entity supporting the research.

A researcher must disclose any interests that may constitute an actual or potential conflict of interest, including any financial or other interest or affiliation that bears on the research

A researcher must disclose any restrictions on publication or dissemination of research findings.

When reporting the research, a researcher must disclose any interests that may constitute an actual or potential conflict of interest, including any financial or other interest or affiliation that bears on the research.

Each researcher, and indeed all researchers on any project, must keep an auditable record of any research they are undertaking that is exempted from ethics review in accordance with paragraphs 5.1.17 and 5.1.18 of the National Statement. This is required to ensure that there is a record of the research where no review has been conducted.



**Complaints**

Complaints about a breach of the Code will be handled according to KOI’s Responsible Conduct of Research Policy and Research Breaches Procedures.

Complaints about the conduct of ethics review bodies and processes in reviewing research proposals should be made to the CEO.

Where a complaint cannot be readily resolved by communication between the complainant and the review body at KOI that is the subject of the complaint, KOI may choose to refer the complaint to an assessor who is independent of the Institute and the review body.

**Associated Information**

Policy title	Human Research Ethics Policy
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\*\*\*\*\* END OF POLICY \*\*\*\*\*