Swinburne Research

Introduction to Human Research Ethics

Overview

- What is human research ethics?
- Types of human research
- Why is ethics approval needed?
- Principles of human research ethics
- Informed consent
- Levels of risk
- Ethics processes at Swinburne
  - Submission
  - Common mistakes
  - Committee decisions
  - Post-approval

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What is human research ethics?

- "Ethics" is defined as *'moral principles that govern a person's behaviour or the conducting of an activity'*

- "Human research" is defined as *research conducted with or about people or their data or tissue*

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Types of human research

Human research is:

1. Research conducted <u>with</u> people
2. Research conducted <u>about</u> people
3. Research dealing in their <u>data</u> or <u>tissue</u>

For example:

- Taking part in *surveys/questionnaires*, *interviews* or *focus groups*
- Undergoing *psychological*, *physiological* or *medical* testing or treatment
- Being *observed* by researchers
- Researchers having *access to personal documents* or other materials
- The collection and use of *body organs, tissues or fluids or exhaled breath*
- *Access to information* (individually identifiable , re-identifiable of non-identifiable form) as part of an existing published or unpublished source or database

Why is ethics approval needed?

- **Ethics approval is a moral and legal requirement**

- National Statement on Ethical Conduct in Human Research (2007) (https://www.nhmrc.gov.au/guidelines-publications/e72)

- Australian Code for the Responsible Conduct of Research (2007) (https://www.nhmrc.gov.au/guidelines-publications/r39)

- Swinburne University Policy: People, Culture & Integrity (http://www.swinburne.edu.au/policies-regulations/policies/people-culture-integrity/)

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- **Ethics review adds value:**

  - Experts from a variety of backgrounds review applications
  - Provide critical feedback and address critical gaps in the project
  - Identifying legal oversights
  - Risk minimisation
  - Respecting the rights of participants
  - Highlighting the obligations of a researcher
  - Identifying issues of safety (e.g. researcher and participants)

Values and principles of human research ethics

- **Research merit and integrity**: research must be worthwhile and have value to the community
- **Respect** for human beings: recognises that each human being has value in him/herself
- **Beneficence**: the obligation to maximise possible benefits and minimise possible harms
- **Justice**: addressing the resolution of the question of who ought to receive the benefits of research and bear its burdens

Research Merit and Integrity

- Justifiable by its potential benefit
- Designed/developed using appropriate methods
- Based on current literature and previous studies
- Designed to ensure respect for participants is not compromised by aims of the research
- Conducted/supervised by persons with appropriate experience/qualifications and competence
- Conducted using appropriate facilities and resources

Justice

- Fair exclusion and inclusion of participants
- Fair recruiting process
- No unfair burden on participants
- Fair distribution of the benefits of participation
- No exploitation of participants
- Fair access to the benefits of research

Beneficence

- The likely benefit of the research must justify any risks of harm or discomfort to participants
- Researchers are responsible for clarifying the potential benefits and risks to participants
- Where the risks to participants are no longer justified by the potential benefits of the research, the research must be suspended to allow time to consider whether it should be discontinued or at least modified
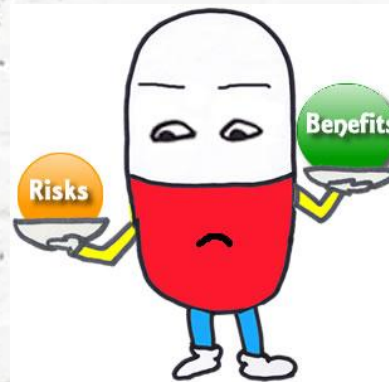
Respect

- Refers to recognition of human beings' intrinsic value
- Regard for the welfare, rights, beliefs, perceptions, customs and cultural heritage
- Researchers should respect the privacy, confidentiality and cultural sensitivities of the participants
- Respect involves giving people the capacity to make their own decisions
- Where participants are unable to make their own decisions, respect involves empowering them where possible and providing for their protection where necessary

Informed consent

- Consent Information Statement (CIS) and Consent Form (CF)
- Purpose of research
- What participants will be doing, for how long and where
- Offer to withdraw at any time for any reason without penalty
- Potential benefits to participant/society
- Potential harm or risk of discomfort
- How privacy will be protected
- Instructions on how to get a copy of the results
- Who the investigators are and how they can be contacted
- Ethics approval statement and contact details
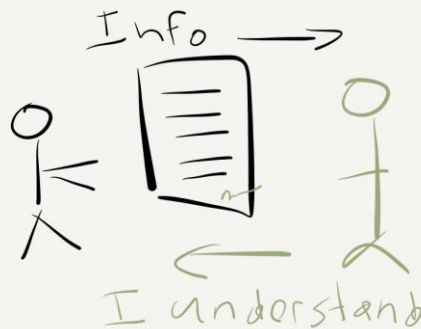
Levels of risk

The National Statement includes provision for institutions to establish different levels of ethical review for research with different levels of risk:

- 'Negligible risk' – no foreseeable risk of harm or discomfort and any foreseeable risk is no more than *inconvenience*
- 'Low risk' – the only foreseeable risk is *discomfort*
- 'More than low risk' – the foreseeable risk is more than discomfort

Low/negligible risk → Swinburne University Human Research Ethics Sub-committee (SHESC)

More than low risk → Swinburne University Human Research Ethics Committee (SUHREC)

Full SUHREC review

National Statement Section 5.1.6

- All research that involves more than low risk
- Interventions and therapies, including clinical and non-clinical trials, and innovations
- Human genetics
- Human stem cells
- Women who are pregnant and the human foetus
- People highly dependent on medical care who may be unable to give consent
- People with a cognitive impairment, an intellectual disability, or a mental illness
- Aboriginal and Torres Strait Islander People and Communities
- People who may be involved in illegal activities

Ethics review process at Swinburne

- Preparation
- Submission
- Common mistakes
- What happens after submission?
- Committee decisions

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Preparation

- Familiarise yourself with the Application Form and Guidelines
- Ensure all questions in your application are answered
- Ensure language is clear and simple (avoid jargon)
- Seek advice from others (e.g. your supervisor, other researchers, Research Ethics Advisor, etc.)
- Obtain approval signatures from all relevant parties
- Allow sufficient time to put your application together; late submissions are not acceptable
- Proof read application and attachments
- The Chief Investigator is responsible for ensuring that the application is suitable for submission

Submission

What do I have to submit?

- An *electronic* copy of the application form (single file pdf) sent to resethics@swin.edu.au
- One *original hardcopy* containing all signatures
- 1 additional copy (SHESC) or 4 copies (SUHREC)
- Consent instruments (ie. Participant Information Statement, Consent Forms, etc.)
- Data collection tools (questionnaires, interview questions, focus group discussion topics, surveys, tests, etc.)
- Advertising material (flyers, social media posts, emails, etc.)
- Supporting documentation (e.g. contracts, funding agreements, letters of approval from other organisations)
- Any other documents relevant to *your* project

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Common mistakes

- Failure to plan; include 'ethics application' in your research project
- Omitting attachments (e.g. questionnaires, advertisements, consent documents, etc.)
- Neglecting to answer questions in the application form
- Omitting information related to recruitment (e.g. sample size, how will participants be identified, how and by whom will they be approached, etc.)
- Lack of information regarding data storage, access, destruction
- Grammar/spelling/typos
- Missing signatures/approvals

What happens after submission?

- Research Ethics Office checks the application
- The application is assigned to the appropriate committee
- SHESCs meet approximately 9 working days after the deadline
- SUHREC meets approximately 11 working days after the deadline
- Committee reviews applications and Ethics Office staff prepare minutes of meeting
- Decisions regarding the ethical review are communicated back to the Chief Investigator (usually within one week of the meeting)
- Researchers provide a written response to the review to the committee member *via the Research Ethics Office*
- The committee member assesses the response and feedback is provided via the Research Ethics Office
- Review/feedback/response process is reiterated until approval
- Research Ethics Office sends ethics clearance email to CI

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Committee Decisions

- Possible outcomes are:

1. Approved as submitted.

2. 'Approved subject to...'.

3. Not approved as submitted but a re-submission is invited, to be considered by committee members out-of-session.

4. Not approved as submitted but a re-submission is invited, to be considered at a subsequent meeting of all members.

- **You cannot commence your research until written ethics approval has been granted**.

Post-approval

- What happens if I need to change something (e.g. protocol, recruiting more participants, changing questionnaire)?
  - → Modification request form

- What happens if I need more time?
  - → Request extension prior to approved end-date

- Project monitoring
  - → Annual/Final Reports

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Common breaches of ethics

- Forgetting to apply for an extension to the approval period
- Modifying the protocol and failing to request ethics approval
- Lack of compliance with reporting requirements
- Changing personnel without requesting ethics approval
- Inadvertent coercion of participants
- Advertising for participants without approval
- Inappropriate use of social media

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Ethics intranet:

Ethics

Swinburne researchers are committed to the highest ethical, professional and scholarly standards. At Swinburne, our research conforms to the Australian Code for the Responsible Conduct of Research. Our People, Culture and Integrity Policy also reflects our commitment to the code.
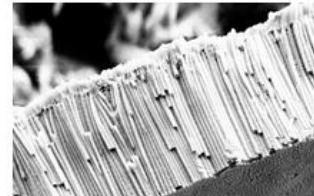
Human research

Research with human participants must meet the requirements of the National Health and Medical Research Council. Learn more about Swinburne's human research activities.

Animal research

All projects involving the care and use of live animals or animal tissue must have the approval of the Swinburne Animal Ethics Committee. Find out more about research with animals.
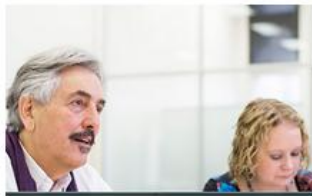
Biosafety

We're committed to ensuring biohazards cause no harm to human, animal and environmental health as a result of our research.

Data management

Learn more about Swinburne's standards for the collection, retention and disposal of research data

Intranet (login required)

Login to access integrity and ethics information for Swinburne research staff and students.

Contact us

Contact Swinburne's Research Ethics Office.

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Intranet info

- Application form
- Guide to application form
- Templates for consent documents
- Modification request form
- Progress/Final Report form
- List of Research Ethics Advisors
- Deadlines for submission of application
- FAQs
- Contact details for Research Ethics Office

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