Ethics
“Ethics and ethical principles extend to all spheres of human activity. They apply to our dealings with each other, with animals and the environment. They should govern our interactions not only in conducting research but also in commerce, employment and politics. Ethics serve to identify good, desirable or acceptable conduct and provide reasons for those conclusions.”

National Statement on Ethical Conduct in Research Involving Humans, 1999
Calvin and Hobbes

Whenever I need to do some serious thinking, I go for a walk in the woods.

There are always a million distractions out here.

As far as I'm concerned, the ends justify the means.

Get what you can while the getting's good—thats what I say! Right makes right? The history books say so.

It's a dog-eat-dog world. So I'll do whatever I have to, and let others argue about whether it's "right" or not.

Hey! Why'd you do that? You were in my way. Now you're not. The ends justify the means.

I didn't mean for everyone you dol! I just me.

Ah...
Quiz

• Question 1

Ethics Committees decide what is right and what is wrong about a research project.

True/False
Quiz

• Question 2
Members of the Ethics Committee are all researchers chosen by the University.

True/False
Quiz

• Question 3

Researchers do not always have to obtain informed consent by asking participants to sign a consent form.

True/False
Quiz

• Question 4

Ethics Committees only review “risky” projects, e.g. projects involving health or medical research procedures.

True/False
Quiz

• Question 5

In preparing an application for ethics approval, it is fine to “cut and paste” technical explanations from the research proposal. Members of Ethics Committees are experts in research.

True/False
What is research ethics?

• Ethics is about making sure that the work and research we do does not hurt others and ourselves
• Research ethics is the study, practice and monitoring of ethical conduct in research
• The way in which people who provide data should be treated by researchers
Why do you need ethics approval?

- **Protection for:**
  - Participants
  - Researcher
  - University
  - Community

- To observe ethical, professional and legal responsibilities

- Legislative requirement

- Access to funding
National Statement on Ethical Conduct in Human Research 2007

National Statement


• Values and principles of ethical conduct
• Research involving particular groups of participants
• Research involving particular types of procedures
Values in the National Statement

• 4 Values – “The design, review and conduct of research must reflect each of these values”
  – RESEARCH MERIT AND INTEGRITY
  – JUSTICE
  – BENEFICENCE
  – RESPECT
Research Merit and Integrity

• Potential benefit, contribution to knowledge
• Appropriate methods and thorough study of literature
• Experience, qualifications and competence
• Appropriate facilities and resources
• Peer review
• Honest conduct of research
• Communication of results
Justice

- Fair inclusion/exclusion of participants
- Process of recruitment is fair
- No exploitation of participants
- No unfair burden of participation
- Outcomes accessible in a timely and clear way
- Fair access to benefits and fair distribution of the benefits of participation
Beneficence

• Likely benefit justifies any risks
• Research responsibility
  – Minimise risks
  – Tell participants the risks and benefits
  – Welfare of participants in research context
• No likely benefit – risk should be lower
• If risks not justified by benefits – can lead to suspension of research
Respect

• Due regard for welfare, beliefs, perceptions, customs and cultural heritage
• Privacy, confidentiality, cultural sensitivities
• Capacity of human beings to make their own decisions
• If unable to make decisions, empowering participants and providing for protection
Ethical considerations specific to research methods or fields

• 3.1 QUALITATIVE METHODS
• 3.2 DATABANKS
• 3.3 INTERVENTIONS AND THERAPIES, INCLUDING CLINICAL AND NON-CLINICAL TRIALS, AND INNOVATIONS
• 3.4 HUMAN TISSUE SAMPLES
• 3.5 HUMAN GENETICS
• 3.6 HUMAN STEM CELLS
Ethical considerations specific to participants

- 4.1 WOMEN WHO ARE PREGNANT AND THE HUMAN FOETUS
- 4.2 CHILDREN AND YOUNG PEOPLE
- 4.3 PEOPLE IN DEPENDENT OR UNEQUAL RELATIONSHIPS
- 4.4 PEOPLE HIGHLY DEPENDENT ON MEDICAL CARE WHO MAY BE UNABLE TO GIVE CONSENT
- 4.5 PEOPLE WITH A COGNITIVE IMPAIRMENT, AN INTELLECTUAL DISABILITY, OR A MENTAL ILLNESS
- 4.6 PEOPLE WHO MAY BE INVOLVED IN ILLEGAL ACTIVITY
- 4.7 ABORIGINAL AND TORRES STRAIT ISLANDER PEOPLES
- 4.8 PEOPLE IN OTHER COUNTRIES
Values and Ethics

Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research

Keeping research on track
A guide for Aboriginal and Torres Strait Islander peoples about health research ethics
Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research

- Guidelines for the conception, design and conduct of research

6 Values

- Reciprocity
- Respect
- Equality
- Survival and Protection
- Responsibility
- Spirit and integrity

Diagram 1: Aboriginal and Torres Strait Islander Peoples values relevant to health research ethics
Human Research Ethics Committee (HREC)

• Established by ECU Council
• Constituted and functioning according to the National Statement
• Relevant experience and/or expertise
• Resourced sufficiently
• More information

Categories of membership

- Chairperson
- A person with knowledge of, and current experience in, the areas of research that are regularly considered by the HREC (e.g. health, medical, social, psychological, epidemiological, as appropriate)
- A person with knowledge of, and current experience in, the professional care, counselling or treatment of people (e.g. medical practitioner, clinical psychologist, social worker, nurse, as appropriate)
- A person who is a minister of religion, or a person who fulfils a similar role in a community such as an Aboriginal elder
- A person who is a lawyer
- Two lay people, one man and one woman
Role of the HREC

- Guidelines
  - National Statement
  - Values and Ethics
  - Privacy legislation
- Protect participants (and researchers)
- Encourage good research
HREC Member Responsibilities

• Deciding whether a proposal meets the requirements of the National Statement and is ethically acceptable
• Familiarity with the National Statement and other guidelines
• Professional development
• Disclosure of conflict of interest
HREC Membership - realities

• Review over 250 applications per year!
• Not all are ECU staff/researchers
• All members are voluntary
• Members are unpaid
• Attend monthly meetings
• Happy to talk to researchers
What is human research?

- Taking part in surveys, 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
- Access to information as part of an existing published or unpublished source or database
Ethics and your project

- Participants
  - Who are they?
  - How will you ask them to take part?
- Procedures
  - What are you asking participants to do?
- Data/information/samples
  - Confidentiality
  - Data retention
Informed Consent

• Read this and sign here – information letters and consent forms
• Who is it for?
• You want me to do what??
• What would your mother think?
• Saying “no”
Information about the project

• THE INFORMATION MUST BE PRESENTED IN WAYS SUITABLE TO EACH PARTICIPANT
  • Plain language
  • Opportunity to think about information
  • Ask any questions
Negotiating consent

• “Process” of communicating information and seeking consent not just a formal requirement
• Mutual understanding between researchers and participants
• Based on sufficient information

Remember: Informed Consent is more than just a form - it is an on-going process that starts as early as recruitment, continues throughout the person’s participation in the research, and may extend until the completion of the research.
Consent

• Absolutely voluntary
• No coercion or pressure
• Informed
• No penalty for refusal
• Right to discontinue at any time

www.ecu.edu.au/research/week
AMAZING! THE INSCRIPTION APPEARS TO BE AN ANCIENT CONSENT FORM FOR AN EXPERIMENTAL MUMMIFICATION PROCESS!

Cartoon © 2006 by IRC. Permission granted for non-commercial reproduction with attribution, all other rights reserved. dion国土资源.com
Risks and benefits

• Risky research
  – What are the potential risks for participants?
  – Any risks to the researcher?
• Benefits
  – What will participants get from your project?
  – What are the benefits of the research?
• Balance
  – Do the potential benefits of the research justify the risks involved?
"The biggest risk in this study is just reading the consent form!"
Managing Risks

• Risk = a potential for harm, discomfort or inconvenience.

• Harm – physical, psychological, devaluation of personal worth, social, economic, legal.

• Discomfort – e.g. minor side-effects, discomfort with measuring blood pressure, anxiety induced by interview

• Inconvenience – e.g. filling in a form, giving up time.

• Involves likelihood of occurrence and severity

• In designing a research project, researchers have an obligation to minimize the risks to participants.
"Make sure everything's done ethically. Within reason, of course."
CASE STUDY 1

Investigating staff satisfaction within a small business

• This research project will investigate staff satisfaction within an organisation and explore complaints management strategies.

• PhD student (also CEO of the business)
Participants

• Employees and supervisors of the business
• Customers of the business

Recruitment

• Employees and supervisors will be told to complete a survey and return it to the CEO
• Some employees might be interviewed
• Customers will be emailed
Information

• Participants will be emailed some information about the project

Consent

• Employees and supervisors will be told to do the survey and interviews

• Customers will complete the survey if they want to be part of the research
Research procedures

• Employees and supervisors will fill out a survey
• Survey results will be linked to staff records
• If employees complain about satisfaction, they will also be interviewed
• Supervisors will also be notified if there is a complaint about them and asked to comment
• Customers of the business will also be surveyed
• If a customer names an employee, the employee will also be questioned
Employee Survey

Name...........................................................................
Staff number..............................................................
Supervisor.................................................................

• What do you like about working here?
• What don’t you like about working here?
• How well does your supervisor do his/her job?
• Do you have any complaints?
• What would make you more satisfied about working here?
Customer Survey

Name.................................................................................................

• What do you like about this business?
• What don’t you like about this business?
• How well does did the person who served you do his/her job?
• Please provide the name of the person who served you:
  Employee Name..............................................................................
• Do you have any complaints?
Risk and Benefit

• RISK: No risks
• BENEFIT: Finding out more about satisfaction in this organisation

Data Confidentiality

• The researcher will keep all the surveys and interviews.
• The CEO has access to staff records anyway.
• Data may be used for further studies.
CASE STUDY 2
Impact of lifestyle of the treatment of diabetes

• This research project aims to assess the impact of lifestyle factors such as diet and exercise on the rate and severity of the development of diabetes related complications in elderly patients.

• Staff member who also works in a private nursing home providing medical treatment to the residents
Description

- Project involves the use of information in the medical records of the patients.
- Information was initially collected in the course of providing treatment for diabetes.
- Medical record data will be supplemented by data routinely collected by staff about diet, exercise habits and overall wellbeing.
- Researcher aims to use the results to identify factors that may contribute to improved management of diabetes in elderly patients.
Participants

• 12 residents of the nursing home who are undergoing regular treatment for diabetes.
Information and Consent

• The researcher does not intend to seek consent from each patient to review his/her medical records or to access information held by staff.

• Reasons:
  – The researcher has access to the medical records anyway
  – Information will be used to provide better treatment to the patients
  – The researcher is the only one who will access the data
  – The data will be stored securely
Section 95A Guidelines

If you are a Commonwealth agency, refer to the NPPs. If you are a State or Territory public sector agency, refer to relevant State/Territory legislation or codes of practice.

Are you covered by the NPPs? (i.e. are you an organisation? See definition of organisation—Key Concepts, page 9).

Is the data to be collected, used or disclosed from an organisation in the private sector?

Yes

Does the data include information that identifies the individual(s) involved?

Yes

Could the research, statistical or health service management activity be conducted using de-identified information?

Yes

Is the use or disclosure a directly related secondary purpose within the reasonable expectations of the individual?

Yes

Is it proposed to undertake the research, statistical or health service management activity with the consent of the individual(s) involved?

Yes

Apply the Section 95A Guidelines

No

No

No

No

No

No

If the data is held by a Commonwealth agency see the Information Privacy Principles (NPPs) and the Section 95 Guidelines.

The National Privacy Principles (NPPs) and the Section 95A Guidelines do not apply.

If the data is held by other than a Commonwealth agency assess the research proposal according to the National Statement. The principles of the Section 95 or 95A Guidelines may be helpful, but are not a requirement.

The Section 95A Guidelines do not apply. No extra steps need to be taken when using or disclosing relevant personal information for the purpose of a health service management activity. Refer to the NPPs.

The Section 95A Guidelines do not apply. Refer to the NPPs for overall privacy requirements for handling health information held by organisations in the private sector.
CASE STUDY 3
Resilience and sports performance

• The aim of this research is to investigate how individuals deal with adverse conditions in sport.
• The research will provide a unique understanding of the effect of resilience on sport performance by investigating resilience of adolescent athletes following a stress test.
• Research team including researchers from psychology and sports science.
Participants

• 20 elite athletes (10 male and 10 female) aged between 15 – 17 years

• All currently resident at a sporting academy

Recruitment

• Head Coach will assist with recruitment

• Athletes will be asked if they wish to participate
Research procedures

- Participants will be given a specific stress test
- They will be asked to try to achieve their personal best (try as hard as they can)
- Visual feedback on performance will be provided – but adjusted so that it shows a slower time (poorer performance)
- Response will be recorded – either attempting to perform faster or giving up
- A battery of resilience tests will be given following the trials
- Duration of the testing sessions will be approx 2 hours
Research procedures – cont.

• Full intention of the study will NOT be disclosed to the participants

• “If they were aware of the full intentions, then they may anticipate what is being examined and what may be required of them in regard to their repeated performance. Their performance would not then truly represent their resilience or non-resilience.”

• Aim of the project is to determine whether resilient individuals, identified by the instrument battery, are capable of performing the test to the best of their abilities, despite the difficulties.
Information

• The Head Coach will be provided with the full information about the project.
• Limited information (not disclosing the full intentions) will be provided verbally to the athletes

Consent

• The Head Coach will provide permission for the athletes to participate
• Athletes will provide verbal consent
• No parent consent will be obtained
Risk and Benefit

• RISK: Participants may be upset with the initial outcome of the test and may experience feelings of disappointment or frustration if they perform lower than their own expectations. Upon completion of the trials, the full intentions of the study will be revealed to each participant.

• BENEFIT: Insight into how individuals deal with adverse conditions

Data Confidentiality

• Results from the testing will be stored with the athlete’s file at the sporting academy
CASE STUDY 4

Investigating Student Attitudes to Late Lecture Times

• This project aims to investigate the attitudes of students to attending lectures after hours (i.e. after 5.00 pm).

• Honours researcher
Participants

• Undergraduate students at ECU

Recruitment

• A global email will be sent to ECU undergraduate students

• The researcher will also hand out information about the project in lectures (with the permission of the lecturer)
Information

• A written information letter will be prepared
• The researcher will answer any questions about the project

Consent

• Participants will be asked to sign a consent form
• Parent consent for students under 18 years will not be sought as it is deemed that these students are competent to give their own consent and the research is low risk
Date

Dear Potential Participant

**Investigating Student Attitudes to Late Lecture Times**

You are invited to participate in this research project, which is being conducted as part of the requirements of a Honours degree at Edith Cowan University.

The purpose of the project is to explore the attitudes of students to the attendance of lectures outside of normal working hours (i.e. after 5:00 pm).

If you choose to participate in this project you will be asked to:
- complete a survey
- participate in a focus group

It is estimated that the survey will take approximately 15 minutes to complete. The focus group will be conducted at ECU and will take approximately 30 minutes. The focus group will also be tape-recorded.

You are free to choose to participate in either the survey or the focus group or both. The only identified risk for participants in this project is inconvenience.

Any information will only be used for this research project and only the student and the supervisor(s) will have access to the information.

Any information or details given for this study will be kept confidential. You will not be identified in any written report or presentation of the results of this research project. You will be provided with a summary of the results of the project.

Participation in this project is voluntary. If you choose to participate, you are free to withdraw from further participation at any time without giving a reason and with no negative consequences. You are also free to ask for any information which identifies you to be withdrawn from the research project.

If you have any questions or require any further information about the research project, please contact:

Ms Researcher
Contact details

If you would like to participate in this project, please complete and return the consent form.

Researcher

This research project has been approved by the Human Research Ethics Subcommittee. If you have any concerns or complaints and wish to talk to an independent person, you may contact the Research Ethics Officer, phone: (08) 6314 2170, email: research.ethics@ecu.edu.au
Research procedures

• Students will be asked to complete a survey
• The survey will collect demographic information as well as attitudes
• Once the results of the survey have been analysed, some students may be invited to participate in an interview
• The interview will explore themes arising from the survey (a copy of the interview questions will be supplied to the ethics committee when they have been developed)
Risk and Benefit

- **RISK:** Inconvenience in filling out the survey
- **BENEFIT:** Finding out more about student attitudes to late lectures

Data Confidentiality

- Data will be permanently deidentified once analysis has been completed
- Data will be stored securely at ECU for 5 years
“Research, like everyday life, often generates ethical dilemmas in which it may be impossible to find agreement on what is right or wrong.”

National Statement on Ethical Conduct in Human Research, 2007
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