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# Doing ethical research in learning and teaching.

Heather Worth

SCHOOL OF PUBLIC HEALTH  
AND COMMUNITY MEDICINE

# What is this thing called ethics?

Ethics comes from the Greek *ethos* meaning customs, habits. Ethics relates to the precepts which should control moral behaviour. It is concerned with the nature and grounds of moral obligations, distinguishing what is right from what is wrong and the reasons for it.

Ethics is concerned with:

- how moral values should be determined
- how a moral outcome can be achieved in specific situations
- how moral capacity or moral agency develops



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# Why do we need to consider ethics in research?

- Our research deals with people – their health, experience and perceptions. This can involve individuals, groups or even communities.
- We also have to manage issues where the rights of an individual conflict with those of the community (e.g. immunization programs or contact tracing for STIs, or quarantine)
- We have to do research in sites where it might be difficult to guarantee anonymity or confidentiality



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# Universal ethical research principles

- It is essential to include fundamental ethical principles in the design and implementation of research involving human participants.
- Ethical research principles are considered universal, transcending geographic, cultural, economic, legal and political boundaries.
- 3 principles:
  - Beneficence
  - Autonomy, or respect for persons
  - Justice



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# Benficence

Benficence means: only doing good

- Obligation to help others further their important and legitimate *interests*.
- Researchers then must confer benefits and *actively* prevent and remove harms
- Makes researcher responsible for the participant's physical, mental and social well-being as related to the study. All risks should be kept to a minimum. The protection of the well-being of the participant is the primary responsibility of the researcher.
- Protecting the participant is more important than:
  - the pursuit of new knowledge
  - the benefit to science that will result from the research
  - personal or professional research interest



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# Autonomy

- Ethical research ensures that research make informed and voluntary decisions to take part, without controlling influences that would mitigate against a free and voluntary act.
- Research among vulnerable groups (such as children, prisoners and the mentally ill) needs careful attention to protect them.
- This principle is the basis for of "informed consent". This includes:
  - the nature of the research
  - risks, benefits, and uncertainties involved
  - How they can change their mind about participation
  - How they can seek redress if not happy



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# Justice

- Forbids placing one group of people at risk solely for the benefit of another.
- The researcher's obligation to distribute equally the risks and benefits of participation in the research.
- Recruitment and selection of research participants should be done in an equitable manner.
- Justice would not permit using vulnerable groups—such as minors, poor people, or prisoners—as research participants for the exclusive benefit of more privileged groups.

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# Questions researchers should ask themselves

- Does my research impinge on an individual's personal autonomy?
- Have the research subjects freely consented to take part?
- Who benefits from my research?
- Will anyone be harmed by my research?
- What steps can I take to minimise this harm?
- Have I communicated risks involved in a truthful and open manner?
- Is my proposed research equitable?



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# Reasons why we have research ethics committees

## **Nuremberg Code (1948).**

- Trials for Nazi doctors for medical experiments on thousands of concentration camp prisoners without their consent. The Nuremberg Code was established in 1948. Stated that: “voluntary consent of the human subject is absolutely essential”.

**Tuskegee Syphilis Study (1932-1972).** U.S. Public Health Service study of 600 low-income African-American males, 400 of whom were infected with syphilis, were monitored for 40 years. Even though penicillin became available in the 1950s, the study continued until 1972 with participants being denied treatment.

**Declaration of Helsinki (1964)** World Medical Association recommendations for biomedical research involving human subjects.

- Research protocols should be reviewed by an independent committee prior to initiation
- Informed consent from research participants is necessary
- Research should be conducted by medically/scientifically qualified individuals
- Risks should not exceed benefits



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# Research Ethics in Australia

The *National Health and Medical Research Council Act 1992* specifies that NHMRC will issue advice and guidelines on ethics and related issues in the fields of health and human and animal research.

- The *National Statement on Ethical Conduct in Human Research (2007)* (National Statement) consists of a series of primary guidelines for researchers, Human Research Ethics Committees (HRECs), and organisations. It is designed to clarify the responsibilities of:
  - institutions and researchers for the ethical design, conduct and dissemination of results of human research; and
  - review bodies in the ethical review of research.
- In addition, the *Australian code for the responsible conduct of research (2007)*<sup>1</sup> (the 'Research Code')



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# UNSW ethics

- All research involving human subjects must be passed by one of two bodies:
  1. HREC: reviews all projects which contain significant ethical concerns (e.g. Research on sexuality, drugs, vulnerable populations, international research)
  2. HREA (Human Research Ethics Advisory Panels) which are concerned with research which has minimal ethical impact



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# Usefulness of Ethics

- You will be required to think about your study differently from when you wrote the proposal (much more from the point of view of those being studied).
- You may start to think about how to engage participants more in the process of research (design, research advisory committee, feedback)
- Ethics committees are NOT scientific review committees
- Journals will require ethical statements (some with details)



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# Grants Management Office

- [http://www.gmo.unsw.edu.au/Ethics/HumanEthics/HumanEthicsInformation\\_index.html](http://www.gmo.unsw.edu.au/Ethics/HumanEthics/HumanEthicsInformation_index.html)
- Standard HREA Panel application form
  - 5 copies
  - Must be in by 4.30pm on the 1<sup>st</sup> Wednesday of each month (not January). Committee meets on 2<sup>nd</sup> Monday of each month.
  - Christina Rofe is now the secretary of the HREA ([c.rofe@unsw.edu.au](mailto:c.rofe@unsw.edu.au)), ph: x51396. Temp office is



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## Hints to get through HREA

- Make sure you fill the form out correctly. Most applicants do not do this.
- Make sure you follow the HREC template for Participant Information Sheet and Consent Form.
- Don't keep on researching medical students 😊
- 



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For HREA panel use only:

Approved    Change    Refer    Reject

Reference No:

*The University of New South Wales*  
Human Research Ethics Advisory (HREA) Panels - APPLICATION FORM

**Please download this application form (begin typing at ^^ the border will expand)**  
**You may add rows if required (e.g. for additional supervisors)**  
**Please attach documentation where required. Please answer all questions.**

**1. Investigators:**

School/Unit/Centre: ^^

Investigators	Title	Family Name	First Name	Phone/Mobile	Fax	Email
First Investigator	^^					
Co-Investigator						
Supervisor (if the applicant is a student)						

Make sure phone number is a university phone number

**2. Status of Investigator:**    Academic    Student.

*If student, please indicate the candidate level:*

PhD    Masters    PG Dip    Honours    Other^^ \_\_\_\_\_

Make sure you accurately fill this bit in

**3. Project title:**

^^

Make sure the project title makes sense to a lay person (no acronyms)

**4. Project description - aims, hypotheses/research questions, methods:**

Please provide a description of the project (300 words max) on a **separate page**.  
Please attach a copy of **questionnaires** and **interview schedules** if applicable.

Make sure recruitment is 'hands off'. This means no **direct recruitment**

1. Make sure you attach adverts
2. Be careful about teacher/student research
3. Be careful of inducements

Written consent is the 'gold standard' but sometimes oral consent is O. With a survey, proceeding to answering the questions (if online or self-administered) is enough. Ethics statement should be read to all interviewer administered questionnaires

**5. Potential for harm to participants and/or Investigators:**

Refer to the National Statement: <a href="#">1.Principles</a>	
<b>Is there any potential for harm, physical, psychological, social, cultural or financial?</b>	<input type="checkbox"/> YES <input type="checkbox"/> NO
<b>Are there potential risks to researchers?</b>	<input type="checkbox"/> YES <input type="checkbox"/> NO
If you answered "YES" to either of these questions, please describe the risk(s) and estimate their probability.	

**6. Recruitment of participants:**

Refer to the National Statement: <a href="#">4.Children/Young people</a> ; <a href="#">5.Mental impairment</a> ; <a href="#">6.Dependent on medical care</a> ; <a href="#">7.Unequal relationships</a> ; <a href="#">8.Collectivities</a> ; <a href="#">9.Indigenous</a>	
<b>Are participants to be recruited to take part in the project?</b>	<input type="checkbox"/> YES <input type="checkbox"/> NO
<b>Is there any possibility of coercion of participants to enrol in the study?</b>	<input type="checkbox"/> YES <input type="checkbox"/> NO
<b>Are participants in a dependent relationship with the Investigator (eg teacher-student)?</b>	<input type="checkbox"/> YES <input type="checkbox"/> NO
<b>Will participants be offered an inducement to encourage their involvement?</b>	<input type="checkbox"/> YES <input type="checkbox"/> NO
If you answered "YES" to any of these questions, please describe fully how participants are to be recruited and how other issues are to be resolved. Please attach any recruitment <b>advertisements</b> and <b>posters</b> .	

**7. Informed consent**

Refer to the National Statement: <a href="#">1.Principles</a> ; <a href="#">6.Dependent on medical care</a> ; <a href="#">14.Epidemiological research</a> ; <a href="#">15.Tissue samples</a> ; <a href="#">16.Genetic research</a>	
<b>Will you seek written informed consent from participants?</b>	<input type="checkbox"/> YES <input type="checkbox"/> NO
If you answered "NO", please justify why not. If you answered "YES", please attach a <b>Participant Information Sheet</b> and <b>Consent Form</b> prepared in close accordance with HREC proforma.	
^^	

**8. Privacy**

<b>Is there a requirement for the researchers to identify, collect, use or disclose information of a personal nature (either identifiable or potentially identifiable) about individuals without their consent (eg. from Commonwealth departments or agencies, State departments or agencies or other third parties such as non-government organisations)?</b>	<input type="checkbox"/> YES <input type="checkbox"/> NO
If you answered "YES" to any of these questions, please complete the <a href="#">HREA Panel Privacy Data Form</a>	

If using records or databases make sure you have the necessary permissions (e.g. letters from hospital management, consent from participants)

This is seen as very important

**9. Observation and records:**

Refer to the National Statement: [17.Covert observation](#)

Is it necessary in your research to make recorded observations of participants (eg audiotapes, videotapes)?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Is it necessary to use records or database information?	<input type="checkbox"/> YES <input type="checkbox"/> NO

If you answered "YES" to either question, please explain why and outline how this will be done.

**10. Confidentiality, privacy, anonymity:**

Is there a possibility of participants being inappropriately identified or confidential data being divulged during or after the research has taken place?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Please confirm that data will be stored for a minimum of 7 years in a secure location, preferably on UNSW premises.	<input type="checkbox"/> YES <input type="checkbox"/> NO

If you answered "YES", please describe the measures you will take to ensure privacy, confidentiality and anonymity are preserved.  
^^

**11. Deception/debriefing:**

Refer to the National Statement: [17.Deception](#)

Is it necessary during your research to deceive participants?	<input type="checkbox"/> YES <input type="checkbox"/> NO
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If you answered "YES", please explain why, and outline how this will be done. In addition, please attach a description of your **de-briefing procedure** for participants.  
^^

**12. Conflict of interest, including financial involvement:**

Refer to the National Statement: [18.Privacy](#); [19.Intellectual property](#); [Information Privacy Principles](#)

Is the research being funded by an agency outside the UNSW?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Is there any conflict of interest (including financial gain) likely to result from this project?	<input type="checkbox"/> YES <input type="checkbox"/> NO

If you answered "YES" to either of these questions, please provide details and attach **documentation**.  
^^

Make sure this is signed by ALL investigators

**13. Organisations other than the University of New South Wales:**

<b>Are there organisations other than UNSW involved in this research?</b>	<input type="checkbox"/> YES <input type="checkbox"/> NO
If you answered "YES", please provide <b>details</b> . Please attach a <b>letter of support</b> for the research from the organisation.	
^^	

**14. Declaration of investigators**

I/we apply for approval to conduct the research. If approval is granted, it will be undertaken in accordance with the protocol described in this application and other relevant guidelines, regulations and laws.

Investigator(s)	Name (Block letters)	Signature	Date
<b>First Investigator</b>			
<b>Co-Investigator</b>			
<b>Supervisor (if applicable)</b>			

Don't forget the checklist

**CHECKLIST** (to be filled in by the Applicant)

Question	Document/copies	Check
4	Project description	<input type="checkbox"/> Needed
	Questionnaire	<input type="checkbox"/> Needed <input type="checkbox"/> Not needed
	Interview schedule	<input type="checkbox"/> Needed <input type="checkbox"/> Not needed
6	Recruiting advertisement	<input type="checkbox"/> Needed <input type="checkbox"/> Not needed
	Recruiting poster	<input type="checkbox"/> Needed <input type="checkbox"/> Not needed
7	Participant information sheet	<input type="checkbox"/> Needed <input type="checkbox"/> Not needed
	Consent form	<input type="checkbox"/> Needed <input type="checkbox"/> Not needed
8	HREA Panel Privacy Data Form	<input type="checkbox"/> Needed <input type="checkbox"/> Not needed
10	De-briefing procedure	<input type="checkbox"/> Needed <input type="checkbox"/> Not needed
11	Funding details	<input type="checkbox"/> Needed <input type="checkbox"/> Not needed
12	Letter of support from organisations other than UNSW	<input type="checkbox"/> Needed <input type="checkbox"/> Not needed
Other		<input type="checkbox"/> Needed <input type="checkbox"/> Not needed
	Signatures of all investigator(s) and supervisor	<input type="checkbox"/> Needed
	Original + 1 copy to panel administrator	<input type="checkbox"/> Needed

<http://www.gmo.unsw.edu.au/Ethics/HumanEthics/InformationForApplicants/ProformasTemplates/HumanEthicsProformas.html>

*[Insert UNSW and other organisational letterhead for page 1]*

Approval No (when available)

THE UNIVERSITY OF NEW SOUTH WALES *(AND OTHER PARTICIPATING ORGANISATION[S])*

### PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

*(Title of project)*

#### **Participant selection and purpose of study]**

You *(i.e. the research participant)* are invited to participate in a study of *(state what is being studied)*. We *(i.e. the investigators)* hope to learn *(state what the study is designed to discover or establish)*. You were selected as a possible participant in this study because *(state why the participant was selected)*.

#### **Description of study and risks]**

If you decide to participate, we *(or other designated research person[s])* will *(describe in simple language the procedures to be followed, including the use of placebos, their purpose(s), how long the procedures will take, and their frequency)*.

*(Describe the discomforts and inconveniences reasonably to be expected. An estimate of the total time required should be included.)*

*(Describe the possible risks reasonably to be expected. Describe any benefits to the participant reasonably to be expected.)*

*If benefits are mentioned, add:* We cannot and do not guarantee or promise that you will receive any benefits from this study.

*(Describe appropriate alternative procedures that might be advantageous to the participant, if any. Any standard treatment that is being withheld must be disclosed.)*

#### **Confidentiality and disclosure of information]**

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission, except as required by law. If you give us your permission by signing this document, we plan to *discuss/publish* the results *(state the persons or agencies to whom the information will be furnished, the nature of the information to be furnished, and the purpose of the disclosure)*. In any publication, information will be provided in such a way that you cannot be identified.

#### **Recompense to participants]**

*(If the participant will receive remuneration, describe the amount or nature. If there is a possibility of additional costs to the participant because of participation, describe it.)*

Complaints may be directed to the Ethics Secretariat, The University of New South Wales, SYDNEY 2052 AUSTRALIA (phone 9385 4234, fax 9385 6648, email [ethics\\_sec@unsw.edu.au](mailto:ethics_sec@unsw.edu.au)). Any complaint you make will be investigated promptly and you will be informed of the outcome.

#### **Feedback to participants]**

*Describe the mechanism(s) by which a summary of research findings will be offered to research participants at the completion of the study. If there are potential negative effects of providing this feedback to participants these need to be described and the participants need to consent to receiving feedback, eg: by a tick-a-box mechanism.)*

#### **Your consent]**

Your decision whether or not to participate will not prejudice your future relations with the University of New South Wales *(and the participating organisation[s])*. If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time without prejudice.

If you have any questions, please feel free to ask us. If you have any additional questions later, *(Title, name, phone number)* will be happy to answer them.

You will be given a copy of this form to keep.



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**PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM (continued)**  
(Title of project)

**You are making a decision whether or not to participate. Your signature indicates that, having read the information provided above, you have decided to participate.**

.....  
Signature of Research Participant

.....  
Signature of Witness

.....  
(Please PRINT name)

.....  
(Please PRINT name)

.....  
Date

.....  
Nature of Witness

**REVOCAION OF CONSENT**  
(Title of project)

I hereby wish to **WITHDRAW** my consent to participate in the research proposal described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with The University of New South Wales, (other participating organisation[s] or other professional[s]).

.....  
Signature

.....  
Date

.....  
Please PRINT Name

The section for Revocation of Consent should be forwarded to *(INSERT name and address of Chief Investigator)*.

# Summing Up

- Process is not to STOP you from doing research
- Make your research better
- You can always come and see me beforehand for advice (esp. If you are coming one day before it's due in)
- Ph: 58658 (h.worth@unsw.edu.au)



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