Tips and Tricks for Ethics Applications
Outline

- Process
- National Guidelines
  - Four ethical guidelines
  - Key populations
  - Consent
- Scenarios (4)
- Sample Applications (1 full; 1 minimal)
- Odds and ends
Review Process

- Internal Review
  - Full and Minimal – Me!

- Head of School sign off
  - Karen (scientific merit)

- External Review
  - Full Risk – HREC committee
    - Meet monthly
    - Volunteers (UTAS, lay people, health profession, law, pastoral care)
  - Minimal risk - Chair
National Guidelines

• National Statement on Ethical Conduct in Human Research (NHMRC, 2007)

• Australian Code for the Responsible Conduct of Research (NHMRC, 2007)
Ethical conduct" is *more than simply doing the right thing*. It involves acting in the *right spirit*, out of an abiding respect and concern for one's fellow creatures. This National Statement on "ethical conduct in human research" is therefore oriented to something more fundamental than ethical *"do's" and "don'ts"* namely, an ethos that should permeate the way those engaged in human research approach all that they do in their research.
1. Research Merit and Integrity

- Has the potential to make a contribution to knowledge and understanding, to improve social welfare and individual well being

- Appropriate methods

- Based on review of literature

- Experienced, qualified research team/individual

- Peer review
2. Beneficence

- Maximise possible benefits
- Minimise possible risks or harm (physical, psychological, emotional, economic or social)
3. **Justice**

- Recruitment (who is in/who is out?)
- Distribution of benefits
- No unfair burden
- Research outcomes accessible
4. **Respect**

- Due regard for welfare, beliefs, perceptions
- Respect privacy, confidentiality, cultural sensitivities
- Capacity to make own decisions
- When unable to make decisions, empower where possible
Key Populations (Chapter 4 of NS)

Women who are pregnant (4.1)
Children and young people (4.2)
People in dependent or unequal relationships (4.3)
People highly dependent on medical care who can’t give consent (4.4)
People with cognitive impairment, an intellectual disability or a mental illness (4.5)
People who may have been involved in illegal activities (4.6)
Aboriginal or Torres Strait Island Peoples (4.7)
People in other countries (4.8)
Consent (Chapter 2.2 of NS)

- Voluntary participation, based on sufficient information (p.20)
- Renegotiating consent over time (e.g., longitudinal study)
- Coercion and pressure (e.g., uni lecturer who gives a grade)
- Reimbursement (i.e., proportional to time/energy involved)
- Giving consent for others (e.g., parents)
- Declining consent/withdrawing consent (suffer nothing)
- Limited disclosure consent (e.g., watching behaviours in public)
- Implied consent (e.g., filling in a questionnaire assumes consent)
Full or minimal risk application?

- Identify risks
- Assess likelihood and severity
- Identify who the risks will affect
- Identify how to minimize the risks
- Identify potential benefits (and to whom)
Full or Minimal?

The National Statement (2007) categorises potential risks to research participants as follows:

**Harms** such as pain including physical, psychological, social, economic and legal harms, and the devaluation of personal worth.

**Discomforts** such as the anxiety induced by an interview. If discomfort becomes distress, then it is considered to be harm.

**Inconveniences** such as filling in a form.
Negligible risk: Research in which there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience. Can be exempt from ethical review (NS 2.1.7; NS 5.1.22)

Low risk: Research in which the only foreseeable risk is one of discomfort. Approval granted from Chair (NS 2.1.6; NS 5.1.18)

More than low risk = High risk reviewed by committee (NS 5.1.24)
Does your research specifically target any of the following groups of people?

Women who are pregnant (4.1)

Children and young people (4.2)

People in dependent or unequal relationships (4.3)

People highly dependent on medical care who can’t give consent (4.4)

People with cognitive impairment, an intellectual disability or a mental illness (4.5)

People who may have been involved in illegal activities (4.6)

Aboriginal or Torres Strait Island Peoples (4.7)

People in other countries (4.8)
Does your research involve an in-depth discussion of any of the following topics, whether by interview or as part of a questionnaire or survey?

a. Parenting practices  
b. Sensitive personal issues  
c. Sensitive cultural issues  
d. Grief death or serious traumatic loss  
e. Depression mood states or anxiety  
f. Gambling  
g. Eating disorders  
h. Illicit drug taking or substance abuse  
i. Psychological disorders  
j. Suicide  
k. Gender identity and/or sexuality  
l. Race and/or ethnic identity  
m. Fertility and/or termination of pregnancy
For each scenario:

1. Determine if the applicant needs to fill out a full or minimal risk application
2. Identify the key ethical issues
   - Research Merit and Integrity, Justice, Beneficence, and Respect
   - Consent
   - Populations
   - Topics
Scenario A

- Chris works in the Faculty and wants to administer an online questionnaire to the students she worked with last semester to get their insight into the assessment procedures she used.
- She e-mails all students an invitation to participate.
- If they follow the ‘link’, they’ll read the information sheet and then complete the anonymous survey.
- Students can elect to win a $20 voucher if they put their contact details on the questionnaire.
Scenario A

- Chris works in the Faculty and wants to administer an online questionnaire to the students she worked with last semester to get their insight into the assessment procedures she used.
- She e-mails all students an invitation to participate.
- If they follow the ‘link’, they’ll read the information sheet and then complete the anonymous survey.
- Students can elect to win a $20 voucher if they put their details on the questionnaire.
- MINIMAL RISK: Implied consent (if you complete the questionnaire, you’re agreeing to participate), pressure to participate, how separate names from questionnaires.
Scenario B

- Paulo is an PhD student
- He wants to trial an intervention that will help prepare students for NAPLAN tests
- He wants to access two grade 5 classes
  - Control group – get regular lessons pre-NAPLAN
  - Intervention group – trials new lessons pre-NAPLAN
- Compares test scores from NAPLAN to understand if intervention made a difference on scores
Scenario B

- Paulo is an PhD student
- He wants to trial and intervention that will help prepare students for NAPLAN tests
- He wants to access two grade 5 classes
  - Control group – get regular lessons pre-NAPLAN
  - Intervention group – trials new lessons pre-NAPLAN
- Compares test scores from NAPLAN to understand if intervention made a difference on scores

- FULL RISK: Minors, consent, unfair advantage to one group over another
Scenario C

- Nahid is a lecturer in the MTeach program in Hobart
- She teaches Literacy
- She wants to photocopy and collect the written work (Assessment Task 1) of her students (N=117) and perform content analysis and then do follow up focus groups
Scenario C

- Nahid is a lecturer in the MTeach program in Hobart
- She teaches Literacy
- She wants to photocopy and collect the written work (Assessment Task 1) of her students (N=117) and perform content analysis and then do follow up focus groups

- MINIMAL RISK: Power relations, timing of data collection and analysis, focus groups (confidentiality/anonymity)
Scenario D

- Sarah is a PHD student who also has a part time job as an educational assistant at a highschool.
- For her project, she is interested in getting students at the school where she works to talk about issues related to homosexuality (e.g., are they gay? Do they know someone whose gay? Are gay people welcome? Safe?)
- She wants to invite all students and teachers at the middle school to complete anonymous questionnaires and then volunteer to be included in follow up 1:1 interviews.
Scenario D

- Sarah is a RHD student who also has a part time job as an educational assistant at a highschool.
- For her project, she is interested in getting students at the school where she works to talk about issues related to homosexuality (e.g., are they gay? Do they know someone whose gay? Are gay people welcome? Safe?)
- She wants invite all students and teachers at the middle school to complete anonymous questionnaires and then volunteer to be included in follow up 1:1 interviews.

"FULL RISK: Minors, personal/private issue, power relationships, fall out and follow up from study, how keep questionnaires anonymous if details needed for follow up survey"

- She really should do the study at another school.
Look at sample applications

- Full and Frank
Minimal

1. Title
2. Dates
3. Investigators
4. Purpose
5. Outline
   • Aims, justifications
6. Review of ethical considerations
7. Funding
8. Participants
9. Data source/identifiability
10. Literature
11. Procedures
12. Monitoring
13. Data storage
14. Information sheet
15. Consent form
16. Other approvals
17. Declarations
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<td>Rationale and background</td>
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Checklist (all clearly labelled)

- Telephone preambles
- Email invitations
- Information sheets
- Consent forms
- Questionnaires
- Interview schedules
- Copy of other permissions
Other permissions

- Department of Education
- Private schools
- Catholic schools
Amendments

- Changing members of research team
- Changing design
Reporting issues

- Progress reports
- Final reports
- Requests for extension
Tour of our website