What makes a project Ethical?

What is human research?

- A computer programme for doctors to use in prescribing medicine to their patients.
- Measuring the effectiveness of a new insulator for high voltage wires.
- Understanding participant behaviour in wholesale electricity markets
- Testing a GPS system for mountain bikes

https://www.nhmrc.gov.au/book/section-1-values-and-principles-ethical-conduct

Background for human research ethics

Nuremberg Trial (1946-47), Nuremberg Code (Alexander and Ivy, 1946)

1964 Declaration of Helsinki.

1932 - 1972 USA Tuskegee Syphilis study revelations

Statement on Human Experimentation (1966)

Statement on Human Experimentation and Supplementary Notes (1985)

National Statement on Ethical Conduct in Research Involving Humans (1999, 2007, 2015)

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Basic principles for human research ethics

1. Research merit and integrity
2. Justice
3. Beneficence
4. Respect

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Basic principles for human research ethics

What is research?

"There is no generally agreed definition of research; however, it is widely understood to include at least investigation undertaken to gain knowledge and understanding or to train researchers."

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Basic principles for human research ethics

1. Research merit and integrity

- *justifiable by its potential benefit*
- *uses appropriate methods*
- *based on current literature*
- *designed to respect participants*
- *uses appropriate facilities*
- *researchers who are*
  - *searching for knowledge and honest*

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Basic principles for human research ethics

1. Justice

- *inclusion and exclusion is fair*
- *recruitment is fair*
- *burden of research on certain groups is fair*
- *distribution of and access to benefits is fair*
- *no exploitation*

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Basic principles for human research ethics

1. Beneficence

- *benefit of research must justify risk of harm to participants*

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Basic principles for human research ethics

1. Respect

- *recognition of intrinsic value*
- *privacy, confidentiality, cultural sensitivities*
- *capacity of human beings to make their own decisions*
- *empowering and protection of those who cannot make their own decisions*

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Basic principles for human research ethics

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Procedural

Personal

Case Study 1

Section 1.0 General Details

1.1 Project Identification

The title should be succinct and in terms that an educated, but non-scientifically trained person can understand.

a. Project Title Attachment and Emotional Learning

To index the relationship between sex and stress hormones and response to exertion, salivary samples will be obtained to assay progesterone, estrogen, cortisol and salivary alpha-amylase (sAA). Saliva samples will be acquired via the drool method, using Salimetrics cortisol ELISA kits. All attachment sessions will commence following 30 minute rest periods to allow for baseline assessments of BDF, sAA, and cortisol. To index psychophysiological arousal responses in conditioning, extinction, reconsolidation studies, the research will index EMG, skin conductance response, and heart rate using an ADInstruments system.

3.7 Research involving blood, tissue or physical hazards

a. Does this section apply to your research? ☒ No ☐ Yes

Case Study 2

Section 1.0 General Details

1.1 Project Identification

The title should be succinct and in terms that an educated, but non-scientifically trained person can understand.

a. Project Title Drug law enforcement policy: The deterrent effects of Australian policing strategies

It will use a purpose-built online survey involving a series of 10 hypothetical vignettes or scenarios depicting different policing strategies and settings that could be encountered in Australia. The survey will be administered to a national sample of patrons: people who attend outdoor music festivals and licensed entertainment precincts in Australia. It will then assess and compare patron willingness to use, possess, purchase or traffick illicit drugs under two hypothetical policing scenarios, and where relevant the likely type of drug(s) and quantities that they would use, possess, purchase or traffick. The adopted approach extends our pilot study that used this method.

c. Will the information collected by the research team about participants be in the following form(s):

i. Individually identifiable? ☐ No ☒ Yes

Please provide details

It will be optional for participants to provide identifiable information (the only identifiable information sought is an email address - this will be collected only for the prize draw, dissemination of results and for notification about future research studies). As such most information will be anonymous / non-identifiable. To ensure anonymity all email addresses provided for entering the prize draw and for dissemination of results will be stored separately to survey data. No one except the investigators will have access to the data. Such measures follow the procedures used in previous online surveys (such as Hughes et al, 2012; Lancaster et al, 2014: Hughes, Weatherburn & MacCoun, 2014; Shanahan, Hughes and McSweeney, forthcoming), and will ensure privacy, confidentiality and anonymity in analysis and dissemination of the research findings.

ii. Re-identifiable? ☒ No ☐ Yes

iii. Non-identifiable (please indicate which organisation will be responsible for de-identifying the data)? ☒ No ☐ Yes

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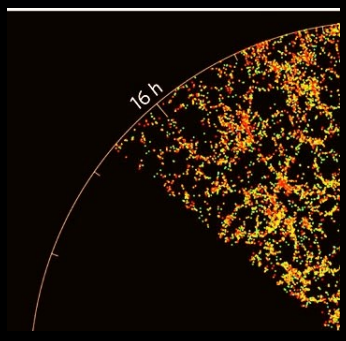
UNSW Research Human Research Ethics Committee Members

Human Research Ethics Committee Members

chairperson	at least one member with knowledge of the professional care, counselling or treatment of people
at least two members who are lay people, one man and one woman	at least one member who is a minister of religion
at least one member with knowledge of the areas of research...	at least one member who is a lawyer

UNSW HREC Committee B – Membership List

Name	Membership Category
Dr Holly Seale	Chairperson
Dr Deborah Lum	Lawyer
Dr Lesley Ann Heath	Lawyer
Mr Peter Robertson	Layman
Ms Coty Cortese	Laywoman
Mr Lewis Jones	Pastoral Care
Dr Olga Vujovic	Professional Care
Professor Carla Treloar	Researcher
Dr Bayzidur Rahman	Researcher
Dr Yael Perry	Researcher

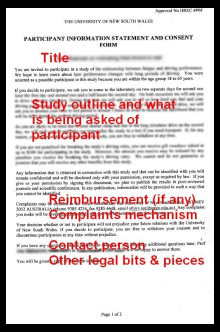


The visible mass in the universe is arranged like soap bubbles in a sink, therefore we should...

The ice caps are melting, therefore we should...

Smoking tobacco kills 15,000 people every year in Australia, therefore we should...

Informed Consent



PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

Title

Study outline and what is being asked of participant

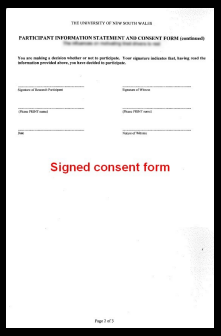
Reimbursement (if any)

Complaints mechanism

Contact person

Other legal bits & pieces

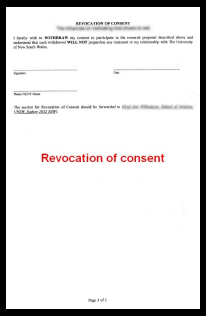
Informed Consent



PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM (continued)

Signed consent form

Informed Consent



REVOCATION OF CONSENT

Revocation of consent

Informed Consent

"The guiding principle for researchers is that a person's decision to participate in research is to be voluntary, and based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it."

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Informed Consent

https://www.nhmrc.gov.au/book/section-1-values-and-principles-ethical-conduct

Informed Consent

"Participation that is voluntary and based on sufficient information requires an adequate understanding of the purpose, methods, demands, risks and potential benefits of the research."

https://www.nhmrc.gov.au/book/section-1-values-and-principles-ethical-conduct

Informed Consent

"This information must be presented in ways suitable to each participant"

https://www.nhmrc.gov.au/book/section-1-values-and-principles-ethical-conduct

Informed Consent

"The process of communicating information to participants and seeking their consent should not be merely a matter of satisfying a formal requirement. The aim is mutual understanding between researchers and participants. This aim requires an opportunity for participants to ask questions and to discuss the information and their decision with others if they wish."

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Informed Consent

- Information on the following matters should also be communicated to participants.
  - *how the research will be monitored;*
  - *provision of services to participants adversely affected by the research;*
  - *contact details of the researchers;*
  - *how privacy and confidentiality will be protected;*
  - *the amounts and sources of funding for the research;*
  - *financial or other relevant declarations of interests of researchers, sponsors or institutions;*
  - *the likelihood and form of dissemination of the research results, including publication;*
  - *any expected benefits to the wider community;*

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Informed Consent

- Duties to your employer, profession, and government
  - *contracts, relevant codes, laws*
- Potential benefits weighed against risks
  - *identify benefits*
  - *identify risks*
  - *risk mitigation strategies*
  - *distribution of and access to benefits*
- Rights of the individual participant
  - *identify participants*
  - *participant specific information*
  - *no coercion*
- What kind of person you are going to be
  - *generous, kind, helpful, thorough, selfless*

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