

# REDI HUMAN RESEARCH ETHICS

RESEARCH | ENGAGEMENT | DEVELOPMENT | INNOVATION

## Recruitment – Use of ‘Opt Out’ or Passive Consent in Human Research

The following is intended to help Researchers by clarifying the:

- types of research that may be considered for ‘opt out’ consent
- Guidelines and Policies that underpin this approach

The preferred consent model for assessment by the Western Sydney HREC is ‘opt in’ (voluntary, informed, active) consent.

When asked to consider requests for ‘opt out’ consent the HREC relies on the guidelines in the *National Statement*. The following guidelines are intended to advise researchers of the HREC’s opinion of when this form of consent may be appropriate and what conditions need to be met.

The *National Statement* explains the ‘opt out’ approach as:

*“...a method used in the recruitment of participants into research where information is provided to the potential participant regarding the research and their involvement and where their participation is presumed unless they take action to decline to participate.”*

### General statements and procedures

1. ‘Opt out’ consent increases risk to the participants, the researchers and the University. In order to manage this risk the HREC has determined that it will consider requests for opt out consent when:
  - the use of opt out consent is allowable under State and Commonwealth law and institutional policy as applicable, and
  - the nature of the research and the issues in relation to gaining full consent clearly warrants consideration of opt out consent, and
  - the researchers have the necessary research experience to manage an opt out consent process, and
  - the data to be published which was obtained through opt out consent is not identifiable.
  - In most instances, the risk level of the research is less than Low 2 risk
  - and, evidence of the agreement of other relevant stakeholders is provided.
2. An application that is eligible to be considered for opt out consent must:
  - be reviewed by the full HREC
  - include a Participant Information Sheet that will be distributed to participants
  - provide detailed mechanisms regarding how participants will be able convey a decision not to participate. This will include mechanisms for contact and timelines.
3. Opt out consent will only be approved for a specified series of research activities and changes to a research protocol will require reconsideration of the consent process each time a change is made.

### Opt Out for Research which involves Children and Young People

Opt out consent will be considered for research with children which is classified as Low 2 (i.e. generally low risk research but includes children) with consideration to the issues above plus the:

- a) age of the children or young people
- b) nature of the research, and
- c) nature of the participant experience, and where the following conditions are met:
  - evidence is provided that appropriate strategies for relaying the information to parents and guardians will be used

- parents or guardians must have sufficient time to consider and respond to the opt out request and it must be clear how they can opt out
- mechanisms are provided for the parents to seek additional information before the opt out request is actioned
- strategies are developed to ensure that Culturally and Linguistically Diverse parents and low literacy parents are able to make an informed decision.

Where the research is integral to usual classroom activities or the school curriculum, approval for the consent type must also be obtained from SERAP or its equivalent in non-public schools.

### **Opt Out for Research being conducted outside of Australia**

Although research practices can vary across countries, Western Sydney researchers are expected to make every effort to apply the same conduct standards as research undertaken within Australia.

Requests for opt out consent will be considered as per the general principles stated earlier in this document. In addition, researchers may want to provide evidence of standard or acceptable research practice as it relates to opt out consent within the country in which the data is being collected.

### **Human Research Ethics Guidance Documents available from REDI**

- Guidance for Researchers New to Human Ethics Review
- Guidance on Choosing the most appropriate PIS and Consent
- Guidance on Levels of Risk and the Ethical Review Process
- Guidance on Making an Amendment to an Approved Project
- Guidance on Questions Related to Cultural Sensitivities
- Guidance on Questions Related to Restrictions on Publication of Results
- Guidance on Receiving and Responding to Ethics Committee Assessor Comments
- Guidance on Research Projects Seeking to use Western Sydney Staff as Participants
- Guidance on Reimbursements
- Guidance on the use of 'Opt Out' or Passive Consent in Human Research
- Guidance on Writing Participant Information Sheets and Consent Forms
- Guidance on Data Storage and Retention Questions
- Guidance on Ethics Review Exemption
- Guidance on Research Involving Young People
- Guidance on Using Focus Groups in Research
- Guidance on Complaints
- Guidance on Research being done with, or for, Organisations

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