WESTERN SYDNEY UNIVERSITY

REDI HUMAN RESEARCH ETHICS

RESEARCH | ENGAGEMENT | DEVELOPMENT | INNOVATION

Choosing the most appropriate Participant Information Sheet and Consent Form templates

There are 3 forms of consent that can be requested from participants.

- Specific – the data collected will be used for this project only
- Extended - the data collected will be used for this project and may be used for similar like projects
- Unspecified - the data collected will be used for this project and may be used for other projects in the future, not necessarily directly related to this project and not necessarily by these researchers (open access).

Whilst specific consent may be appropriate in some cases, under the University's Open Access policy extended or unspecified are the preferred consent types. The capacity to reuse collected data can be viewed as a more respectful valuing of the participants' time and input as participants' data can make a contribution to many projects instead of just one.

To assist researchers to create information sheets and consent forms which reflect the practical application of these consent types for different types of participants, templates have been provided for the following:

- Parent / carer - where the person giving consent does so on behalf of a child under their authority.
- Guardian – when the participant does not have the capacity to give consent in their own right but there is a designated person with the authority to give consent on their behalf– not child or child relationship (use above).
- Medical – where the research is medical/ health related involving a patient / medical/health relationship.
- General – all other participant types.

The templates must be tailored for the individual project.

The templates are at http://www.westernsydney.edu.au/research/forms

The key issues around data collection, security and storage are that

- Participants must be told what type of consent they are being asked for and how that impacts on the ability to withdraw data; the dissemination of the research results; and data storage.
- In most cases the data should be de-identified before storage and reuse and if this isn't possible or intended this needs to be made very clear to participants (and the rationale explained to the ethics committee).
- Researchers **cannot** reuse data if the initial request and approval was for specific consent.

The Templates Summary

Name	Description
Participant Information Sheet – General (Extended)	For use when the participant gives consent for themselves and data will be used for this project and possibly other similar projects
Consent form – General (Extended)	
Participant Information Sheet – General (Specific)	For use when the participant gives consent for themselves and data will only be used for this project
Consent form – General (Specific)	
Participant Information Sheet – General (Unspecified)	For use when the participant gives consent for themselves and data will be used for this project and possibly other projects
Consent form – General (Unspecified)	
Participant Information Sheet – Parent or Carer (Extended)	For use when consent is being given via a parent or carer for a child and data will be used for this project and possibly other similar projects
Consent form – Parent or Carer (Extended)	
Participant Information Sheet – Parent or Carer (Specific)	For use when consent is being given via a parent or carer for a child and data will only be used for this project
Consent form – Parent or Carer (Specific)	
Participant Information Sheet – Parent or Carer (Unspecified)	For use when consent is being given via a parent or carer for a child and data will be used for this project and possibly other projects
Consent form – Parent or Carer (Unspecified)	
Participant Information Sheet – Guardian (Extended)	For use when consent is being given via a Guardian of the participant and data will be used for this project and possibly other similar projects
Consent form – Guardian (Extended)	
Participant Information Sheet – Guardian (Specific)	For use when consent is being given via a Guardian of the participant and data will only be used for this project
Consent form – Guardian (Specific)	
Participant Information Sheet – Guardian (Unspecified)	For use when consent is being given via a Guardian of the participant and data will be used for this project and possibly other projects
Consent form – Guardian (Unspecified)	
Participant Information Sheet – Medical/Health (Extended)	For use when medical information is being collected and data will be used for this project and possibly other similar projects
Consent form – Medical/ Health (Extended)	
Participant Information Sheet – Medical/Health (Specific)	For use when medical information is being collected and data will only be used for this project
Consent form – Medical/Health (Specific)	
Participant Information Sheet – Medical/Health (Unspecified)	For use when medical information is being collected and data will be used for this project and possibly other projects
Consent form – Medical/Health (Unspecified)	

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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