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Issues with Informed Consent in Research

Overview

Except in defined circumstances, human research is generally only considered to be ethically justifiable when voluntary and informed agreement to take part (consent) is actively obtained from participants.

The National Statement is the Australian standard reference for human research ethics matters. Section 2.2 of the National Statement addresses the general requirements for informed consent in human research. The National Statement also addresses special issue-specific requirements for informed consent that may apply to some specific research designs, potential participant pools and contexts.

The National Statement recognises voluntary, informed and active consent as the appropriate consent for most research, but also accepts there are projects that may require opt out consent or a waiver.

This guidance sheet is focused on delineating the issues and processes for obtaining voluntary, informed, active consent. It also includes brief coverage of situations where opt out[1] and waiver may apply.

What is the 'participant experience'?

From the outset, researchers need to be clear about what participation in the research will entail.

Participation includes taking part in activities that will generate the research data eg a survey or an interview; it may be agreement for the researcher to access existing data; it may be agreeing to provide tissue or samples such as blood. It can also include the researcher using data without the participant knowing. In such cases a waiver of consent is required.

The *participant experience* covers what the participant will do that enables the researcher to collect the data needed for the research. It also addresses possible participant positive and negative experiences.
If the research activity has an integral link with other activities that the participant may be doing irrespective of the research, the researcher needs to clearly delineate what is research (and therefore usually optional) and what is not (which may be a required activity).

What are participants being asked to consent to?

Consent can include

1. Agreeing to take part in the research activities and/or have existing data accessed
2. Allowing processes specific to the activities e.g. having the interview recorded; having imagery taken and used. Particular details need to be provided about specific activities and their risk.
3. Allowing the researcher to use the data collected in specified ways[2]

[1] There is a separate guidance sheet on opt out consent

4. Allowing the data to be stored and perhaps destroyed within specified time periods.

Researchers should consider whether a participant can consent to some aspects but not others. If there is choice the information and consent materials provided need to clearly articulate the options with a process to show consent, or not, e.g. tick boxes.

What is informed consent?

Informed consent refers to the decision by a potential participant as to whether they wish to participate in a research project. The person making the decision must have 'capacity' i.e. there mustn't be anything which impairs their ability to make the decision, and they must be given the information they need to make the decision.[3]

Section 2.2 of the National Statement describes the standard requirements for informed consent as being that it "should be a voluntary choice, and should be based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it".

The provision of informed consent by the participant does not take away the researcher's requirement to act with a duty of care towards all participants at all stages of the research.

What is a voluntary choice?

The notion of 'voluntary' is not necessarily stated explicitly in an ethics application but it is gleaned from answers to questions about the power dynamics, and or current or future relationships between the

- researcher / participant (or the person who stands in for them) and/or
- participant (or the person who stands in for them) / organisation / researcher

and answers regarding the possibility of withdrawing consent.

To show that consent is voluntary, the researcher needs to address any possibilities of participant coercion. Coercion may come to bear because of a perceived power imbalance or other pressure.
Examples:

- Asking family and friends to participate in research may place pressure on them to agree because of their current relationship with the researcher.
- An employee may feel coerced if the recruitment message comes through their employer.
- If not handled appropriately coercion can also be brought into play by offering a reimbursement or incentive to participate, particularly if it's not clear whether the reimbursement will be given if the participant withdraws.[4]
- A child may feel pressured to take part in an activity that a parent has agreed they will do.[5]

What is sufficient information?

Voluntary consent requires that the potential participant understands what is required of them.

To assist researchers to develop information sheets and consent forms that contain *sufficient information* Western Sydney U has a range of information and consent form templates[6], which vary slightly depending on the participant group and whether the data will be used for one research project or potentially more than one.

These templates cover the key issues considered necessary to assist a person to determine if they want to be involved in, or provide their data to, the research.

Key issues in relation to the templates

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[2] Including whether the data is used for the initial project only or used for other projects. The options are specific, extended and unspecified consent.
[3] If capacity is lacking a guardian or other legal authority may be approached to consider participation on behalf of the potential participant.
[4] See Guidance sheet on reimbursements
[5] For this reason it is usually necessary to also seek the agreement of the child (child assent).
[6] A list of the available templates is at https://www.westernsydney.edu.au/research/forms

- The templates should be tailored to the participants[7]
- All matters of consequence must be disclosed. For example, who is doing the research; who is funding it; what is it for; are there any risk of participation and if so how will they be managed; how will the data be used and how will the results be published? These questions form the key headings in the templates.
- The participant experience – what the participant will actually do – must be fully explained. This includes issues around how many activities and how long they will take.
- Any risk involved in participation must be outlined. Risk is not limited to the possibility of physical harm but also psychological, economic, social and legal risk.
- The language must be understandable:
    - Use lay language at a level pitched to the participants' abilities eg no jargon; if acronyms are used ensure they are written in full the first time used; age appropriate
    - Provide translated versions when necessary
    - Spelling and grammar can impact on a person's understanding so edit appropriately.

Nevertheless, informed consent may require more than a participant reading a sheet. The potential participant should be given the chance to discuss the project with the researcher and other parties who could assist them to understand what they will be agreeing to. The researcher should be prepared to answer queries even if they aren't covered by the information sheet.

The ethics committee may want evidence in the application that the person consenting participants has experience and/or expertise in the consent process. This may be crucial if the research will involve vulnerable groups or research projects with high risk levels.

Mechanisms of consent

Consent may be

- Expressly given
    - written
    - verbal
- Implied.

Implied consent is most often seen when the project involves an online survey and consent is considered to have been given if the participant completes and submits the survey. In this case there is usually a text which summarises this assumption.

Ongoing consent and the possibility of withdrawal of consent

The voluntary nature of consent means that ideally consent, both for engagement in activities and any data already collected, can be withdrawn at any time.

Consent to engage in activities

Consent will be given before joining the project but may also need to be sought and re-given during the project. Two examples:

- a longitudinal research project may seek consent to continue at a number of time points
- a project which places a participant under duress may need to include a plan for checking at regular intervals that the participant still consents (doesn't want to withdraw).

The consequences of withdrawal need to be considered and explained to participants

The researcher must have mechanisms which ensure that withdrawal of consent requests are acted on in a timely manner and show due consideration for the management of withdrawal when necessary.

For example, a child participating in research as part of a group may make it clear they no longer want to be involved. The researcher will need a plan for any debriefing that may need to take place and/or what alternate activities the child will be doing after they withdraw.

Consent for data to remain as research data

[7] See Guidance on Writing Participant Information Sheets and Consent Forms

A participant may take part in a data collection activity, or allow their data to be collected and used, but later decide they no longer want the data included in the research.

There may be legitimate reasons as to why withdrawal of already provided data is not feasible.[8] Researchers need to inform participants of whether withdrawal of consent is possible for the life of the data or only up to a certain point.

Obviously, any data which is provided anonymously cannot be withdrawn after submission.

Consent of others who are not the 'subject' of the research

In the text above there is a presumption that the 'participant' can be included in the research independently of any other people. However, this is not always the case. Two examples:

1. A researcher might be interested in the coping strategies of high school teachers when confronted with extremely disruptive behaviour. The teachers could be described as the subjects of the research. However, if there will be recording of the teacher practice in action, there is a very real possibility that students, support staff and even other teachers might be 'captured within the frame' of data collection, and so should be considered to be participants, even though they are not directly the subjects.
2. A participant may be commenting on the behaviour of another party where that behaviour might be considered sensitive, or the results about a participant could have significant import for other direct relatives. In such situations both the researchers and the ethics reviewers need to consider whether it is appropriate to seek the consent of the third parties, and what impact the decision of the third party can and should make on the participation of the direct participant. Even if consent of the third party is not necessary there may be other risk management strategies that need to be in place.

The 'Opt Out' approach

At Western Sydney U projects which intend to rely on the opt out approach must be reviewed by the HREC. When asked to consider requests for 'opt out' the HREC relies on the guidelines in the National Statement.

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."

For more information on opt out consent see the Guidance Sheet *Use of 'opt out' or Passive Consent In Human Research.*

Waiver of consent

The National Statement (2.3) says:
When neither explicit consent nor an opt-out approach are appropriate, the requirement for consent may sometimes be justifiably waived. When an HREC or, where appropriate, another review body grants a waiver of consent for research conducted prospectively or retrospectively, research participants will characteristically not know that they, or perhaps their tissue or data, are involved in the research.

Researchers seeking a waiver of consent should refer to 2.3.9 – 2.3.12 of the National Statement.

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Resources
National Statement on Ethical Conduct in Human Research (2007)-Updated May 2015
https://www.nhmrc.gov.au/guidelines-publications/e72
Research Ethics Manual Booklet 22 Voluntary and Informed Consent
http://www.westernsydney.edu.au/research/research_ethics_and_integrity/human_ethics
Participant Information Sheet and Consent Form Templates
https://www.westernsydney.edu.au/research/forms

[8] For example, see guidance sheet on focus groups.

Scholarship of Teaching and Learning Human Research Ethics Resource Manual (SoTL Manual)
http://www.ahrecs.com/resources/scholarship-teaching-learning-human-research-ethics-resource-manual-sotl-manual

Human Research Ethics Guidance Documents available from REDI

- Guidance for Researchers New to Human Ethics Review
- Guidance on Answering NEAF Question 6.1.1
- 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 in the NEAF
- Guidance on Questions Related to Restrictions on Publication of Results in the NEAF
- 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 in the NEAF
- 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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