

Title of procedure: **Informed Consent in Research**

Key words: **consent, information statement, consent form, competent, research, parent/guardian, participant, investigator, witness**

Alternative alphabetical listing: **Consent Process and Requirements for Research**

1. Overview/procedure description

Respect for human beings involves giving due scope to people's capacity to make their own decisions. In the research context, this normally requires that participation be the result of a choice made by participants – commonly known as 'the requirement for consent'. This requirement has the following conditions: consent 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 (National Statement, 2007).

This procedure outlines the process for obtaining informed consent from a participant and/or their parent/guardian for participation in a research project conducted at the Royal Children's Hospital.

2. Related Policy

Research

3. Definition of Terms

Competence or "capacity to consent": capability to understanding information regarding participation in a research project in order to provide informed consent. This is dependant on maturity and intelligence and will be judged by a member of the study team.

Information Statement & Consent form: a document detailing all the necessary information regarding a research project that a participant will need to know in order to decide whether or not to participate in said research project. The document includes a page for the participant to sign stating that they consent to participate (the 'consent form').

Informed Consent: a person's agreement, based on adequate knowledge and understanding of all relevant material, to participate in research

Investigator: A researcher assigned 'Investigator' status by the Principal Investigator due to their senior role in the research project.

Parent/guardian: the person legally responsible for a person under the age of 18

Participant: a person participating in the research (unless otherwise specified, the participants discussed below are less than 18 years of age). Please note participating can mean both physically participating and participating due to the fact that individual data about the person is being used in the research.

Plain Language Advisor: a member of the Research and Ethics office. The role of the PLA is to provide help and advice to researchers regarding their Information Statements.

Witness: any person present at the time the information statement is signed by the participant or parent/guardian. The witness must be over 18 years of age.

4. Procedure details

4.1. RCH Information Statement Template and Plain Language Advisor (PLA)

- Information Statements must be created using the appropriate RCH template (available at: http://www.rch.org.au/ethics/app_new.cfm?doc_id=10895) and must be approved by the HREC prior to use.
- Information statements must be correctly branded in line with the institutions' branding policy. Please note information statements for multicentre trials need only contain the logo(s) of the institution(s) they are to be used at, i.e. it is best for each institution to have an information statement displaying its own logo.
- Projects being run by other organisations (i.e. not RCH, MCRI or UoM) may use templates approved by their own HREC, however the RCH HREC reserves the right to request changes where necessary.
- Researchers are strongly advised to seek PLA advice (contact details at above link) prior to submission.

4.2. Investigator (or delegate) Responsibilities

- The person conducting the informed consent process:
 - May be an Investigator or delegate of research team.
 - Must have suitable expertise and adequate training in order to conduct the consent discussion with each subject and obtain fully informed consent.
 - Must be the one to sign the consent form and in doing so declares that he or she has explained the project to the participant (who signs above) and believe that the participant understands the purpose, extent and possible effects of their involvement in this project.
 - Must sign and date each consent form on the same day as the participant.
- Every possibility must be made to ensure there is not an unequal relationship between the participant and the person conducting the consent process, i.e. it should not be the participants own doctor.
- The consent process must be detailed in the HREC application.

4.3. Judging Capacity for Consent

- Participants (under 18 years of age) who are evaluated by the investigator (or member of research team) as having sufficient maturity and understanding to grasp the nature and consequences of the project should be provided with a Participant Information Statement and Consent Form to allow them to give or refuse their consent
- There may be some cases where the competent underage participant gives verbal consent to participate but does not wish to sign the consent form; the investigator should try to ascertain whether or not this is a refusal to consent. The participant does not have to sign the consent form. However, in order for their child to participate the parent/guardian must provide written consent, unless an alternative procedure has been approved by the HREC (section 4.4).
- This consent should be in addition to the parental (or guardian) consent. The process for judging capacity to consent (i.e. by whom and how) must be addressed in the HREC application.
- Investigators should bear in mind that the capacity to consent may fluctuate, and that even without full competence people may have some understanding of the research and the benefits and burdens of their participation and as such should be involved in the discussion and decision making even if not asked to provide consent themselves.
- As a general rule participants over 12 years old should be offered the opportunity to consent, however this age will vary based on the nature and complexity of the trial and the investigator must judge the competence of each potential participant on a case by case basis.

4.4. Parent/Guardian Consent

- Where a potential participant lacks the capacity to consent, a parent (or guardian) should be provided with relevant information and decide whether he or she will participate. That decision must not be contrary to the participant's best interests.
- A participant who is not deemed (by the investigator) to have the capacity to consent should not be asked to provide their consent; parental (or guardian) consent is sufficient in these cases.
- Parent/guardian consent must be sought if the participant is less than 18 years of age except if alternative is approved by the HREC prior to the trial commencement. Reasons for not requiring parental consent are detailed in the National Statement (Chapter 4.2).

4.5. Consent must be informed and voluntary

- Participants and parent/guardians must be given an opportunity to ask questions of the person conducting the informed consent process. They must also be given the option of discussing the research and their options with a person independent of the research, i.e. another member of the department conducting the research. This process of providing independent advice must be addressed the application to the HREC.
- Participants must then be given adequate time to read the information statement and to discuss the information and their decision with others (e.g. friend, family, GP) if they wish.
- No person should be subjected to coercion or pressure in deciding whether to participate. A person should be included as a participant only if his or her consent is voluntary.
- In cases where a parent provides consent for their child to participate but the child (deemed competent by the researcher) declines participation the child should not be forced to do so. However in the rare cases where participating in the research is deemed (by the treating team) to be in the child's best interests the parent and treating team may override the child's non-consent. Any variations to this process should be clearly outlined in the original submission and must be approved by the HREC.
- All participants and/or parent/guardians must have completed a fully informed, written and dated consent, with all study procedures and risks fully explained, prior to undergoing any study treatments or procedures (including screening procedures).
- The consent must be given on the most recently approved version of the participant consent form, complete with the correct version number and date.

4.6. Consent can be withdrawn

- Participants must be aware that they can withdraw their consent at any time without adversely affecting their relationship with the study team or the RCH.
- If a participant withdraws they should be given the ability to consent to the use of previously collected data and/or tissue for the research. If the participant will not be given the choice (i.e. any information previously collected must be used, or cannot be destroyed as it is non-identifiable) then this must be outlined in the HREC application and the Information Statement.

4.7. Using a Witness

- A witness signature is necessary in the cases where the participant or the participant's parent/guardian cannot read. In these cases the witness:
 1. Must be someone independent of the trial
 2. Must present at the informed consent process
 3. Is signing to say that the information relayed to the participant is a true account of the information in the information statement.
- The process for the use, or not, of a witness must be approved by the HREC prior to the trial commencing.
- If a witness is to be used (except in the case above) it may be any person present at the time the information statement is signed by the participant and/or parent/guardian; this

may be a member of the research team and it may be the same person who signs as the investigator (or delegate of the research team) conducting the informed consent.

- The witness must be present at the time the consent form is signed and must sign and date each consent form on the same day as the participant.
- The witness is declaring that he or she was present at the time of consent and witness the form being signed. They are not declaring that they confirm the identity of the person signing, nor are they declaring that they believe the person signing understands the information provided to them.

4.8. Using an Interpreter

- If the project is aiming to recruit participants who are not proficient in English (i.e. not covered by the inclusion/exclusion criteria) then:
 1. An interpreter should be present for the informed consent process and
 2. A translated copy of the information statement (in the participant or parent/guardian's native language) should be provided to them where possible.This process must be approved by the HREC prior to the research commencing and requires the support and sign-off of the Head of the Department of Interpreter Services.
- If an interpreter is used they should sign in the space of the witness to state that they have translated the information statement to the participant. Please note that some interpreters may feel uncomfortable signing the document, if this is the case then a separate witness should be used (as explained above in section 4.7) and it must be documented that an interpreter was used (as explained in section 4.9).

4.9. Participant & Investigator must keep copies of the Information Statement

- All participants must be provided with a copy of the complete Information Statement and Consent Form (of the version they consented to) to keep at the time of consent.
- A copy of each signed Information Statement and Consent Form must also be kept and filed at the study site.
- If the version and date of the Information Statement and Consent Form document is clearly written on the Consent Form page then the Investigator may tear the consent page off and file the consent page(s) only. However, the participant must keep a copy of the complete document, therefore if this is to be the case then the Information Statement must have 2 copies of the consent page (or each consent page if there are multiple consent pages) attached to it, one for the researcher to remove and file and one for the participant to take away.
- A complete unsigned copy of each approved Information Statement and Consent Form must be kept in the study file for reference and must be archived following study completion.

4.10. Documenting the process

- The consent process should be documented in the participant's medical record (medical progress notes) where necessary. That is, if the research impacts the ongoing clinical care of the patient, i.e. if the treating team needs to be aware that the patient involved in research, then the consent process must be documented. This should include: date of consent, who conducted the consent, the name and HREC number of the trial, a certified interpreter was used (if applicable) and contact person and any relevant information other members of the participant's treating team may need to know in order to conduct routine clinical care (e.g. contraindicated medicines).
- Please note for high risk trials the researcher should consider having an alert sticker or using the alert page on the medical record to alert other members of the participants treating team to the fact that the participant is on a clinical trial. This process should be included in the original application to the HREC.

4.11. Modifications and Re-consent

- Any modifications to the information statement and consent form must be approved by the HREC prior to use.
- If the information statement is updated during the study the Principal Investigator must determine whether the new information is relevant to the willingness of current participants to continue their participation in the study.
- If there are any changes that may affect participants' decision to continue participation, then the participants should be informed of these changes via re-consenting to the updated information statement with a clear explanation from the person conducting the re-consent of what the new information is. An alternative process, such as an addendum to the information statement which contains the new information only must be approved by the HREC prior to use.
- The participant must understand and be given the opportunity to either continue their participation or withdraw from the study with no adverse consequences or impact on their continued care or relationship with the institution.

5. Reference

- National Statement on Ethical Conduct in Human Research (2007): <http://www.nhmrc.gov.au/PUBLICATIONS/synopses/e72syn.htm>
In particular:
 - Chapter 2.2: General Requirements for consent
 - Chapter 2.3: Qualifying or Waiving conditions for consent
 - Chapter 4.2: Children and Young People
- Guardianship and Administration Act 1986: [http://www.legislation.vic.gov.au/Domino/Web_Notes/LDMS/PubLawToday.nsf/95c43d44eac71a68ca256dde00056e7b/d3a92dff8d1ec182ca25700b0020921e/\\$FILE/86-58a063.pdf](http://www.legislation.vic.gov.au/Domino/Web_Notes/LDMS/PubLawToday.nsf/95c43d44eac71a68ca256dde00056e7b/d3a92dff8d1ec182ca25700b0020921e/$FILE/86-58a063.pdf)
- International Conference of Harmonisation Good Clinical Practice (ICH GCP) (*Annotated with TGA comments*): <http://www.tga.gov.au/DOCS/pdf/euguide/ich/ich13595.pdf>
- Australian Code for the Responsible Conduct of Research 2007: <http://www.nhmrc.gov.au/publications/synopses/r39syn.htm>

6. Contacts

RCH Strategic goals	Excellence in Healthcare Focus on Quality and Safety Leadership in Research Education
Category	Research
ACHS Function	Support
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