Purpose

This document provides introductory guidance for researchers on matters related to how and when to seek consent for participation in research

Target Audience

Researhers, research support staff, people involved in ethical oversight of research, consumers

Definition

The National Statement on Ethical Conduct in Human Research states that:

> *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.*
> *What is needed to satisfy these conditions depends on the nature of the project, and may be affected by the requirements of the codes, laws, ethics and cultural sensitivities of the community in which the research is to be conducted.*
> *Variations of these conditions may be ethically justified for some research. Respect for human beings must, however, always be shown in any alternative arrangements for deciding whether potential participants are to enter the research.*
> *It should be noted that a person's consent to participate in research may not be sufficient tojustify his or her participation.*

Note: the entry in the reference list gives full details of the publication under The National Health and Medical Research Council, the Australian Research Council and the Australian Vice-Chancellors' Committee, (2014, March, p16)
http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72_national_statement_march_2014_140331.pdf

The National Statement chapter 2.2 *General requirements for consent,* provides guidelines on the requirement for consent; Chapter 2.3: *Qualifying or waiving conditions for consent* then discusses and provides guidelines on conditions under which the requirement may be qualified or waived. (The National Health and Medical Research Council, et.al., pp16-22).

Guideline

Contents

Methods of Seeking Consent

There are a number of different types of consent (active, passive, opt-in, opt-out, waived) and ways in which consent can be sought from potential research participants (written, verbal, implied). Many factors must be considered by researchers to ensure the most appropriate approach is used for their research project. This document provides some introductory guidelines on the various considerations in seeking consent.

Research Involving Invasive procedures, drug trials and other moderate or high risk research:

- **Active, Opt-in, Written Consent**

In general, written informed consent is required for research that is greater than low risk and is mandatory for research involving invasive procedures and clinical interventions. Examples include research involving drugs, surgery, sensitive questioning, sample collections, genetic testing (irrespective of the method of sample collection). A plain language information statement should be provided to inform the potential participants about all aspects of the research. Verbal consent is never acceptable for invasive procedures and drug trials. Researchers are strongly encouraged to use exiting templates for participant information and consent available on the Department of Health's website. http://www.health.vic.gov.au/clinicaltrials/application-instructions.htm

Research Involving Provision of data to third parties:

- **Active, Opt-in, Written**

Written consent is required for the release of identifiable information to an external third party (e.g. external researcher, group, organisation etc) for research purposes.

Research Involving Questionnaires and surveys:

- **Active, Implied, verbal, written**

For this type of research researchers must provide participants with written information regarding the study and how the participant's information and responses will be used. The return of a completed survey by a participant can be considered to imply consent. However, best practice for obtaining consent from participants for questionnaire and survey project activities is for the researcher to consent from participants for questionnaire and survey project activities is for the researcher to request that the participants acknowledge they have read and understood the information provided to them. This can be achieved by the use of a tick box on the front page of a questionnaire or survey. If verbal consent is given by participants it must be documented by the researcher (written or audio documentation). See also the REGI template for a short PICF to be used with online surveys. http://www.barwonhealth.org.au/forms-guidelines-and-templates

- **Passive Consent/Opt out**

Passive consent or opt out consent may be appropriate where a research project would not be achievable if researchers had to rely on obtaining active consent i.e. if whole population data are required such as establishing a registry. Researchers must provide participants with written information about the study using a reliable method (i.e. ideally delivery by hand) with an option for opting out. In this case "no response" is taken to imply consent.
Researchers must provide justification for the use of passive consent and why it is necessary to achieve the study outcomes. Researchers are encouraged to speak with the Research Ethics & Governance Unit (REGI) if they believe that opt out passive consent would be appropriate for their study.
Note: Chapter 2.3 of the *National Statement* has now been updated to provide guidance for the use of the opt-out approach. The guidance can be found in Chapter 2.3 before guidance on waiver of consent, to encourage researchers and HRECs to consider employing an opt-out approach in

preference to waiver in circumstances where participants may be able to be contacted so as to afford them an opportunity to decline to participate in the proposed research.

Variations and exceptions to the standard consent process

Participants Unable to Sign for themselves

a) **Where the project involves a medical research procedure.**
The Guardianship & Administration Act 1986 (GAA) prescribes a process of obtaining consent for medical research procedures to be conducted on patients who are unable to provide consent for themselves

Process for obtaining consent.
The GAA sets out a 4 step process regarding how researchers may obtain consent for the recruitment of incompetent patients into research studies.

Step 1 - **Approval of research by Human Research Ethics Committee**

The first step is to ensure that the relevant research project has been approved by a Human Research Ethics Committee (HREC).

Step 2 - **Is the patient likely to recover within a reasonable time?**

The second step is to determine whether the patient is likely to be capable to consent to the procedure within a reasonable time. The period that constitutes a reasonable time will vary depending upon each patient's circumstances.

If the patient is likely to be capable of giving consent within a reasonable time, then a practitioner must not proceed to step 3 or step 4 (as the case may be).
If the patient is not likely to recover within a reasonable time, then a practitioner may proceed to step 3 and step 4 (as the case may be).

Step 3 - Consent of person responsible

The third step is to seek the consent of the person responsible for the patient before the carrying out of the medical research procedure on the patient.

The person responsible is often a close relative or might be someone appointed by the Medical Treatment Act. The person responsible may only consent to the carrying out of the procedure if he or she believes that the carrying out of the procedure would not be contrary to the best interests of the patient.

Step 4 - Procedural authorisation

The fourth step involves the concept of 'procedural authorisation'. A practitioner may proceed to this fourth step only if the person responsible for the patient cannot be ascertained or contacted.

There are a number of conditions that must be followed if using procedural authorization including that the practitioner believes on reasonable grounds that:

- the medical research procedure is to assess the effectiveness of the therapy being researched; and
- the medical research procedure poses no more of a risk than is inherent in patient's condition and alternative treatment.

A registered practitioner involved in the research project must inform the person responsible (if any) or the patient (if the patient gains/regains capacity) as soon as reasonably practicable of:

- the patient's inclusion in the research project; and
- the option to refuse consent to continue to be involved in the research and to withdraw from the project without prejudice to the patient's ability to receive any alternative treatment.

b) Where the project does not involve a medical research procedure, the Guardianship Act is not used but the project reviewed on a case by case basis.

c) Research Involving Children: Where the project involves children, please refer to the guidance from the Royal Children's Hospital HREC
http://www.rch.org.au/ethics/new_applications/RCH_Information_Statements_and_Consent_Forms/

d) Deteriorating ability: Where the project involves participants whose ability to provide consent is anticipated to deteriorate through the course of the project, researchers are expected to make provisions for this eventuality, for example, by ensuring that a person responsible is involved.

e) Use of phone consent. In general, the HREC discourages 'cold contact' phone consent. However the HREC may approve phone consent on a case by case basis. The application for phone consent should provide a phone script – including how the person is greeted and informed about the reason for the phone call, and how participation will be invited and consent sought and recorded.

Consent Form Revisions
Researchers are encouraged to think of the obtaining informed consent as an ongoing process: Consent forms should be revised when new information about reasonably foreseeable risks, potential benefits, or other information becomes available. Amendments to consent documents must be reviewed and approved by an HREC. Researchers are strongly encouraged to use exiting templates for participant information and consent available on the Department of Health's website.
http://www.health.vic.gov.au/clinicaltrials/application-instructions.htm

Waiver of consent

The National Statement recognises that there may be circumstances in which the use of identifiable information in research may be justified without complying with the requirement of individual consent from all participants (NS, Section 2.3: Qualifying or waiving conditions for consent, March 2014). This can occur in epidemiological research but is also possible for human tissue research and genetic research.
The National Statement requires that 'only an HREC may grant a waiver of consent for research using personal information in medical research, or personal health information'. (Section 2.3.9). HRECs may 'sometimes' waive consent "where neither consent nor an opt-out approach are appropriate" (Section 2.3 Introduction), after taking into account a number of factors (Section 2.3.9 - 2.3.12). The matters that may be taken into account are:

- Involvement in the research carries no more than a low risk
- the nature of any existing consent relating to the collection and storage of the sample;
- the justification presented for seeking waiver of consent including the extent to which it is impossible or difficult or intrusive to obtain specific consent;
- the likelihood that participants would have consented had their been provision for this;
- the proposed arrangements to protect privacy including the extent to which it is possible to de-identify the sample;
- the extent to which the proposed research poses a risk to the privacy or well-being of the individual;
- whether the research proposal is an extension of, or closely related to, a previously approved research project;
- the possibility of commercial exploitation of derivatives of the sample; and
- the relevant statutory provisions.

Waiver of consent and tissues obtained for clinical purposes

Waiver of consent issues often arise where researchers propose to access and use material collected for therapeutic or diagnostic purposes, such as pathology samples. The individuals from whom such

samples have been taken may not have consented to the use of these samples in any research at all, let alone in unspecified research.

Where tissue derived from clinical practices is used for the purposes of quality assurance, rather than for research, consent requirements may be avoided. The Office of the Federal Privacy Commissioner's Guidelines on Privacy in the Private Health Sector state that an organisation's quality assurance or clinical audit activities may constitute directly related secondary purposes, for which consent may not be required.

Completing the application for a waiver of consent

Researchers that wish to apply to waive the requirement to seek consent should complete the *Waiver of Consent Application* available on the REGI website. This document briefly outlines the relevant Statutory Guidelines and summarises the key privacy principles, and provides information regarding the project, the nature of access to information and consent (section1-7) and for the HREC review. This should be submitted to the REGI team for review.

HREC review and approval of applications for a waiver of consent

The Barwon Health Human Research Ethics Committee (BH HREC) reviews all applications for waiver of consent. These are reviewed out of session and ratified by the full HREC, Approval of the waiver is required in order for full project approval to be granted.

REGI is required to report annually to the Health Services Commissioner all projects for which consent has been waived according the conditions set out in National Statement, section 2.3.10 and 2.3.11 (see the section below on reporting).

When is a waiver not required?

An application for approval of a waiver of consent should not be confused with the application for exemption of ethics review, which is only relevant for negligible risk projects using de-identified data, or projects which have prior approval from other institutional HREC's

Waiver of consent applications are not required where data or tissue derived from clinical practices is used for the purposes of quality assurance, The Office of the Federal Privacy Commissioner's Guidelines on Privacy in the Private Health Sector state that an organisation's quality assurance or clinical audit activities may constitute directly related secondary purposes, for which consent may not be required.

Research projects must comply with all of the criteria outlined in paragraph 2.3.6 of the National Statement on Ethical Conduct in Human Research to be considered for waiver of consent. Researchers should seek advice from the REGI and refer to the section on the REGI website when considering waiver of consent.

HREC reporting of waiver of consent

For the purposes of transparency and accountability supporting the desire to instil public faith in research, research institutions are required to make publicly available a summary of all the research projects for which consent has been waived according the conditions set out in National Statement, section 2.3.10 and 2.3.11 (with the exception of research which seeks to expose illegal activity, which should be made publicly available only after the completion of the research).
Barwon Health makes this information available via its Annual Reports and the Research website.

Guides and flowchart

Approval Process for Medical Research Flowchart (PDF 17KB)

Can your adult patient consent flowchart (PDF 231KB)

Guides and flowcharts from the Office of the Public Advocate

Introduction to Guardianship List VCAT (PDF 20KB)

Office of the Public Advocate, (Home)

Office of the Public Advocate. Fact Sheet. Medical Research for Patient swho cannot Consent:

The person responsible

Interaction of Health Records Act (HRA) and Guardianship & Administration Act (GAA) Part 4A Div 6

Special Medical Procedures for Children (PDF 35KB)

Evaluation

Review to incorporate updates by REGI

Key Aligned Documents

Advance Care Planning Procedure, PROMPT: Barwon Health \ Clinical Practice \ Respecting Patient Choices

Consent Policy for Investigations, Procedures & Treatment, PROMPT: Barwon Health \ Organisational Services \ Risk Management

Key Legislation, Acts & Standards

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