OFFICE FOR RESEARCH
PROCEDURE

INFORMED CONSENT PROCEDURES & WRITING PARTICIPANT INFORMATION AND CONSENT FORMS FOR RESEARCH

Purpose:

To describe the procedures related to informed consent procedures and writing patient information consent forms (PICF). To ensure that Austin Health adheres to the legal and ethical responsibility of obtaining a valid and informed consent for research participants.

Scope:

All phases of clinical investigation of medicinal products, medical devices, diagnostics and therapeutic interventions and research studies.

Staff this document applies to:

Principal Investigators, Associate Investigators, Clinical Research Coordinators, other staff involved in research-related activities.

State any related Austin Health policies, procedures or guidelines:

Austin Health Clinical Policy – (Informed) Consent (To Diagnosis & Treatment) Policy

Document No: 2179

Policy Overview:

A valid and informed consent will be obtained and documented prior to Austin Health research commencing. Emergency research procedures will be undertaken in compliance with the Guardianship and Administration Act 1986.

Summary:

For consent to be **valid**, it must be:

- freely given;
- specific to the proposed research and/or intervention;
- given by a person who is legally able to consent.

1. Elements of Consent:

A consent is valid if it is:

a) Freely given.
b) Specific to the proposed research and/or intervention;
c) Given by a person who is legally able to consent.

The failure to warn of risks and side effects of research does not necessarily invalidate the consent but might expose the relevant investigator to liability in negligence.

1.2. Informed consent

It is necessary to obtain "informed consent" of the research participant. The expression has come to be used as a convenient means to **express the legal duty to exercise reasonable care in the provision of information, advice and warnings as to the proposed research, its risks, side effects, complications and alternatives.**

2. Informing the Participants::

2.1 What risks should be disclosed?

The NHMRC has provided Guidelines for the disclosure of information based on the general principle that participants are entitled to make their own decisions about medical treatments or procedures and should be given adequate information on which to base those decisions.

2.2 What should be discussed with participants?

The following lists the information, which the NHMRC believes, should ordinarily be discussed with participants, unless the intervention is so minor or part of the information is self-evident, when it may not be necessary to elaborate:

- the possible or likely nature of the illness or disease;
- the proposed approach to investigation, diagnosis and treatment;
- what the proposed approach entails;
- the expected benefits;
- common side effects and material risks of any interventions;
- whether the intervention is conventional or experimental;
- who will undertake the intervention, noting that in a teaching hospital environment it is not always possible to specify this beyond stating that care is provided by a team working under the supervision of a senior investigator;
- other options for investigation;
- other options for diagnosis and treatment, including alternatives;
- the degree of uncertainty of any diagnosis arrived at;
- the degree of uncertainty about the therapeutic outcome;
- the likely consequences of not choosing the proposed diagnostic procedure or treatment, or of not having any procedure or treatment at all;
- any significant long-term physical, emotional, mental, social, sexual or other outcome which may be associated with a proposed intervention;
- the time involved, and
- the costs involved, including out of pocket costs.

3. Form of Consent:

3.1. Consent Forms

The legal requirement is that a participant provides a valid consent and is informed of all material risks of the research. A signed consent form does not, by itself, provide conclusive evidence of adequately informing a participant or that they have given informed consent. However, consent forms are evidence that discussion about the proposed research took place.

It is not enough for the participant to be given a form to sign – the nature of the research and its material risks must be explained to the participant. The investigator is responsible for ensuring that adequate information has been given and that the participant has provided informed consent.

The provision to participant of available education material is a useful way of informing them. However, it is not a substitute for discussion between the investigator and participant about relevant information, risks and significant side effects.

The signed consent form in its entirety should be sent to Health Information Services (HIS) to be scanned into the participants scanned medical record (SMR). A copy of the signed consent form she be given to the participant for their personal records.

3.2. The Participant's Record

The participant's scanned medical record should include documentation of the participant's consent to research. It should include an outline of what was discussed, including risks. The amount of recording necessary depends on the circumstances of the consent and the amount of information provided on a consent form. It is not necessary to repeat information already documented on the consent form.

Documentation of consent is best thought of as an important part of performing the planned procedure.

4. Who has Legal Capacity to Give Consent?:

4.1 Who is competent?

In order to be legally competent to consent, a participant must generally be an adult (that is 18 years of age or over, although persons under 18 years of age might be able to consent in appropriate circumstances). The participant must also have the cognitive capacity to provide informed consent. This decision is a matter of clinical judgment. However, where there is uncertainty about capacity to consent or whether to disclose information to a person responsible.

A young person under 18 years may have capacity to consent to research provided that they have the capacity to understand the nature of the research and the consequences of their participation. This decision is a matter of clinical judgment. However, where there is uncertainty about capacity to consent or whether to disclose information to a parent or guardian.

4.2 Special Rules where participant is likely to be able to consent in a reasonable time.

Not all medical research involves medical research procedures. Some medical research may involve observations of the participant, or non-intrusive examinations, or surveys collecting information.

If a participant cannot consent to medical research and there is no person responsible available to provide consent, the procedures can be carried out if the legislative requirements under Section 42T of the Guardianship and Administration Act 1986 are met.

A medical research procedure can go ahead without the consent of the person responsible when:

- it is an emergency, or
- the medical practitioner (doctor) is unable to find the person responsible or if there is no person responsible, and
- the medical practitioner believes the procedure is not contrary to the best interests of the participant and follows the procedure set down in the *Guardianship and Administration Act 1986*.

If a medical research procedure begins without consent, the person responsible may consent to the participant's continued involvement with the research, or withhold their consent. When making this decision, the person responsible considers whether the continuation of the treatment is not contrary to the best interests of the participant.

If the medical practitioner believes the treatment is in the best interests of the participant, they must submit a **Section 42T Certificate** to OPA's Advice Service. A **Section 42T Continuing Certificate** must be completed for each month the procedure continues.

Please refer to Appendix 2. Approval process for medical research (Guardianship and Administration Act 1986) Office for the Public Advocate

5. Research Consent Procedure

5.1 Informed consent procedures

The investigator(s) should:

- Comply with local HREC requirements, NHMRC National Statement on Ethical Conduct in Human Research (2007) and other applicable regulatory requirement(s), and adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki.

- Obtain the HREC's written approval of the written informed consent form and any other written information to be provided to participants prior to the beginning of the trial.

- Ensure that the written informed consent form and any other written information to be provided to participants is revised whenever important new information becomes available that may be relevant to the participant's consent.

- Obtain the HREC's approval in advance of use for any revised written informed consent form, and written information.

- Ensure the person or persons taking the informed consent have an adequate understanding of the trial and of the informed consent process.

- Inform the participant or the participant's legally acceptable representative in a timely manner if new information becomes available that may be relevant to the participant's willingness to continue participation in the trial. The communication of this information should be documented. Where the PI determines that the new information

provided in a revised written consent form (e.g. amended/updated informed consent form provided by a clinical trial sponsor) does not have any relevance to an individual participant, the participant does not need to be informed of the revised consent form.

- Examples of this are:
    - when the changes only relate to the active phase of the trial and the participant is in long term follow up,
    - the participant is not required to be given or sign the revised version and
    - where a participant's physical condition has declined and the treating physician feels that the new information in the consent form is not relevant to the participant, for example a participant that has entered a palliative care facility.
- A file note must be made by the PI stating the reason that the revised written consent was not relevant to each individual participant in question. The file note must be signed and dated by the PI (not a research nurse or study coordinator) and filed in the participants' study file.
- Consent via telephone can be used in situations that meet the criteria stated in the "*Guidelines to telephone consent/re-consent appendix 3*".
- Not, nor permit trial staff to, coerce or unduly influence a patient/or volunteer to participate in or continue to participate in a trial.
- Permit any of the verbal and written information concerning the trial, including the written informed consent form, to contain any language that causes the participant or the participant's legally acceptable representative to waive or to appear to waive any legal rights, or that releases or appears to release the investigator, the institution, the sponsor, or their agents from liability for negligence.
- (Or a person designated by the investigator), fully inform the participant or, if the participant is unable to provide informed consent, the participant's legally acceptable representative, of all pertinent aspects of the trial including the written information and the approval/ favourable opinion by the HREC.
- Ensure that language used in the verbal and written information about the trial, including the written informed consent form is as non-technical as practical and should be understandable to the participant or the participant's legally acceptable representative and the impartial witness, where applicable.
- Ensure that before informed consent is obtained, they, or a person designated by the investigator, provide the participant or the participant's legally acceptable representative ample time and opportunity to inquire about details of the trial and to decide whether or not to participate in the trial. All questions about the trial should be answered to the satisfaction of the participant or the participant's legally acceptable representative.
- Ensure prior to a participant's participation in the trial, that the written informed consent form is signed and personally dated by the participant or by the participant's legally acceptable representative, and by the person who conducted the informed consent discussion.

- Ensure if a participant is unable to read or if a legally acceptable representative is unable to read, that an impartial witness i.e. a person who is present during the entire informed consent discussion, and signs the consent form in addition to the participant or the participant's legal representative.

- Ensure that participants who are unable to read and who do not speak English as their first language have the consent form read to them by a qualified interpreter and that the interpreter signs the consent form as well as the participant and the PI.

- Where English is not the first language of the participant a qualified interpreter should be present during the consent process. The provision of a PICF translated into the native language of the participant without an interpreter is not sufficient as the participant may not be able to have their questions answered by the PI. The interpreter must document in the participants SMR their presence during the consenting process, with time, date and NARI certification number listed.

- Ensure that after the written informed consent form and any other written information to be provided to participants, is read and explained to the participant or the participant's legally acceptable representative, and after the participant or the participant's legally acceptable representative has verbally consented to the participant's participation in the trial and, if capable of doing so, has signed and personally dated the informed consent form, the witness should sign and personally date the consent form.

- Ensure prior to participation in the trial, the participant or the participant's legally acceptable representative receives a copy of the signed and dated written informed consent form and any other written information provided to the participants.

- Ensure that the original signed PICF is stored in the source data file (not the investigator file) with a copy to be stored in the participant's medical record in its entirety.

- Ensure a Cerner alert that the participants are enrolled in a research study is created. **Please refer to Appendix 4. Adding an alert to CERNER 2016.**

- Ensure during a participant's participation in the trial, the participant or their legally acceptable representative receive a copy of the signed and dated consent form updates and a copy of any amendments to the written information provided to participants.

- Ensure that when a clinical trial (therapeutic or non-therapeutic) includes participants who can only be enrolled in the trial with the consent of the participant's legally acceptable representative (e.g., minors, or participants with severe dementia), the participant is informed about the trial to the extent compatible with the participant's understanding and, if capable, the participant should sign and personally date the written informed consent.

- Ensure that (except as described immediately below), a non-therapeutic trial (i.e. a trial in which there is no anticipated direct clinical benefit to the participant), is conducted in participants who personally give consent and who sign and date the written informed consent form.

Note: Non-therapeutic trials may be conducted in participants with consent of a legally acceptable representative provided the following conditions are fulfilled:

a. The objectives of the trial cannot be met by means of a trial in participants who can give informed consent personally.

b. The foreseeable risks to the participants are low.

c. The negative impact on the participant's well-being is minimized and low.

d. The trial is not prohibited by law.

e. The approval/favourable opinion of the HREC is expressly sought on the inclusion of such participants, and the written approval/ favourable opinion covers this aspect.

The investigator(s) should ensure:

- That such trials, unless an exception is justified, are conducted in participants having a disease or condition for which the investigational product is intended. Participants in these trials should be particularly closely monitored and should be withdrawn if they appear to be unduly distressed.

- That in emergency situations, when prior consent of the participant is not possible, the consent of the participant's legally acceptable representative, if present, is requested. When prior consent of the participant is not possible, and the participant's legally acceptable representative is not available, enrolment of the participant should require measures in accordance with relevant Australian and/or Victorian legislation and as described in the protocol and/or elsewhere, with documented approval/favourable opinion by the HREC, to protect the rights, safety and well-being of the participant and to ensure compliance with applicable regulatory requirements.

- That the participant or the participant's legally acceptable representative is informed about the trial as soon as possible and consent to continue and other consent as appropriate is requested.

Please refer to the *National Statement on Ethical Conduct in Human Research, 2007* and applicable legislation for details on obtaining consent in special cases.

5.2 Writing participant informed consent forms

Please refer to **https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/how-to-make-an-hrec-application-for-clinical-trials** Section 5 and Section 9 for Department Participant information and consent forms for the Department of Health & Human Services, State Government of Victoria, Australia participant informed consent forms templates (PICF's).

The documents below are the recommended Participant Information and Consent Form (PICF) templates for interventional clinical trial research projects and for genetic clinical trial research are found in Section 5

- PICF interventional for self
- PICF interventional for parent & guardian

- PICF interventional for person responsible
- PICF Participant Partner Pregnancy
- PICF genetic for self
  PICF genetic for parent & guardian
  PICF genetic for person responsible

The documents below are the recommended Participant Information and Consent Form (PICF) templates for other research are found in Section 9.

- PICF non-interventional for self
- PICF non-interventional for parent and guardian
- PICF non-interventional for person responsible
- PICF health and social science for self
- PICF health and social science for parent and guardian
- PICF health and social science for person responsible

(These templates are reviewed and updated regularly and subject to change).

The investigator(s) should:

- Ensure the written informed consent form and any other written information provided to participants include explanations, where appropriate, of the following:

  a. That the trial involves research.

  b. The purpose of the trial.

  c. The trial treatment(s) and the probability for random assignment to each treatment.

  d. The trial procedures to be followed, including all invasive procedures.

  e. The participant's responsibilities.

  f. Those aspects of the trial that are experimental.

  g. The reasonably foreseeable risks or inconveniences to the participant and, when applicable, to an embryo, foetus, or nursing infant.

  h. The reasonably expected benefits. When there is no intended clinical benefit to the participant, the participant should be made aware of this.

  i. The alternative procedure(s) or course(s) of treatment that may be available to the participant, and their important potential benefits and risks.

  j. The compensation and/or treatment available to the participant in the event of trial related injury.

  k. The anticipated prorated payment, if any, to the participant for participating in the trial.

  l. The anticipated expenses, if any, to the participant for participating in the trial.

m. That the participant's participation in the trial is voluntary and that the participant may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the participant is otherwise entitled.

n. That the monitor(s), the auditor(s), the HREC, and the regulatory authority(ies) will be granted direct access to the participant's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the participant, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the participant or the participant's legally acceptable representative is authorizing such access.

o. That records identifying the participant will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the participant's identity will remain confidential.

p. That the participant or the participant's legally acceptable representative will be informed in a timely manner f information becomes available that may be relevant to the participant's willingness to continue participation in the trial.

q. The person(s) to contact for further information regarding the trial and the rights of trial participants, and whom to contact in the event of trial-related injury.

r. The foreseeable circumstances and/or reasons under which the participant's participation in the trial may be terminated.

s. The expected duration of the participant's participation in the trial.

t. The approximate number of participants involved in the trial.

5.3 Training Records

The investigator(s) should:

- Ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties, adverse event reporting, annual reporting requirements and other governance related functions.

- Ensure that documentation of this training be kept current and available for review on request.

APPENDICES

Appendix 1	Standard Operating Procedure (SOP) Change Log
Appendix 2	Approval Process for Medical Research Flowchart
Appendix 3	Telephone Consent/Re-consent Procedure
APPENDIX 3A	Telephone consent obtained under the Guardianship and Administration Act 1986 (Vic)
APPENDIX 3B	Procedure for Telephone Re-consent

6. Glossary

Associate Investigator

Any individual member of the research team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows).

Delegate

A person delegated specific but appropriate tasks in relation to the conduct of a clinical trial.

Good Clinical Practice (GCP)

A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial participants are protected.

Human Research Ethics Committee (HREC)

A body that reviews research proposals involving human participants to ensure that they are ethically acceptable and in accordance with relevant standards and guidelines.
The National Statement requires that all research proposals involving human participants be reviewed and approved by an HREC. The statement also sets out the requirements for the composition of the HREC.

Informed Consent

A process by which a participant voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the participant's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.

International Conference on Harmonisation (ICH)

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a joint initiative involving both regulators and research-based industry focusing on the technical requirements for medicinal products containing new drugs.

Investigator

An individual responsible for the conduct of a research study at a trial site and ensures that it complies with GCP guidelines. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the Principal Investigator. In this instance they may delegate tasks to other team members.

Participant

Any individual who is a participant or was in a clinical trial or research project. Sometimes, participants may be normal healthy volunteers and not all participants have a medical condition.

Protocol

A document that describes the objective(s), design, methodology, statistical considerations and organization of a trial

Witness

An individual who is not a member of the research team, who is present during the consent process and signs the consent documents attesting that the person who they believe to be the participant has freely signed the informed consent documents.

An interpreter cannot act as a witness to the consent process.

Legislation/References/Supporting Documents

1. Note for guidance on Good Clinical Practice (CPMP/ICH/135/96) annotated with TGA comments DSEB, July 2000, sections 4.
2. National Statement on Ethical Conduct in Human Research, (2007).
3. Guardianship and Administration Act 1986 (Vic)
4. Office for the Public Advocate

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Legislation/References/Supporting Documents:

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Keywords: (Delete this section when uploading to ePPIC)

- Informed Consent
- Research
- Participant Information Statement and Consent Form (PICF)
- Telephone Consent Procedure
- Person Responsible Verbal Information and Consent Form

Communication Strategy: (Delete this section when uploading to ePPIC)

Hub

Internet

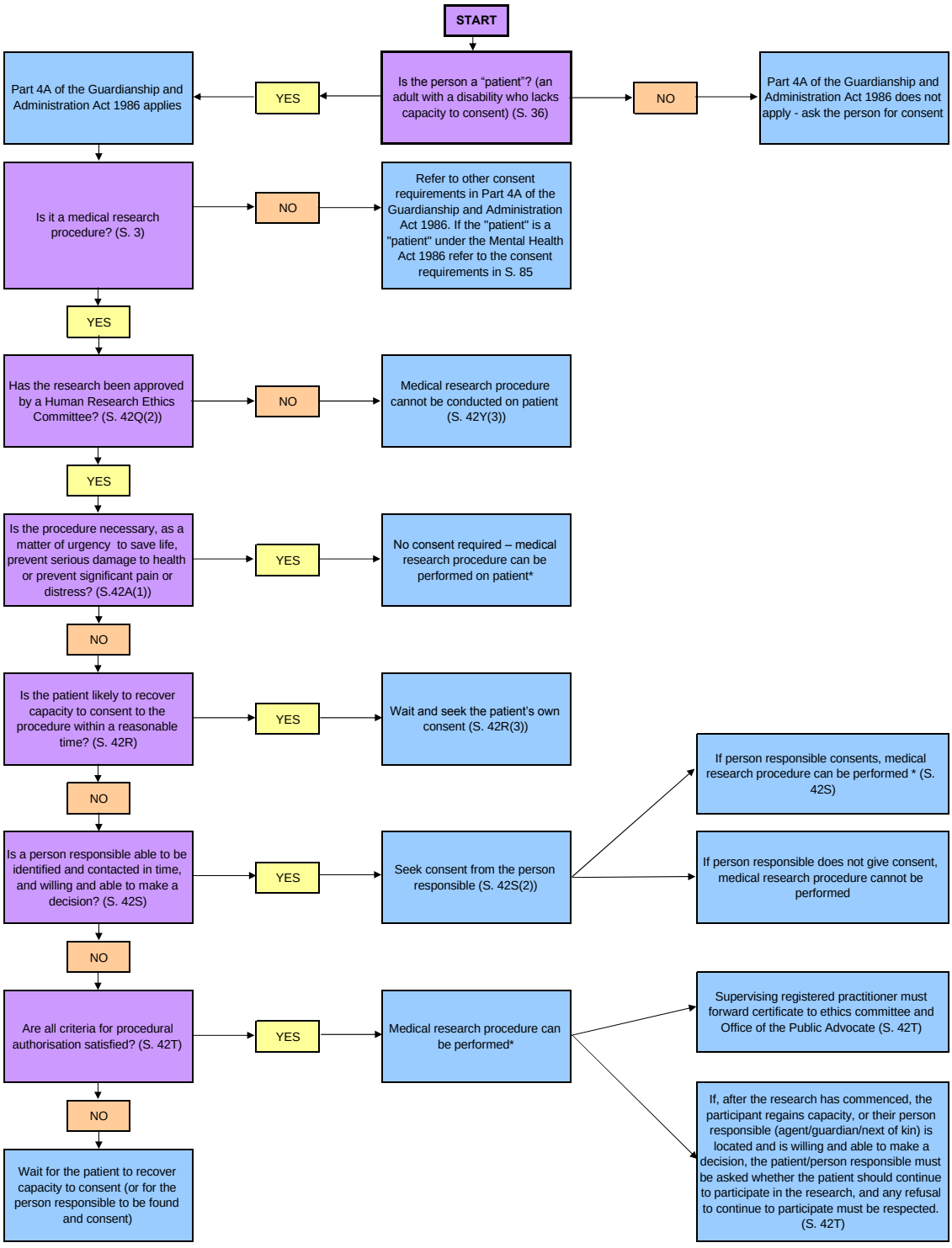
APPENDIX 1: SOP CHANGE LOG

Version No.	*Reason for Issue*
1	February 2015
2	Details definition and use of a witness Details when re-consenting a participant is not necessary Details when a telephone re-consent procedure may be used Appendix 2, 2A and 2B.
3	Update location for storage of original signed PICF

APPENDIX 2 : Approval Process for Medical Research Flowchart

APPROVAL PROCESS FOR MEDICAL RESEARCH PROCEDURES TO BE PERFORMED IN VICTORIA ON ADULTS WITH A DISABILITY WHO LACK CAPACITY TO CONSENT

(GUARDIANSHIP AND ADMINISTRATION ACT 1986)



* Medical research procedure cannot be conducted if there is a relevant refusal of medical treatment under *Medical Treatment Act (S. 42P(5)).*

APPENDIX 3: TELEPHONE CONSENT/RE-CONSENT PROCEDURE

1 Background

In-person, face-to-face, consenting/re-consenting should always be undertaken wherever possible.

At Austin Health consenting/re-consenting is usually undertaken in person with the Principal Investigator (PI), or Associate Investigator (AI) (if that person has HREC approval to obtain consent) to ensure that the participant has understood the information given and has had the opportunity to ask questions before signing.

ICH-GCP requires clinical trial participants to be informed of new information about a study drug or procedure that is discovered during the course of the trial. The common method for presenting this information to participants is to ask them to sign an amended PICF containing the new information

Where in-person consenting/re-consenting in not possible i.e. participant is not conscious or when it places undue burden on the participant, telephone consent may be applicable.

Telephone consent/re-consent can be undertaken when;

1. It is part of a project protocol approved by an HREC

2. Consent is obtained under the Guardianship and Administration Act 1986 (Vic) where the participant is unable to consent for themselves and a “person responsible” cannot be present to consent in-person. Refer to Appendix 3A.

3. Additional or follow-up consent is required when there is a change to the PICF and it would place undue burden on the participant to return to the hospital to re-consent to the study on the updated PICF.e.g. Participant lives at a great distance from the hospital, their physical condition makes it a burden for them to attend the hospital to re-sign consent or when participants have completed the trial and are no longer attending the hospital. Refer to Appendix 3B.

APPENDIX 3A: Telephone consent obtained under the Guardianship and Administration Act 1986 (Vic)

For obtaining Verbal Consent via telephone from the Person Responsible, for participation in a research study

Principles

1. Clinical departments in a tertiary, university-affiliated hospital have an obligation to foster the seeking of relevant new knowledge to improve the care of the participants they are called upon to treat. Importantly, such departments also have access to new and potentially valuable treatment modalities long before their commercial release, but such treatments are available only within a structured research (i.e. evaluative) framework.

2. Participants presenting to the hospital with an emergency neurological condition or other critical conditions (e.g. as a result of trauma) are often unable to provide informed consent themselves for participation in a research study, but without their participation there would be no new knowledge obtained for the improved care of future critically ill participants.

3. Under the Guardianship and Administration Act 1986 (Vic) (**GAA**) the consent of a Person Responsible (effectively, a surrogate decision maker for the participant) may be sought in the event that a particular participant may be unable to give informed consent to participate in a research study. The Person Responsible is the first person listed in section 37 Person Responsible of the GAA who is responsible for the participant and who in the circumstances, is reasonably available and willing and able to make a decision for the participant to participate in the research study.

4. Given the emergency nature of the admission process of many critically ill participants, it is often not possible for the Person Responsible to be personally present in the Emergency department or other hospital department (e.g. ICU) in a timely manner. This particularly applies in a tertiary referral hospital where the participant may have been transported urgently from far afield.

5. Given also the necessity for research in the fields of emergency or critical care to often be commenced very early after the participant's admission to be meaningful, a process for the obtaining of verbal consent from the Person Responsible is necessary to facilitate the functioning of a realistic research program in critical illness. Although the GAA also provides for Procedural Authorisation in specific projects, the GAA requires that if a Person Responsible can be ascertained or contacted, that the Person consent be obtained. Therefore, the option to obtain verbal consent in a timely manner followed by written consent at the earliest opportunity is valuable.

6. The obtaining of verbal consent may be sought only when the Person Responsible is not able to attend the hospital personally in a timely manner.

7. That verbal consent must be confirmed in writing from the same Person Responsible at the earliest reasonable opportunity.

8. The obtaining of verbal consent must follow the formal procedure, as outlined below.

APPENDIX 3: TELEPHONE CONSENT/RE-CONSENT PROCEDURE (continued)

Procedure

1. The Person Responsible must be able to be identified, must be able to understand the planned conversation and must be able to communicate clearly with the research team members involved. The Investigator must confirm by asking the relevant person that there is no other person higher up in the list of possible persons responsible (as defined in the GAA) who, in the circumstances, is reasonably available and willing and able to make a decision.

2. The most senior member of the research team (Investigator) available at the time will conduct the telephone conversation. A second staff member must be present to confirm if and when any research consent has been freely given. A speakerphone should therefore be used.

3. The Investigator should start by introducing himself/herself (name and position) and the second staff member and by then confirming the participant's name and admitting diagnosis.

4. The Investigator must establish that the person to whom he/she is speaking is the Person Responsible and confirm the Person Responsible's name and relationship to the participant. It must be confirmed that this person is the Person Responsible who has been identified for the participant.

5. Initial discussion should confirm that the Person Responsible is aware of the participant's condition and has the opportunity to receive any immediate clinical update.

6. The Investigator must use the approved Person Responsible Verbal Information and Consent Form for the particular study, to conduct the verbal consent process and should then proceed with the following discussion steps, in order.

    - As the participant has been admitted to a major hospital, there may be the opportunity to receive new experimental treatment which is not standard care and is not normally available.
    - However, any such new experimental treatment can only be given as part of a research project that will evaluate the treatment's effectiveness and safety. When the participant's representative (Person Responsible) can be ascertained or contacted, their consent for the participant's participation in the research project is sought. (N.B. Where the Person Responsible cannot be contacted after reasonable steps have been taken to ascertain and contact a Person Responsible, Procedural Authorisation may be employed if previously approved by HREC.)
    - The purpose of the phone call is to discuss the particular research study available for this participant. It is being discussed on the phone because the commencement of any such treatment is understandably urgent in the emergency or critical care setting.
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APPENDIX 3: TELEPHONE CONSENT/RE-CONSENT PROCEDURE (continued)

- If discussion is agreed to, the study will be presented over the phone in detail. The information may be faxed or emailed to the Person Responsible. (Both the Verbal and the written Participant Information and Consent Forms should be provided to the Person Responsible).
- Any participation in the study is entirely voluntary. Neither participation nor non- participation will alter any other aspects of the participant's full usual care. Participation can always be followed by later withdrawal in the event of a change of mind.
- Austin Health has an open disclosure policy with all its participants, and any clinical or research information that is known is always available for sharing with participants and participants' immediate families.
- This study's protocol has been approved by the Hospital's Human Research Ethics Committee (HREC).
- At any stage in the discussion, the Person Responsible may ask questions or terminate the phone call if they wish.
- The approved Participant Information and Consent Form, formulated using the approved Verbal Consent Form, must be read to the Person Responsible by the investigator. It should be emphasized that this is necessary so that the Person Responsible has enough information to understand the risks and benefits of the treatment and procedures to make an informed decision about the participant's participation. A succinct summary may always be provided in addition if requested.
- If verbal consent is given, it must be documented in the patient's medical record by the investigator and witnessed by the second staff member, using the HREC-approved form for the study. Details of questions asked and responses given must be documented in the patient's medical record.
- The Person Responsible must be reminded that their verbal consent must be followed by written affirmation at the earliest convenient time when they visit the hospital. They are welcome to ask further questions then or at any time afterwards, to have their own copy of the participant information document and to discuss it with any family, friends or advisers they may wish. The expected attendance time must be noted so that staff are aware of when they can obtain written consent.

APPENDIX 3B: PROCEDURE FOR Telephone Re-consent

- The Principal Investigator (PI) must make a signed and dated file note in the study file and in the patient's medical record stating why the telephone re-consenting procedure was used in the particular instance in question.

- The participant is then sent (e.g. by post, email, fax) the amended Participant Information Consent Form (PICF) with a covering letter explaining that the PICF contains new information and arranging a time when the PI assistant PI, or AI will telephone them to discuss it.

    - The letter should have been standardised and approved by HREC, to meet the requirements many pharmaceutical companies and other research organisations may have.

- The Investigator (PI), or Associate Investigator (AI) contacts the participant by telephone at the agreed time and discusses the PICF and answers any questions that the participant might have. The discussion is documented in the participant's medical records and/ or research notes and signed and dated.

- If the participant is agreeable, they re-sign the consent form and date it and it is sent back to the site. Where possible participants remotely signing PICFs should also obtain the signature of a witness.

- When it is received at the site, the PI or AI signs and dates the PICF. The date may be different from the date signed by the participant. The reason for the difference in the dates should be documented in the medical records and/or research notes.

- A copy of the fully signed PICF is returned to the participant and the original is kept in the investigator file with a copy to be stored in the participant's medical record.