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.

Related Austin Health policies, procedures or guidelines:
Austin Health Clinical Policy – Consent to Medical Treatment Policy
Document No: 17024

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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 Medical Treatment Planning and Decisions Act 2016.
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 and Austin Health 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). The original to be filed with the research team and a copy of the signed consent form should 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 decision-making capacity to provide informed consent for a medical research procedure. This decision is a matter of clinical judgment where a person must be able to:

• understand the information relevant to the decision and the effect of the decision
- retain that information to the extent necessary to make the decision
- use or weigh that information as part of the process of making the decision
- Communicate the decision and the person’s views and needs as to the decision in some way, including by speech, gestures or other means.

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. Assessment of capacity is a matter of clinical judgment. The Principal Investigator has overall responsibility for determining if a participant has decision-making capacity to consent.

5. **Research Consent Procedure**

5.1 **Informed consent procedures**

The investigator(s) should:

- Comply with reviewing 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 reviewing HREC's and Site Specific/research governance 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 reviewing HREC's and site specific/research governance 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.
A witness is only required if a participant is unable to read. The witness must be:

- Impartial, i.e. not a member of the study team or under the authority of the investigator (e.g., not employed by the investigator); and
- Over the age of 18 years, and not also acting as the interpreter.

By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the participant or the participant's medical treatment decision maker and that informed consent was freely given by the participant or the participant's medical treatment decision maker.

- 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 and site specific/research governance, 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.

5.1.1 Consentin Adult Participants without Decision-Making Capacity

• Researchers should refer to the following chapters of the National Statement on Ethical Consent in Human research which covers:
  o Chapter 4.4: People highly dependent on medical care who are unable to give consent; and
  o Chapter 4.5: People with a Cognitive Impairment, An Intellectual Disability or a mental illness
• In Victoria the Medical Treatment Planning and Decisions Act 2016 governs the obtaining of consent for administration of a medical research procedure for an adult without decision-making capacity.

• The obligations under the Act rest on the ‘medical research practitioner’.

• Capacity to consent must be considered in the context of the person’s condition and treatment, as well as the nature of the research project. If the person is likely to recover capacity in a reasonable time to make the decision about whether to consent to the medical research procedure, the medical research practitioner must wait to allow the person to make their own decision.

• A medical research practitioner must not administer a medical research procedure to a person who does not have decision-making capacity in relation to the procedure unless consent has been obtained. Consent may be obtained through an instructional directive or from the person’s medical treatment decision maker. The only exceptions to this are:
  o In an emergency; or
  o If there is no relevant instructional directive; and
  o No willing and available medical treatment decision maker.

• A medical research practitioner must make reasonable efforts in the circumstances to locate an advance care directive and/or a medical treatment decision maker before administering a medical research procedure to a person without decision-making capacity (unless it is an emergency).

• Reasonable efforts to locate an advance care directive/medical treatment decision maker may include, but are not limited to:
  o Check ‘Legal’ section of the patient’s medical file for a current Advance Care Directive;
  o Check the ACD to locate the Medical treatment decision maker.
  o Contact the NOK to determine if an ACD has been made and a medical treatment decision maker appointed.
  o Ask any family or friends present;
  o Contact the person’s GP
  o Contact any residential care facility or other health facility the person may have attended.

• If a person has consented to a medical research procedure in an instructional directive, this may constitute consent to the medical research procedure. This is only likely to be applicable in limited circumstances, where the person was informed about the medical research procedure when making the advance care directive. This means the person will need to have been informed about the medical research, and this is likely to be possible only for ongoing research when participants are aware of their potential loss of capacity.

• If there is not a relevant instructional directive, a medical research practitioner must turn to the person’s medical treatment decision maker for a decision. The medical treatment decision maker may consent to the administration of a medical research
procedure if they reasonably believe the person would have consented to the procedure if they had decision-making capacity.

- A medical research practitioner must record in writing on the person’s clinical records that the person did not have decision-making capacity in relation to the research procedure and that the person was not likely to recover capacity within a reasonable time, and the reasons for being so satisfied.

- If a person without decision-making capacity does not have an advance care directive or a medical treatment decision maker, a medical research practitioner may still administer a medical research procedure if they (a) believe, on reasonable grounds, that inclusion in the research project and being the subject of the proposed procedure would not be contrary to:
  
  o The person’s values, whether expressed by way of a values directive or otherwise, or inferred from the person’s life; and
  
  o Any other relevant preferences that the person has expressed, having regard to the circumstances in which those preferences were expressed;
  
  o The personal and social wellbeing of the person, respecting the person’s individuality; and

- (b) believe, on reasonable grounds, that the relevant human research ethics committee approved the research project with the knowledge that a person may participate without prior consent of that person or a medical treatment decision maker and

- (c) believe, on reasonable grounds, that one of the purposes of the research project is to assess the effectiveness of the procedure and that the medical research procedure poses no more of a risk to the person than the risk that is inherent in the person’s condition and alternative medical treatments and (d) believe, on reasonable grounds, that the research project is based on valid scientific hypotheses that support a reasonable possibility of benefit for the person compared with standard medical treatment.

- If the medical research procedure is ongoing, the medical research practitioner must continue to take reasonable steps to identify and contact the person’s medical treatment decision maker and seek consent to continuing the procedure.

- Before, or as soon as practicable after, administering a medical research procedure in accordance with this process, a medical research practitioner must sign a certificate certifying that: (a) the person did not have decision-making capacity in respect of the procedure that a medical treatment decision maker could not be identified, and each of the matters set out above; and. (b) the person’s medical treatment decision maker will be informed of the procedure if one is subsequently identified, or that if the person recovers decision-making capacity they will be informed of the procedure.

- The medical research practitioner must forward a copy of the certificate to the Public Advocate and the relevant human research ethics committee within two business days after administering the procedure. If the procedure lasts longer than 30 days,
the medical research practitioner must sign a certificate every 30 days and forward a copy of each certificate to the Public Advocate and the relevant human research ethics committee at intervals of no longer than 30 days.

Please refer to Appendix 2. Approval process for medical research (Medical Treatment and Planning Decision Act 2016) Office for the Public Advocate

5.1.2 Child consent to participate in medical research:
Austin Health will follow the guideline written by the ‘Australia Paediatric Research Ethics & Governance Network’ when consenting children and the process below has been taken directly from their guideline ‘Clinical trials, the child participant and consent: A practical guide for investigators and sponsors’.

- Written informed consent must be obtained from the parent(s)/legal guardian(s) of the child participant
- AND
- Children, deemed by the investigator to have the requisite capacity and maturity to understand the nature and demands of the research, should also be asked to provide their written informed consent to participate in the research. This informed consent can either be obtained on their own Informed Consent Form (ICF) or by counter-signing the parent(s)/legal guardian(s) ICF.
- Parent(s)/legal guardian(s) should be provided with written information and the Parent ICF.
- Children deemed by the investigator to have the requisite capacity and maturity to understand the nature and demands of the research should be provided with written information and a Participant ICF.
- Children not yet mature or competent to provide written informed consent should receive age appropriate information about the proposed clinical trial. This information should highlight in particular any risk and/or benefits of their participation in the study. The information provided can be in written or other form, as may be determined by the investigator and approved by the Reviewing HREC.
- If you are seeking the informed consent of a child, the information provided to the child must be sufficiently detailed in order for informed consent to occur. Generally, this information should mirror the information provided to the parent(s)/legal guardian(s).
- Where an investigator determines that a child does not have the requisite competency or maturity to provide informed consent, the child should be provided with age appropriate information. A written information sheet is a useful tool to assist communications between the investigators and the child regarding the study. Other tools such as short videos, presentations, pictures, and/or story books are means by which investigators can help explain the study to the child.
On completion of the informed consent process, a note should be written into the participant’s medical record and/or study file by the person who performed the consent process. At a minimum this should confirm:

- the date that the consent process took place;
- who took consent;
- who was consented;
- that the person(s) involved in the discussion, and in particular those providing informed consent, have understood and were given the opportunity to ask questions (i.e. the parent only or the parent and child participant). Ideally, the notes would include documentation of any questions asked and the answers provided; and
- that a copy of the signed ICF has been provided to the parents/legal guardians and participant (where applicable).

Investigators should also include in this note discussions conducted with the child and the decision made by the investigator regarding the child’s capacity to provide informed consent. A record of any conversation about the study with the “immature” child should also be documented in detail.

All documentation for a clinical trial should be completed in accordance with the principles embedded in the ICH GCP guideline as a minimum standard.

The informed consent process does not cease once an ICF has been signed. The practice of providing information is an ongoing process throughout a research study. If, during the course of a study, new information becomes available that may be relevant then that information must be presented to the participant and their parents/legal guardians in an appropriate manner (e.g. in writing) and at the earliest possible opportunity. The parents/legal guardians and participant (where applicable) should be asked to re-consent by signing the revised ICF.

If a child becomes mature and competent to provide consent during their participation in a clinical trial, the investigator should take the opportunity to revisit the informed consent discussion and seek the participant’s written informed consent.

5.1.3 Opt-Out Consent Process:

- Principal Investigators (PIs) are responsible to ensure that their projects that use the Opt-Out Consent option follow this process or the process approved by a HREC and AH Site Specific/research governance.

Potential participants must:

- Receive, read and understand information about the research project;
- Understand what their involvement entails;
- Understand that they have a choice about their participation and are able to decline to participate;
• If participants choose to ‘opt-out’, at the initial consenting visit, their personal, health or sensitive information cannot be sent to a third party and a ‘Research Opt-Out’ alert must be entered in the patient’s electronic file.

• PI’s will be the point of contact for their project to receive ‘Opt-Out’ notification from patients, participants or Sponsors. The point of contact can be delegated to a research team member, but ultimate responsibility remains with the PI.

• Upon receipt of an Opt-Out notification, an alert is to be entered into EMR using the ‘Research alert’. In the ‘Comment’ text field include HREC number and short title of project and any other relevant details. An ‘end-date’ should also be entered and would reflect the expected end date of the project.

When opt-out notification is received:
  o Verbally
    ▪ Create an alert as described above;
    ▪ In EMR under the ‘Legal’ tab, create a ‘Progress Note’ and enter the Project HREC Number and Short Title and document the details of the conversation with the participant requesting to opt-out
  o Completed Opt-Out form or Participant Information Consent Form Withdrawal
    ▪ Create an alert as described above;
    ▪ Place the patient’s Bradma label on the form and keep original in research project folder and send a copy to HIS for scanning under the ‘Legal’ tab.

• The PI is responsible for ensuring that the participant’s data is removed from use within the research project as per approved project protocol.

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/medical treatment decision maker
• PICF Participant Partner Pregnancy
• PICF genetic for self
  PICF genetic for parent & guardian
  PICF genetic for person responsible/medical treatment decision maker

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/medical treatment decision maker
• PICF health and social science for self
• PICF health and social science for parent and guardian
• PICF health and social science for person responsible/medical treatment decision maker

(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 if 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 (Medical Treatment and Planning Decision Act 2016) Office for the Public Advocate |
| 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 |
| APPENDIX 4 | Adding an alert to CERNER 2016. |
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.

**Medical Research Practitioner**

A person who is registered under the Health Practitioner Regulation National Law:

(a) a registered medical practitioner; or
(b) a person registered under the Health Practitioner Regulation National Law—
   (i) to practise in the dental profession as a dentist (other than as a student); and
   (ii) in the dentist division of that profession.

**Medical Research Procedure**

A 'medical research procedure' that requires consent in accordance with the Act is a procedure carried out for the purposes of medical research, including as part of a clinical trial, the administration of pharmaceuticals or the use of equipment or a device.

A 'medical research procedure' does not include:

- Any non-intrusive examination (including a visual examination of the mouth, throat, nasal cavity, eyes or ears or the measuring of a person's height, weight or vision);
- Observing a person's activities;
- Undertaking a survey; or
- Collecting or using information, including personal information (within the meaning of the Privacy and Data Protection Act 2014) or
- Health information (within the meaning of the Health Records Act 2001).

**Medical Treatment Decision Maker**

Someone appointed by a person to make medical treatment decisions on behalf of a person when they no longer have decision making capacity. More than one person may be appointed as a medical decision maker, but only one medical treatment decision maker will have the authority to make a medical decision. Once a medical treatment decision maker is required to make a decision, they may access necessary medical records to make a properly informed decision.

There is a hierarchy for determining the person's medical treatment decision maker, and the first available and willing person from the list below will be the medical treatment decision maker.

a) An appointed MTDM
b) A guardian appointed by VCAT (with power to make health care decisions)
c) The first of the following with a close and continuing relationship with the person. Where more than one,

- the spouse or domestic partner;
- the primary carer of the person;
- an adult child of the person (oldest to youngest);
- a parent of the person (oldest to youngest);
- a sibling of the person (oldest to youngest)
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
3. Medical Treatment Planning and Decision Maker Act 2016
4. Office for the Public Advocate
5. Victorian Department of Health & Human Services
6. Australia Paediatric Research Ethics & Governance Network - Clinical trials, the child participant and consent: A practical guide for investigators and sponsors
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Legislation/References/Supporting Documents:
Based on, and with permission of the Victorian Managed Insurance Authority – VMIA GCP SOP No.006 Version:1.0 Dated 17 September 2007

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Office for Research, Austin Health
## APPENDIX 1: SOP CHANGE LOG

<table>
<thead>
<tr>
<th>Version No.</th>
<th>Reason for Issue</th>
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<tbody>
<tr>
<td>1</td>
<td>February 2015</td>
</tr>
<tr>
<td>2</td>
<td>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.</td>
</tr>
<tr>
<td>3</td>
<td>Update location for storage of original signed PICF</td>
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</tbody>
</table>
APPENDIX 2: Approval process for medical research (Medical Treatment and Planning Decision Act 2016) Office for the Public Advocate

2018 Medical research procedures
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.

   •
• 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.
APPENDIX 4: Adding an alert to CERNER 2016.

TIP: In Cerner, an alert will display and populate across all episode types. The terms entered here can be used to populate discharge summaries.

1. Navigate to [ ] within the patient chart

2. In the ‘Problems’ section, click on the Add button

3. Select the Austin Alerts folder

4. Select the appropriate sub folder (i.e. Safety - AH)

TIP: RIGHT click on the folder you use most, and select ‘Set as Home Folder’. Now, whenever you select the [ ] button the alert options from that folder will now display.

5. Scroll down to select the required alert and double click

6. Update the classification to ‘Care Alerts’ and any other necessary fields, then click [ ]

7. The alerts will the display as below:

NOTE: Only alerts selected from the Austin Alerts folder will change the display on the Banner Bar. Features after will NOT trigger this change.