

MELBOURNE HEALTH	OFFICE FOR RESEARCH		
	STANDARD OPERATING PROCEDURE: SOP006		
	Informed Consent Procedures and Writing Patient Informed Consent Forms		
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1. AIM

To describe the procedures related to informed consent procedures and writing patient informed consent forms.

2. SCOPE

Applicable to all clinical research projects undertaken at Melbourne Health, including investigator initiated research, collaborative research and all phases of clinical investigation of medicinal products, devices and diagnostics that involve recruitment of participants.

3. APPLICABILITY

Principal Investigator/Investigator, Sub-Investigator(s), research coordinators and other staff delegated research/trial-related activities by the Principal Investigator.

4. PROCEDURE

4.1 Informed consent procedures

The investigator(s) should:

- Comply with reviewing HREC requirements, Melbourne Health policy and other 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 research/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.

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- 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 ethical approval to do so and an adequate understanding of the research/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 research/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 (1) when the changes only relate to the active phase of the research/trial and the participant is in long term follow up, (2) the participant is not required to be given or sign the revised version and (3) 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 2*".
 - Not, nor permit research/trial staff to, coerce or unduly influence a participant to participate in or continue to participate in a research/trial.
 - Permit any of the oral and written information concerning the research/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 research/trial including the written information and the approval/ favourable opinion by the HREC.
 - Ensure that language used in the oral and written information about the research/trial, including the written informed consent form is as non-technical as practical and should be understandable to the participant or the

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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 research/trial and to decide whether or not to participate in the research/trial. All questions about the research/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 research/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 also sign and date the PICF to indicate that they were present during the consent process.
- 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 orally consented to the participant's participation in the research/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 research/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 participants file or separate PICF folder (not the investigator file) with a copy to be stored in the participant's MH Health Records.

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- Ensure during a participant's participation in the research/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 research project or clinical trial (therapeutic or non-therapeutic) includes participants who can only be enrolled in the research/trial with the consent of the participant's legally acceptable representative (e.g., minors, or patients with severe dementia), the participant is informed about the research/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 can not 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 patients 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

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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.

4.2 Writing patient informed consent forms

The investigator(s) should:

- Ensure the written informed consent form and any other written information provided to participants include explanations of the following:
 - a. That the research/trial involves research.
 - b. The purpose of the research/trial.
 - c. The research/trial treatment(s) and the probability for random assignment to each treatment.
 - d. The research/trial procedures to be followed, including all invasive procedures.
 - e. The participant's responsibilities.
 - f. Those aspects of the research/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 research/trial.
 - l. The anticipated expenses, if any, to the participant for participating in the research/trial.

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- m. That the participant's participation in the research/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 Health Records for verification of research/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 research/trial.
 - q. The person(s) to contact for further information regarding the research/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 research/trial may be terminated.
 - s. The expected duration of the participant's participation in the research/trial.
 - t. The approximate number of participants involved in the research/trial.

4.3 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 research/trial-related duties and functions.
- Ensure that documentation of this training be kept current and available for review on request.

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5. GLOSSARY

Delegate

A person delegated specific but appropriate tasks in relation to the conduct of a research/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 which 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 and sets out the requirements for the composition of an 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 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 projects including clinical trials at a research/trial site and ensures that it complies with GCP guidelines. If a research/trial is conducted by a team of individuals at a research/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.

Investigator file

Documents describing the conduct of study including research team information (delegation and signature log, training records, CV etc.), ethical and research

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governance applications and approvals (initial and amendments), correspondence with the HREC and governance office, other regulatory information including TGA acknowledgement, agreements (collaborative, grants, sponsor CTRA, equipment etc.), protocol, template documents, project specific SOPs (supplied by the sponsor and internal as appropriate) etc. as applicable to the project.

Health Records

Documents held by the Melbourne Health department of Health Information Service that are the record of personal and health information about each patient, including referrals and correspondence, admission notes, treatment, medication and progress notes, theatre sheets, investigation reports, consent forms, Limitation of Medical Treatment forms, powers of attorney (medical), discharge summaries, images/scans, charts, recordings etc (as defined in MH Policy MH05 Documentation and Records Management Policy).

Research visit original clinical notes and copies of the signed PICF form part of the MH Health Record.

Participant Folder

File held by the research team that holds any research project specific participant information that is not held in the Health Records and may include the original signed PICF form, completed case report forms, research only (non-clinical) investigations, copies of the clinical notes (if elected to by the investigator) etc. as applicable to the project.

Participant Information and Consent Form

Document approved by the HREC to inform a participant about the research project and obtain their formal written consent to participant in the research.

Protocol

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

Sub Investigator

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

Source Documents

A source document is the first time a record is completed. MH identifies the Health Records as the legal source document for the patient.

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Source documents may also be stored in the Participant Folder where the information recorded is for research purposes only and does not form part of the clinical care of the participant e.g. CRF, research only investigations that are not used for clinical care.

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.

6. REFERENCES

1. Research Policy MH18
2. Documentation and Records Management Policy MH05
3. Clinical Documentation MH05.01
4. Privacy and Confidentiality of Patient Information MH03.08
5. Note for guidance on Good Clinical Practice (CPMP/ICH/135/96) annotated with TGA comments DSEB, July 2000, sections 4.
6. National Statement on Ethical Conduct in Human Research, (2015).
7. Guardianship and Administration Act 1986 (Vic)

7. APPENDICES

Appendix 1: SOP Change Log.

Appendix 2: Telephone Consent/Re-consent Procedure

DOCUMENT END

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APPENDIX 1 : SOP CHANGE LOG

<i>Version No.</i>	<i>Reason for Issue</i>
1	First issue
2	Details definition and use of a witness Details when re-consenting a patient is not necessary Details when a telephone re-consent procedure may be used Appendix 2, 2A and 2B.
3	3/10/2014: Update location for storage of original signed PICF.
4	15/8/2016: Review and minor formatting updates.
5	28/2/ 2017: Update Glossary definitions and Footers

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APPENDIX 2: TELEPHONE CONSENT/RE-CONSENT PROCEDURE

1 Background

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

At MH consenting/re-consenting is usually undertaken in person with the PI, assistant PI, or 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 trials 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 is 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 2A.
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 2B.

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APPENDIX 2A: Telephone consent obtained under the Guardianship and Administration Act 1986 (Vic)

Principles and Procedures

For obtaining Oral 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 patients 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. Patients 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 patients.
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 patient 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 patient and who in the circumstances, is reasonably available and willing and able to make a decision for the patient to participate in the research study.
4. Given the emergency nature of the admission process of many critically ill patients, 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 patient 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 patient's admission to be meaningful, a process for the obtaining of oral 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 Responsible's consent be obtained. Therefore, the option to obtain oral consent in a timely manner followed by written consent at the earliest opportunity is valuable.
6. The obtaining of oral consent may be sought only when the Person Responsible is not able to attend the hospital personally in a timely manner.
7. That oral consent must be confirmed in writing from the same Person Responsible at the earliest reasonable opportunity.

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

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 patient'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 patient. It must be confirmed that this person is the Person Responsible who has been identified for the patient.
5. Initial discussion should confirm that the Person Responsible is aware of the patient's condition and has the opportunity to receive any immediate clinical update.
6. The Investigator must use the approved Person Responsible Oral Information and Consent Form for the particular study, to conduct the oral consent process and should then proceed with the following discussion steps, in order.
 - As the patient 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 patient's representative (Person Responsible) can be ascertained or contacted, their consent for the patient'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 patient. 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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- If discussion is agreed to, the study will be presented over the phone in detail. The information may be faxed if the Person Responsible has an available fax machine and would like the documents sent in this way. (Both the Oral and the written Participant Information and Consent Forms should be faxed.)
 - Any participation in the study is entirely voluntary. Neither participation nor non-participation will alter any other aspects of the patient's full usual care. Participation can always be followed by later withdrawal in the event of a change of mind.
 - Melbourne Health has an open disclosure policy with all its patients, and any clinical or research information that is known is always available for sharing with patients and patients' immediate families.
 - This study's protocol has been approved by the Hospital's HREC.
 - At any stage in the discussion, the Person Responsible may ask questions or terminate the phone call if they wish.
 - The approved Patient Information and Consent Form, formulated using the approved Verbal Consent Form template, must be read to the Person Responsible by the investigator. It should be emphasized that this is necessary 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 patient's participation. A succinct summary may always be provided in addition if requested.
 - If oral consent is given, it must be documented 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.
 - The Person Responsible must be reminded that their oral 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 patient information document and to discuss it with any family, friends or advisers they may wish. The expected attendance time must be noted so staff are aware of when they can obtain written consent.

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PERSON RESPONSIBLE ORAL INFORMATION AND CONSENT FORM

Version: # Dated: #

Site:

Full Project Title:

Principal Researcher:

Associate Researcher(s):

(Prior to making the telephone call establish who the Person Responsible is for this patient and whether this person is aware that the patient has been admitted to Royal Melbourne Hospital and the patient's condition.)

I am _____ (name/position) and with me on the speakerphone is _____ (name/position).

(Confirm that you are speaking to the Person Responsible.) Are you _____ (name of the previously established, Person Responsible) and you are the _____ (state the relationship to the patient, eg. wife, husband, power of attorney etc.) of _____ (patient's name)?
(Document the response)

(Confirm that the person is not aware of any person higher up in the list of possible persons responsible who, in the circumstances, is reasonably available and willing and able to make a decision.)

Are you aware of any other person in the list of possible persons responsible (you may have to read the list to the person) who, in the circumstances, is reasonably available and willing and able to make a decision for the patient?
(Document the response)

(If this is the first contact (from Royal Melbourne Hospital staff) with the Responsible Person, explain the patient's present condition.)

We would like to include the patient _____ (name) in a research study in the [**specify hospital department**]. We are contacting you about the research study because the patient is unwell and unable to provide consent and the Victorian Law allows the Person Responsible to provide consent in such circumstances. As you are the Person Responsible for _____ (name) we would like to ask for your consent for his/her participation in a particular research study. Participation in a research study is voluntary. Before you decide whether or not you would like the patient to participate we would like to give you information about the study to help you make the decision. We are asking for your oral consent because inclusion in the study must occur within a set time frame. This time frame is very short due to the nature of the patient's illness and the urgency of the treatment required.

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I am now going to explain to you the illness that the patient has.

The patient is invited to participate in this research project because their doctor has determined that the patient has **(include the name of the illness and an explanation of the illness using lay terms)**

I am now going to talk to you about the purpose of the study.

The purpose of this study is to **(provide an explanation of the aims of the study. Include the background and justification for the study i.e. the rationale for the drug or device being trialed.**

Include a comparison with other drugs or devices currently used for the same purposes. Include a statement of the current registration status in Australia eg whether the drug/device has been approved for marketing in Australia.

Include the total number of patients that will be participating in the study.)

If you give us your consent over the phone we will enrol the patient into the study and commence the study procedures. There is a written Person Responsible Information Form, which will explain the study in more detail. You will be given this form to read when you next visit the hospital. After reading the Person Responsible Information Form you will be asked to provide your written consent or you may choose to withdraw your consent for the patient's participation in the study. If you withdraw your consent at that time, you should be aware that the patient is likely to have already undergone certain study procedures on the basis of your oral consent.

Do you have any questions?

Question (written)

Answer (written)

I will now outline the study procedures.

(State the nature, number, timing and time commitment of all procedures. Indicate and describe the nature of the tests or procedures that are in addition to those ordinarily performed as part of the routine care of the patients with this condition.

Explain and describe the randomisation procedures, if applicable. Outline the use of controls and placebos, if applicable).

Full details of all procedures and blood tests are described in the Person Responsible Information sheet that will be given to you when you next visit [**specify hospital department**].

Question: Do you have any questions?

Questions (written):

Answers (written):

I am now going to outline the possible risks of participating in the study.

(List the most common side effects and the most serious side effects, risks and discomforts involved in participating in the clinical trial.)

Other less common side effects are listed in the Person Responsible Information Form that will be given to you when you next visit [**specify hospital department**].

The study may also involve unknown or unforeseen risks.

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Do you have any questions or anything that you would like me to explain further?

Questions (written):

Answers (written):

If you are willing to provide consent for the patient to participate in the research study, we will accept your oral consent and commence the study procedures and ask that when you next visit, you read the full Person Responsible Information sheet and ask any further questions that you may have about the research study. You will be asked to provide written consent at that time, by signing the Person Responsible Information and Consent Form.

When do you think you will be attending the hospital?

(Note date and time: _____)

Please note that participation in any research study is voluntary. If you do not wish for the patient to take part you are not obliged to. If you decide for the patient to take part and then later change your mind, you are free to withdraw the patient from the study at any stage.

Question: Do you have any questions at this stage?

Answer:

Question: Would you like me to repeat any information?

Answer:

Under Victorian Law, you, as Person Responsible may only consent to the patient taking part in this study if you believe that the patient's involvement in the study would not be contrary to their best interests.

Question: Do you believe that _____ (patient's name) participation in this research study would not be contrary to their best interests?

Answer:

Question: Do you give your consent for _____ (patient's name) to participate in this study?

Answer:

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2 APPENIDX 2B: PROCEDURE for Telephone Re-consent

- The PI must make a signed and dated file note in the study file 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 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 PI assistant PI, or 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 Health 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 ass PI signs and dates the PICF. The date be different from the date signed by the participant. Documented the reason for the difference in the dates in the Health 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 Health Record.

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