Western Health

STANDARD OPERATING PROCEDURE

Informed Consent Procedures and Writing Informed Consent Forms

Standard Operating Procedure

Western Health

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Signature and date	

Amendment History

VERSION	DATE	AMENDMENT DETAILS
2.0	04 Dec 2015	
3.0	June 2019	Updated to align with MACH SOPs & Medical Treatment Planning and Decisions Act (2016)

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 Western Health (WH), 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 (PI), Associate Investigator(s), research coordinators, staff delegated research/trial-related activities by the PI and any researchers on projects where obtaining consent is required.

4. PROCEDURE

For investigator initiated trials where WH is also the sponsor, obligations owed to or emanating from sponsor should be interpreted to mean WH.

NOTE: *All Victorian Human Research Ethics Committees (HRECs) use and comply with the standard Participant Informed Consent Form (PICF) that has been issued by the Victorian Dept. of Health. Deviating from this standard form may result in delaying the ethical approval of your study. Furthermore, as the PICF has legal implications, any significant deviation from the Dept. of Health's standard template should be approved by Western Health's legal counsel prior to it being adopted and submitted for ethical review.*

The standard PICF template can be accessed from the below hyperlink:

Victorian Department of Human and Health Services Clinical Trials and Research "How to make an HREC Application"

4.1. Informed consent procedures

The investigator(s) should:

STEP	ACTION
4.1.1	Comply with local HREC and Research Governance Office (RGO) requirements, NHMRC National Statement on Ethical Conduct in Human Research (2007) and other applicable regulatory requirement(s), and adhere to Good Clinical Practice (GCP) and to the ethical principles that have their origin in the Declaration of Helsinki. **ICH GCP 4.8.1**
4.1.2	Obtain the HREC and RGO written approval/authorisation of the written informed consent form and any other written information to be provided to participants prior to the beginning of the research/trial.
4.1.3	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. The communication of this information should be documented as per the Trial Master File (TMF) Checklist (See WH GCP SOP002). **ICH GCP 4.8.2**

4.1.4	Obtain the HREC and RGO approval/authorisation in advance of use for any revised written informed consent form, and written information. **ICH GCP 4.8.2**
4.1.5	Ensure the person/s obtaining the informed consent have an adequate understanding of the project, the informed consent process and is the person/s identified to conduct the process on the delegation log. **ICH GCP 5.7**
4.1.6	Inform the participant or the participant's Medical Treatment Decision Maker (MTDM) 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: 1. when the changes only relate to the active phase of the 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.
4.1.7	Consent via telephone can be used in situations that meet the criteria stated in the "Guidelines to telephone consent/re-consent Appendix 1".
4.1.8	Ensure that all currently enrolled study participants are re-consented when a new version of the informed consent form is approved. **ICH GCP 4.8.11**
4.1.9	Do not, nor permit research staff to coerce or unduly influence a participant to participate or to continue to participate in a project/trial. **ICH GCP 4.8.3**
4.1.10	Not permit any of the oral and written information concerning the project/trial, including the written informed consent form, to contain any language that causes the participant or the participant's MTDM 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.
4.1.11	The PI (Or a person designated by the investigator), fully inform the participant or, if the participant is unable to provide informed consent, the participant's MTDM, of all pertinent aspects of the project including the written information and the approval/authorisation by the HREC and RGO.
4.1.12	Ensure that language used in the oral 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 MTDM and the impartial witness, where applicable. The information that forms part of the informed consent process should be written in layman's terms and generally to a level of comprehension of a thirteen (13) year old (grade 8 standard) **ICH GCP 4.8.6**
4.1.13	Ensure that before informed consent is obtained, they, or a person designated by the investigator, provide the participant or the participant's MTDM ample time and opportunity to inquire about details of the project and to decide whether or not to participate in the study. All questions about the project should be answered to the satisfaction of the participant or the participant's MTDM. **ICH GCP 4.8.7**
4.1.14	Ensure prior to a participant's participation in the project, that the written informed consent form is signed and personally dated by the participant or by the participant's MTDM, and by the person who conducted the informed consent discussion.
4.1.15	Ensure if a participant is unable to read or if a MTDM is unable to read, that an impartial witness be present during the entire informed consent discussion, and that discussion be held in an appropriate language.
4.1.16	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.
4.1.17	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.
4.1.18	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 MTDM, and after the participant or the participant's MTDM has orally 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.
4.1.19	Ensure prior to participation in the project, the participant or the participant's MTDM receive 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). If the project is an interventional project, a signed copy is to be stored in the participant's digital/electronic medical health record.
4.1.20	Ensure during a participant's participation in the project, the participant or their MTDM receive a copy of the signed and dated consent form updates and a copy of any amendments to the written information provided to participants.

4.1.21	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 MTDM (e.g., minors, or patients 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.
4.1.22	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 MTDM 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 minimised and low. d. The trial is not prohibited by law. e. The approval/authorisation opinion of the HREC and RGO is expressly sought on the inclusion of such participants, and the written approval/ authorisation covers this aspect.
4.1.23	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.
4.1.24	That in emergency situations, when prior consent of the participant is not possible, the consent of the participant's MTDM, if present, is requested. When prior consent of the participant is not possible, and the participant's MTDM representative is not available, enrolment of the participant should require measures described in the Medical Treatment Planning and Decisions Act (2016) (Section 80), protocol and/or elsewhere, with documented approval/authorisation by the HREC and RGO, to protect the rights, safety and well-being of the participant and to ensure compliance with applicable regulatory requirements.
4.1.25	That the participant or the participant's MTDM are informed about the trial as soon as possible and consent to continue, and any other consent as appropriate, should be requested.

Please refer to the *National Statement on Ethical Conduct in Human Research (2007 incorporating 2018)* 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 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 MTDM is authorising such access.
o) That the 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 MTDM 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.

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 project-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. (See WH GCP SOP001)

5. GLOSSARY

Associate Investigator (AI)

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

Clinical Research Coordinators

A research worker who works at a clinical research site under the immediate direction of a Principal Investigator, whose research activities are conducted under Good Clinical Practice guidelines. May also be called “Clinical Trial Coordinator”, “Research Coordinator” or “Study Coordinator”.

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 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.

Impartial Witness

A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject’s Medical Treatment Decision Maker cannot read, and who reads the informed consent form and any other written information supplied to the subject.

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.

Legally acceptable representative

An individual or judicial or other body authorised under applicable law to consent, on behalf of the prospective participant to their participation in the clinical trial.

Medical Treatment Decision Maker (MTDM)

Make decisions about medical research procedures on behalf of a person who does not have decision-making capacity. Appointment of a MTDM is outlined in the Medical Treatment Planning and Decisions Act (2016) Part 3 Division 2.

Principal Investigator (PI)

An individual responsible for the conduct of a clinical trial 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.

Protocol

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

Research Governance Office (RGO)

Site/institutional office that are accountable for the research activities conducted at their site to ensure that research is conducted according to established ethical principles, guidelines for responsible research conduct, relevant legislation and regulations and institutional policy.

Sponsor

An individual, company, institution or organisation which takes responsibility for the initiation, management, and/or financing of a clinical trial.

Trial Master File (TMF)

A file that contains all the applicable essential documents that demonstrate that the study/trial has been conducted in accordance with regulatory requirements and ICH GCP, enabling both the conduct of a project and the quality of the data produced to be evaluated. The preparation and maintenance of the Study File resides with the Site Investigator and set up at the start of a trial and is archived at the end of the trial. This may also be called the “Study Site Master File” or “Investigator Site File”.

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. Based on VMIA GCP SOP No.006 Version:1.0, Dated 17 September 2007
2. Based on MACH GCP SOP No.006 Version:1.0
3. Note for guidance on Good Clinical Practice (CPMP/ICH/135/96) annotated with TGA comments DSEB, July 2000, sections 4.
4. National Statement on Ethical Conduct in Human Research (2007 incorporating 2018)
5. Medical Treatment Planning and Decisions Act 2016

7. APPENDICES

Appendix 1: Telephone Consent/Re-Consent Procedure

Appendix 2: Telephone Consent Obtained under the Medical Treatment Planning and Decisions Act 2016 (Vic)

Appendix 3: Procedure for Telephone Re-Consent

8. AUTHORS/CONTRIBUTORS

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9. PRIMARY PERSON/DEPARTMENT RESPONSIBLE FOR DOCUMENT

Western Health Office for Research

APPENDIX 1: TELEPHONE CONSENT/RE-CONSENT PROCEDURE

Background

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

At WH consenting/re-consenting is usually undertaken in person with the PI or AI (if that person has governance authorisation and delegation 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 in not possible i.e. subject 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 and authorised by an HREC and RGO
2. Consent is obtained under the Medical Treatment Planning and Decision Act 2016 (Vic) where the subject is unable to consent for themselves and a “medical treatment decision maker” cannot be present to consent in-person. Refer to Appendix 2.
3. Additional or follow-up consent is required when there is a change to the PICF and it would place undue burden on the subject 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 3.

APPENDIX 2: TELEPHONE CONSENT OBTAINED UNDER THE MEDICAL TREATMENT PLANNING AND DECISIONS ACT 2016 (VIC)

Principles and Procedures
For obtaining Oral Consent via telephone from the Medical Treatment Decision Maker, 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 Medical Treatment Planning and Decisions Act (2016) (MTPDA) the consent of a Medical Treatment Decision Maker (MTDM) (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 MTDM is the first person listed in section 55 of the MTPDA 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 MTDM 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 MTDM is necessary to facilitate the functioning of a realistic research program in critical illness. Although the MTPDA also provides for administering a medical research procedure if person has no medical treatment decision (Section 80(1)), the MTPDA requires that if a MTDM can be ascertained or contacted, that the MTDM 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 MTDM is not able to attend the hospital personally in a timely manner.
7. That oral consent must be confirmed in writing from the same MTDM at the earliest reasonable opportunity.
8. The obtaining of oral consent must follow the formal procedure, as outlined below.

Procedure

1. The MTDM 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 MTDM (as defined in the MTPDA Section 55) 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 MTDM and confirm the MTDM's name and relationship to the patient. It must be confirmed that this person is the MTDM who has been identified for the patient.
5. Initial discussion should confirm that the MTDM is aware of the patient's condition and has the opportunity to receive any immediate clinical update.
6. The Investigator must use the approved MTDM 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.
    a. 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.
    b. 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 (MTDM) can be ascertained or contacted, their consent for the patient's participation in the research project is sought. (N.B. Where the MTDM cannot be contacted after reasonable steps have been taken to ascertain the patient's instructional directive and contact a MTDM, administering a medical research procedure if person has no medical treatment decision (MTPDA Section 80) may be employed if previously approved by HREC.)
    c. 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.
    d. If discussion is agreed to, the study will be presented over the phone in detail. The information may be faxed if the MTDM has an available fax machine or emailed and would like the documents sent in this way. (Both the Oral and the written Participant Information and Consent Forms should be faxed/emailed.)
    e. 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.

f. Western 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.

g. This study's protocol has been approved by a HREC and authorised by the RGO.

h. At any stage in the discussion, the MTDM may ask questions or terminate the phone call if they wish.

i. The approved Patient Information and Consent Form, formulated using the approved Verbal Consent Form template, must be read to the MTDM by the investigator. It should be emphasised that this is necessary that the MTDM 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.

j. If oral consent is given, it must be documented by the investigator and witnessed by the second staff member, using the HREC-approved and RGO authorised form for the study. Details of questions asked and responses given must be documented.

k. The MTDM 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.

APPENDIX 3: PROCEDURE FOR TELEPHONE RE-CONSENT

1. 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.
2. The participant is then sent (e.g. by post, email or fax) the amended PICF with a covering letter explaining that the PICF contains new information and arranging a time when the PI or AI (if formally delegated) will telephone them to discuss it.
    - The letter should have been standardised and approved by HREC and authorised by the RGO, to meet the requirements many pharmaceutical companies and other research organisations may have.
3. The PI or AI (if formally delegated) 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.
4. If the participant is agreeable, they re-sign the consent form and date it and it is sent back to the site. Where possible subjects remotely signing PICFs should also obtain the signature of a witness.
5. When it is received at the site, the PI signs and dates the PICF. If the date is different from the date signed by the participant, the reason must be documented for the difference in the dates in the medical records and/or research notes.
6. 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.