



SOP 25 - Obtaining Informed Consent to Continue After Initial Enrolment as a Medical Emergency

1.1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to define the investigator's responsibilities in obtaining consent to continue participation after initial enrolment as a medical emergency for approved research projects.

1.2 Scope & Responsibilities

This SOP applies to all staff involved in conducting University of Melbourne sponsored investigator-initiated trials (IITs). Sponsor-Investigators/Coordinating Principal Investigators (CPIs), Principal Investigators (PIs), Associate/Sub-Investigator(s), central trial coordinating teams/research coordinators and other staff involved in research duties.

1.3 Procedure

As per the Medical Treatment Planning and Decisions Act 2016 medical treatment includes participation in research, i.e. unduly with-holding participation in research is equivalent to with-holding treatment. There is, however, a requirement for healthcare workers to ascertain existence of advance care plans and appointed medical treatment decision maker/s prior to administering an intervention.

To operationalise the Act, the research team should:

- i. Identify eligible patients ensuring all inclusion and no exclusion criteria are met as per the trial protocol.
- ii. Discuss patient's condition and potential inclusion in the trial with the doctor treating the patient to identify concerns regarding the patient's suitability for the trial that may not be immediately apparent to the research team. The research team will also need to ascertain whether further discussion with other hospital units is required.
- iii. If the patient is not capable of providing informed consent for participation in a trial, the RC will make reasonable efforts in the circumstances (weighing up the risk of delaying delivery of medical treatment) to locate an advance care plan and identify the appropriate medical treatment decision maker (MTDM) for the patient, as per the Medical Treatment Planning and Decisions Act 2016 (part 4 section 55).
- iv. In the absence of an advance care directive, and when it is not feasible for the patient to provide timely informed consent prior to randomisation, and subject to the approval by the relevant Human Research Ethics Committee (HREC) and governance approval, the patient may be enrolled into a study without consent.
- v. For those patients who have a MTDM identified, or it appears that there is a person who will be identified using the established criteria, enrolment into the trial should be clearly documented in the patient's medical history. Documentation should include that the patient did not have an advance care plan or at the time of randomisation, that they were not likely to recover decision making capacity within a reasonable time, it was not feasible to obtain consent from the MTDM within a reasonable time and the patient was enrolled without prior consent as per the HREC and governance

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- approvals. Enrolment will occur under Section 53 of the Medical Treatment and Planning Decisions Act 2016.
- vi. For patients with no MTDM identifiable, the patient may be enrolled into the trial without consent if they meet the criteria as per the Medical Treatment Planning and Decisions Act 2016, and if the study approves enrolment using section 80/81. A Medical research practitioner's certificate must be completed and forwarded to the Office of the Public Advocate (OPA), the lead HREC (without including any identifying information) and the relevant governance office within two business days of administering the study procedure. This enrolment will occur under section 80 of the Medical Treatment and Planning Decisions Act 2016.
 - vii. The role of the OPA is not to provide consent to the procedure but to ensure that the legislative requirements have been met. The certificate is available on the OPA website. (Section 81 of the Medical Treatment and Planning Decisions Act 2016).
 - viii. A copy of the certificate is to be kept in the patient's medical record.
 - ix. For participants enrolled under Section 53 of the Medical Treatment and Planning Decisions Act 2016, i.e. in instances where a patient is enrolled without prior consent and the MTDM has been identified, the research team should attempt to provide the relevant information (as per the HREC approved process for that study) to the MTDM/patient at the next earliest and appropriate opportunity.
 - x. The process to provide the relevant information should be documented in the patient medical records.
 - xi. The research team will leave a contact number with the bedside clinician so that as soon as a MTDM or patient is available during business hours, and the treating doctor considers it appropriate, the research team will provide the relevant information to the MTDM or patient.
 - xii. If after five consecutive working days, and using the approach described above, the research team has not been able to make in-person contact with the MTDM, the research team will attempt to contact the MTDM via telephone.
 - xiii. If the RC is not able to speak directly to the MTDM via telephone but has access to the MTDM's voice message, the research team will leave a message providing a telephone number to use to contact the research team. If the MTDM does not have a voice messaging service, the research team will try calling again 1 working day later.
 - xiv. If after three consecutive working days the research team has not been able to contact the MTDM via the telephone, no further attempts will be made. The research team will wait to be able to speak to the patient. All attempts to make contact via telephone will be recorded in the patient's medical records.
 - xv. Discussions with the MTDM/patient to obtain consent to continue participation should be conducted as per MCCT SOP 23 - Obtaining Informed Written Consent from a Medical Treatment Decision Maker.
 - xvi. If the MTDM/patient decides not to provide consent to continue participation and withdraw the patient from the study, the research team member present at the time will request permission to use the study related data collected up to that time and permission to use the outcome data that will be available from the hospital databases. If the MTDM/patient declines the request they should be informed that all data that has been collected up to that time will be removed from the database.
 - xvii. If the patient dies prior to the relevant information being provided to the MTDM or patient the research team will record this in the patient medical records. No further contact will be made, as this may cause unwarranted distress, unless specified by the

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approving HREC. Subject to HREC approval all available data will be used for the study.

- xviii. If the patient is discharged from the hospital prior to the research team being able to discuss whether they would like to continue their participation in the trial, the research team will contact the patient, provide an explanation of the study and offer to provide them with study information via the post or email, when deemed appropriate. The patient will be informed that their participation is voluntary and that they can withdraw at any time without affecting their relationship with the hospital. In instances where a patient's written consent to continue is required and the research team has not received the signed consent form back from the patient, the research team will attempt to contact the patient at the next follow up at which point an additional attempt will be made to obtain written consent to continue. If the research team does not receive written consent to continue following completion of the final follow up a note to file will be completed outlining the attempts and if necessary the research team will seek advice from the approving HREC to determine if further action is required.
- xix. Attempts to notify a patient of their involvement in a study when consent to continue participation has been obtained by the MTDM will be determined by the protocol approved by the HREC. If there is a requirement or preference for notification, ideally this should take place once the patient has been discharged to the ward and when deemed appropriate. If the patient's active involvement in the study (i.e. intervention period) is complete and follow up is required for the study, the research team may wait until the time of follow up to notify the patient of their involvement in the study. Alternatively, if no follow up is required, the research team or delegate should make a maximum of 2 attempts to review the patient on the ward to discuss their involvement in the study. In instances where the patient's involvement in the study is complete but the patient is unable to meaningfully participate in research related discussions, then a copy of study related information (either study brochure or Participant Information and Consent Form (PICF)) will be provided to the patient either in person, via mail or email, whichever is deemed more appropriate. Contact details for the research team will also be given to the patient, if not already a part of the study information.

1.4 References & Useful Links

- ICH Guideline for Good Clinical Practice
<https://www.tga.gov.au/resources/publication/corporate-reports/ich-guideline-good-clinical-practice>
- NHMRC: National Statement on Ethical Conduct in Human Research (2007) - Updated 2018 <https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018>
- Australian Clinical Trial Handbook – Guidance on conducting clinical trials in Australia using 'unapproved' therapeutic goods
<https://www.tga.gov.au/resources/guidance/australian-clinical-trial-handbook>
- Medical Treatment Planning and Decisions Act 2016
<https://www.legislation.vic.gov.au/in-force/acts/medical-treatment-planning-and-decisions-act-2016/012>
- Office of the Public Advocate
<https://www.publicadvocate.vic.gov.au/>

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1.5 Supporting Templates and Work Instructions

- MCCT SOP 09 - Participant Informed Consent Process and Documentation
- MCCT SOP 23 - Obtaining Informed Written Consent from a Medical Treatment Decision Maker
- MCCT SOP 24 - Obtaining Informed Verbal Consent from a Medical Treatment Decision Maker

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1.6 Glossary

Advance Care Directive (ACD)	This is a document that sets out a person's binding instructions or preferences and values in relation to medical treatment of that person in the event that the person does not have decision making capacity for that medical treatment. The ACD may contain an instructional directive and /or a values directive There is no requirement that an advance care directive be in a prescribed form.
Clinical Trial	Clinical trials can involve investigating new or existing medicines, medical devices and other medical or non-medical interventions. For example, a clinical trial could involve new drugs, medical devices, biologicals, vaccines, surgical and other medical treatments and procedures. Psycho-therapeutic and behavioural therapies help service changes, preventative care strategies and educational interventions are also examples of clinical trials. Researchers might also conduct clinical trials to evaluate diagnostic or screening tests and new ways to detect and treat disease.
Good Clinical Practice (GCP)	A standard for the design, conduct, performance, monitoring, auditing, recording, analyse, 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 subjects 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.
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 legally acceptable representative cannot read and who reads the informed consent form and any other written information supplied to the subject.
Informed Consent	A process by which a subject 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 subject's decision to participate, Informed consent is documented by means of a written, signed and dated informed consent form.
Investigator	<p>A person responsible for the conduct of the clinical trial at a trial site. There are four types of Investigator roles used to describe Investigators with different levels of responsibility for the conduct of clinical trials. These are described below.</p> <ul style="list-style-type: none"> Sub-Investigator Any individual member of the clinical trial team designated and supervised by the Principal 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). May also be referred to as Associate Investigator. Coordinating Principal Investigator (CPI) If a study is conducted at more than one study site, the Principal Investigator taking the additional responsibility for coordination of the study across all sites in a region is known as the Coordinating Principal Investigator (CPI). This role applies to externally sponsored studies where the Sponsor may be a collaborative research group, commercial Sponsor or an institution. The Principal Investigator at each site will retain responsibility for the conduct of the study at their site.

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	<ul style="list-style-type: none"> • Principal Investigator The PI is the person responsible, individually or as a leader of the clinical trial team at a site, for the conduct of a clinical trial at that site. As such, the PI supports a culture of responsible clinical trial conduct in their health service organisation in their field of practice and, is responsible for adequately supervising his or her clinical trial team. The PI must conduct the clinical trial in accordance with the approved clinical trial protocol and ensure adequate clinical cover is provided for the trial and ensure compliance with the trial protocol. • Sponsor-Investigator An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a participant. The term does not include any person other than an individual (eg, it does not include a corporation or an agency). The obligations of a sponsor investigator include both those of a sponsor and those of an investigator.
Investigator-Initiated Trials (IITs)	A clinical trial which is initiated and organised by an Investigator i.e. an individual rather than a collaborative group, company, or organisation. In these cases, the Investigator will take on the role of the trial sponsor and will then be responsible for the extensive GCP and regulatory requirements associated with both the management and conduct of the trial.
Medical treatment Decision Maker (MTDM)	A person who will make medical treatment decisions on the patient's behalf when they do not have the capacity to make the decision. The hierarchy for determining the patient's MTDM is according to the Medical Treatment Planning and Decisions Act 2016 – Section 55. At any one time there can only be one MTDM.
Participant	A participant is a person that is the subject of the research.
Participant Information and Consent Form (PICF)	The PICF provides information about research and its requirements so that the prospective participant can decide if they wish to take part in the research. In general, this includes the purpose, methods, demands, risks, and benefits of the research. It must provide information to participants in a concise format that they are likely to understand. It must be participant centred.
Protocol	A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial.
Recruitment	Recruitment of participants for a research project (known as a study) is the process where people are identified and contacted for further discussion, provide informed consent, are screened and (where eligible) enrolled in a study.
Research	"Includes at least investigation undertaken to gain knowledge and understanding or to train researchers" (National Statement on Ethical Conduct in Human Research 2007 [Updated 2018]). For the purpose of this guidance, research includes any research that requires submission to and approval from an HREC and/or research governance office. This may include (but is not limited to) observational research, clinical trials, quality assurance projects and laboratory research.
Section 80/81 of the Medical Treatment Planning and Decisions Act	Is the process used to for carrying out a medical research procedure on a patient where the MTDM cannot be identified or contacted. Prior HREC approval must be obtained for the study. The conditions for using Section 80 and 81 are detailed in the Medical Treatment Planning and Decisions Act 2016 Part 5 sections 80 and 81.
Trial Coordinator	A Trial Coordinator has a significant role in the management of the clinical trial at the Sponsor level and provides leadership in clinical trial activities to ensure that

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the trial is completed within budget, on time and of the highest quality. A Trial Coordinator is responsible for managing the planning, implementation, and tracking of the clinical monitoring process, administration, and start-up of the clinical trial at the participating site and maintaining an overview of the conduct of the trial at sites. Some common roles and responsibilities performed by the Trial Coordinator include:

- Participate in protocol development, CRF design and clinical study report writing
- Guide in the creation and development of important study documents and manuals
- Conduct feasibility assessments
- Develop study budgets
- Oversee participant recruitment
- Oversee overall trial conduct
- Ensure compliance of site-staff with the trials Standard Operating Procedures
- Ensures compliance to all regulatory requirements both at a local and international level
- Ensures compliance to all data protection requirements both at a local and international level
- Ensures compliance to all safety reporting requirements both at a local and international level
- Conduct team meetings and site-staff training programs
- Overall responsibility of the trial
- Supervise in-house clinical trial staff

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1.7 Revision Chronology

Document History			
Version	Effective Date	Summary of Changes	Author
1.0	06 May 2026	Initial Version	Renata Phyland