Melbourne Centre for Clinical Trials
Standard Operating Procedure
SOP No.: 26
Issue date: 06/05/2026
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THE UNIVERSITY OF MELBOURNE

SOP 25 – Opt Out Consent Process

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 and 'opt out consent' for approved clinical trial 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

Comply with local HREC requirements, NHMRC National Statement on Ethical Conduct in Human Research (2007) and other applicable regulatory requirement(s) including the Medical Treatment Act (2016), adhere to Good Clinical Practice (GCP) and to the ethical principles that have their origin in the Declaration of Helsinki, and MCCT SOP 09 – Participant Informed Consent Process and Documentation.

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 this, the research team should:

i. Identify eligible patients ensuring all inclusion and no exclusion criteria are met as per the trial protocol.

ii. Discuss the 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. Consider further discussions with other hospital units if required.

iii. If the patient is not capable of providing informed consent for participation in a trial, the research team will make reasonable efforts in the circumstances (weighing up the risk of delaying delivery of medical treatment) to locate an advance care directive (ACD) and identify the appropriate medical treatment decision maker (MTDM) for the patient, as per the Medical Treatment and Planning 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 in to a study without consent.

v. Enrolment into the trial should be clearly documented in the patient's medical record. Documentation should include that the patient did not have an advance care plan or at the time of randomisation they were not likely to recover decision making capacity within a reasonable time, it was not feasible to obtain consent from the MTDM at that time of randomisation and the patient was enrolled without prior consent.

vi. If a patient is enrolled without consent in line with HREC approval and in accordance with section 53 of the Medical Treatment Planning and Decisions Act, the research team should attempt to provide the relevant information (as per the HREC approved process and the Site Delegation and Signature Log for that study) to the MTDM/patient at the next earliest and appropriate opportunity.

vii. The process to provide the relevant information should be documented in the patient medical records.

viii. The research team will leave a contact number with the bedside clinician so that as soon as a MTDM or patient is available, and the treating doctor considers it appropriate, the research team will provide the information to the MTDM or patient.

ix. If after five consecutive working days the research team has not been able to make contact with the MTDM, the research team will attempt to contact the MTDM via telephone.

x. If the research team is not able to speak directly to the MTDM via telephone but has access to the MTDMs 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 voice messaging service the research team will try calling again one working day later.

xi. If 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.

xii. If the MTDM informs the research team via telephone that they will be visiting the hospital after hours, when the research team are unavailable to discuss the study with them, the research team if designated to perform consent discussions may take the opportunity at that time to explain the study to the MTDM.

xiii. As part of the information the MTDM/patient will be informed that participation in the study is voluntary and that the MTDM/patient can "opt out" and withdraw their participation at any time throughout the study without penalty.

xiv. If the MTDM has no objection to the patient's participation the research team will ascertain the best way to provide Participant Information and Consent Form (PICF) to the MTDM. The PICF may be posted or left at the bedside for collection by the MTDM.

xv. If the MTDM/patient decides to "opt out" and withdraw the patient from the study, the Investigator or research team 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.

xvi. The research team will follow up on the next working day to check the medical records to confirm that the PICF has been provided to the MTDM.

xvii. If the PICF has not been provided to the MTDM or patient, or the provision of such information has not been recorded in the patient medical records, the research team will leave the PICF with the bedside clinician and record this as above.

xviii. If after five consecutive business days the information has not been provided to the MTDM, the research team will telephone the MTDM and suggest that the research team will post or email the PIS. This will be recorded in the patient's medical records.

xix. If the patient dies prior to the relevant information being provided to the MTDM or patient the RC will record this in the patient medical records. No further contact will be made, as this may cause unwarranted distress. Subject to HREC approval all available data will be used for the study.

xx. If the patient is discharged from the hospital prior to the research team being able to provide them with the PICF and there is further participation required, the research team will make contact with the patient during one of the study follow up telephone interviews and ensure they are aware of their enrolment and offer to provide them with study information via the post or email. 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.

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/

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

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	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. • 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. • 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 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

1.7 Revision Chronology

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