SOP 23 - Obtaining Informed Written Consent from a Medical Treatment Decision Maker

1.1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to define the investigator's responsibilities in obtaining informed written consent from the medical treatment decision maker (MTDM) in a clinical trial. This option for consent can only be used when written consent from the MTDM has been approved by the Human Research Ethics Committee (HREC).

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

The following sections provide a description of the processes to be followed when implementing this document's procedure.

It is the research team member's responsibility to:

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

b) Discuss the patient's condition and potential inclusion in the trial with the doctor/s treating the patient, identifying and addressing any concerns regarding the patient's suitability for the trial that may not be immediately apparent to the investigator.

c) Determine who can obtain consent e.g., investigators or research coordinator (this information is in the trial delegation log).

d) Determine if the patient is able to give informed consent by discussing the patient's mental acuity with the treating doctor and bedside nurse. The research coordinator should speak to the patient to ascertain capacity but if uncertain an Abbreviated Mental Test (IP 8L) may be used.

e) If the patient is deemed incapable of providing consent, the patient's MTDM will be approached for consent. The patient's MTDM is identified in the patient's electronic medical record. If there is no MTDM identified in the electronic medical record, the research team may assist clinical staff in identifying the MTDM.

f) Ensure that prior to any discussion regarding research the MTDM has recently received information about the patient's condition by the clinical team.

g) Research team member must introduce their role to the MTDM, advising them of the patient's potential to participate in a research trial. Confirm if required any clinical details with the MTDM that may impact on the patient's eligibility for the trial.

h) Ensure the trial is explained to the MTDM by a person designated to perform consent discussions and time is given to the MTDM to read the consent form, reflect and ask any

questions. This may involve arranging a subsequent meeting. If the MTDM is unable to read an impartial witness should be present for the entire consent process.

i) If consent is obtained ensure the MTDM signs and dates the medical treatment decision maker information consent form (MTDM-ICF).

j) If consent is not obtained, the MTDM should be thanked for their time and consideration of the trial. They should be reassured that declining to participate in the trial does not affect the care the patient receives.

k) The MTDM should receive a copy of the signed and dated information and consent form. The original copy of the signed and dated ICF should be labelled with the participant's hospital label and scanned into the patient's electronic medical record. Once the original ICF is returned to the research team, the form should be stored in the participant's research file or separate trial folder as per the study protocol.

l) The research team member must document the consent process in the electronic medical record. This will inform all staff of the patient's participation in the study and ensure study related information is available to staff.

m) Update the patient/ MTDM if new information becomes available at a later date that may be relevant to the patient/MTDMs' willingness to continue in the trial.

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*

1.5 Supporting Templates and Work Instructions

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

1.6 Glossary

Abbreviated Mental Test	Ten questions designed to test the patient's cognitive state. Each correct question is given 1 point. A score of 9 – 10 indicates intact cognitive state. As per the Falls Risk Assessment Tool (FRAT) IP 8L.
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.
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