STANDARD OPERATING PROCEDURE (SOP)

TITLE: INFORMED CONSENT

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1. PURPOSE:

The purpose of this SOP is to describe the procedure for obtaining consent from potential participants In the MiNDAUS Clinical Registry. The provision of sufficient information to make an informed decision is understood as "informed consent" and this term will be applied in this context in this SOP.

2. SCOPE:

It is important that this SOP is read and understood before people are approached for their consent to participate and should be referred to if any doubt arises regarding the process of obtaining informed consent.

3. APPLICABILITY:

This applies to all Site PIs, MiNDAUS Project Staff, and to all relevant persons or parties engaged in the MiNDAUS Clinical Registry.

PROCEDURE:

The Principal Investigator (PI) for the clinical research retains overall responsibility for ensuring a participant's consent has been obtained in the correct manner prior to the participant's entry into any study However, at their discretion, the PI can delegate the duty for obtaining consent to a suitably qualified delegate. The PI remains responsible for any delegated activity.

Delegation for obtaining consent to participate in the MiNDAUS Clinical Registry

For delegation of the consent process, the following criteria must first be met by the delegate:

- Must have received the appropriate research specific training and have the experience and knowledge to enable them to explain fully the implications of participating in the Registry to the potential participant.
- Where there is a need to answer questions or make decisions that require medical expertise this should only be delegated to persons with relevant qualifications working within their scope of practice.
- An effective line of communication is maintained between the delegate and the PI. The PI is ultimately responsible for the participant's welfare and the process of ensuring participants, or their legally acceptable representative, have fully understood what they are consenting to.

Pre-requisites before obtaining Informed consent

- The PI or delegate must ensure that the current approved versions of any information used to provide information to potential participants is available and used for obtaining consent.
- As described in the *National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research 2007 (Updated 2018)* (*the National Statement*)[1] sufficiently informed consent must be gained before a participants personal or clinical data is entered onto the MiNDAUS Clinical Registry.

Process for obtaining Informed consent:

- The PI and delegate must comply with *the National Statement*[1] and other applicable regulatory requirements as relevant.
- Potential participants, or their legally acceptable representative, should be given adequate time, to read, listen to or view any relevant information and to discuss with any family and friends and/ or their family doctor, prior to agreeing to participate. The PI or delegate may also offer the potential participant the opportunity to bring a friend or family to the meeting with the PI/delegate.
- The PI/delegate must assess the potential participant's understanding of what they are agreeing to, why they are being asked to participate and has sufficient understanding of the implications of their participation.
- Potential participants who wish to participate will have their intention recorded, noting that this may be verbal, written or electronic.
- Witnesses are not a requirement in Australia unless they are providing a signature on behalf of a person who cannot sign themselves or are attesting to a potential participant having read or listened to information related to participation.
- Once participants have recorded their intentions to participate, they should be shown how to access the copies of the Participant Information and Consent Form stored on the MiNDAUS Registry and provided a printed copy if requested. The original documentation of their intention to participate should be recorded in accordance with the requirements laid down by the HREC and/or the institution if it is different to this.
- Third party research approved by the MiNDAUS Partnership must acknowledge the process by which consent was obtained, and an electronic copy of the fully signed Participant Informed Consent Form (PICF) must be uploaded to the MiNDAUS Registry in the Consent section.

Process for confirming consent where new information arises:

- This process applies to the necessity to obtain and document a participant's expressed willingness to remain in a study. In the case of the MiNDAUS Clinical Registry, this will only be sought for substantive changes that impact on processes that increase burdens or risks for the participants and will not be purely administrative changes.
- If substantive changes need to be made, it will likely need review by Monash Health HREC to determine if further action should be taken and it does, the PI or delegate is responsible for obtaining this review.

Consenting in special populations

- Please refer to *the National Statement (NHMRC, Australian Research Council et al. 2007)* for details on obtaining consent in special cases.
- The MiNDAUS Registries policy is to enroll all possible people with MND across Australia. This inevitably means that participants may have English as a second

language. In this event, the PI will assess the need for an Interpreter, and one will be organised in accordance with the policies of the institution.

REFERENCES AND RELATED DOCUMENTS:

NHMRC, Australian Research Council and Universities Australia (2007). The National Statement on Ethical Conduct in Human Research 2007 (updated 2018). Australian Government Department of Health and Ageing. Canberra, National Health and Medical Research Council**:** 116.

Related SOPs

VERSION CONTROL

Document History	
Version	**Summary of Changes**
1.0	N/A - First Issue
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3.0	