STANDARD OPERATING PROCEDURE (SOP)

TITLE: INFORMED CONSENT

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Author:	Helen Christensen Research Quality Coordinator
Approved by:	Prof Nik Zeps Group Director of Research and Development
Signature:	Nikolajs Zeps (Nov 17, 2020 15:49 GMT+11)
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TITLE: INFORMED CONSENT

1. PURPOSE:

The purpose of this SOP is to describe the procedure for obtaining consent from research participants at Epworth. 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:

All clinical research conducted at Epworth.

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

3. APPLICABILITY:

This applies to all Epworth employees, non-employed staff and Visiting Medical Officers (VMOs) and to all relevant external persons or parties engaged in the research activity at Epworth.

4. GLOSSARY OF TERMS:

Please refer to Epworth SOP Glossary of Terms (see *Related Documents*).

5. 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 (see also *SOP-TM-14 Delegation of Duties*). Delegation of research activities must be recorded on the delegation log. The PI remains responsible for any delegated activity.

5.1 Delegation for obtaining consent to participate in research

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 research 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.

5.2 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 received before the initiation of any procedures, tests or treatments required by the research protocol and which are not considered part of routine clinical care at Epworth.

5.3 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 in a manner approved by the HREC and/or the institution, 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 provided either a printed copy of this or provided an electronic copy they can readily refer to. 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.
- The process by which consent was obtained must be documented in an appropriate place which may include a copy of the fully signed Participant Informed Consent Form (PICF) in the participant's medical record for clinical trials.
- *Appendix A* includes instructions for uploading signed PICFs to the relevant section of the Patient's Scanned Medical Records at Epworth.

5.4 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. This may arise if changes / amendments are made to the protocol after the research has started that may have a material impact on a person's decision to continue participation. This should only be for substantive changes that impact on processes that increase burdens or risks for the participants and should not be purely administrative changes such as to addresses of sponsors etc.

- Substantive changes will likely need review by the approving HREC to determine if further action should be taken and it does, the PI or delegate is responsible for obtaining this review and notifying the Epworth RDGU if required.
- Where the HREC requires it, the PI will ensure that all currently enrolled participants are re-contacted in a timely manner with the relevant new information as approved by an HREC. Unless there is a significant safety concern HRECs will not usually require that patients be recontacted immediately. There are potential implications for blinding of any studies and care must be taken when developing the process for recontact.
- Participants may express their willingness to continue participating through opt-out mechanisms where the HREC determines there is a low risk related to the protocol amendment.
- Where the amendment is more than low risk the HREC may require formal written confirmation of a willingness to continue participation. This must be recorded in a manner approved by the HREC and/or the institution.

5.5 Consenting in special populations

- Please refer to *the National Statement* [1] for details on obtaining consent in special cases.
- For non-English speaking participants, the research team may identify a non-English speaking person as a potential participant. In these circumstances the research team must provide information and record how this is presented and understood in accordance with the process approved by the HREC and/or Institution.

5.6 Waiver of consent / opt-out consent

- There are specific instances where the need for consent can be waived or instead an opt-out approach used. Details of these are provided in Section 2.3 of the *National Statement*[1] and any use of these must be approved by an HREC.

5.7 Financial consent – clinical trials

- All research must be clear regarding any costs associated with participation in research as a private patient (see PICF Content Checklist *SOP-RG-01-FORM-01* for standard wording).
- The Epworth Financial Consent Form (*SOP-TM-03-FORM-01*) should also be used, where relevant, as part of the informed consent process for clinical trials to further assist patients with understanding any potential out-of-pocket costs which may be incurred as a result of participation in a clinical trial and that would otherwise be incurred as part of standard of care treatment.

6. REFERENCES AND RELATED DOCUMENTS:

The Epworth Research Policy, handbook, SOPs and supporting forms and templates can be found on the *Epworth Resources for Researchers* webpage.

1. NHMRC Statement on Ethical Conduct in Medical Research 2007 (Updated 2018) *https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018*

2. Epworth, 2019. *Patient Identification Protocol* (available *here* on the Epworth Intranet Page)

6.1 Related Forms and Templates

- SOP-TM-03-FORM-01 Clinical Trials Financial Consent Form
- SOP-RG-01-FORM-01 PICF Content Checklist

6.2 Related SOPs

- SOP-TM-14 Delegation of Duties
- SOP-Glossary-of-Terms

7. VERSION CONTROL

Document History	
Version	**Summary of Changes**
1.0	N/A - First Issue
2.0	Scope of SOP broadened to include all research at Epworth (not just clinical trials). Major revision including further clarifications on criteria for delegating duty for obtaining consent, process for obtaining informed consent and confirming consent where new information arises. Addition of the following new sections: • 5.6 Waiver of Consent / Opt-out Consent • 5.7 Financial Consent – Clinical Trials • Appendix A – instructions for uploading PICFs to BOSSnet SOP formatting and links updated throughout.
3.0	Section 5.3 – clarification the fully signed PICF is to be uploaded to medical records (where appropriate) Appendix A – Instructions for uploading PICFs revised (including further guidance on when it is appropriate to upload PICFs to Epworth medical records).

Appendix A: Instructions for Uploading PICFs to Epworth Scanned Medical Records.

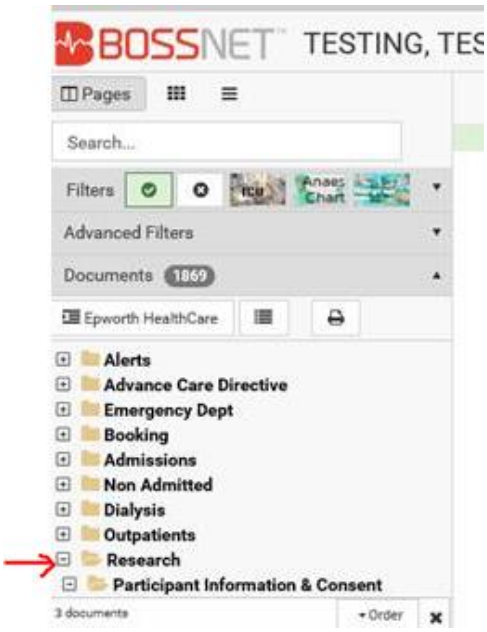
Research participants should only be registered on IPM and be given an Epworth UR and medical record if they have:

- an episode of admitted care to Epworth as an inpatient (including Day Procedures or Hospital In The Home);
- an Emergency Department presentation; or
- Outpatient attendance at Epworth for care and treatment.

Treatment within a clinical research trial at Epworth does not automatically constitute an episode of care by Epworth unless one of the above points apply (i.e. research participants are not always Epworth patients).

Where an Epworth patient who is currently receiving care and treatment at or from Epworth also consents to participating in a research trial at that time, then the PICF documenting consent should be uploaded to the Research folder in BOSSnet.

This folder will only be visible once documents have been uploaded to this location.



To facilitate automatic uploading to the relevant folder, the fully signed PICF should include the research folder barcode in the top left hand corner (see *SOP-RG-01-FORM-01 PICF Content Checklist*) and 3 points of identification on the first page as per Epworth *Patient Identification Protocol*[3]. This barcode must be present in the correct location for it to be scanned/uploaded to the "Research" folder of BOSSnet. If not it will be scanned/uploaded into the "Admission" folder.

Where ever possible **the process for uploading the PICF to BOSSnet should be aligned with the existing practice**. For example, the PICF for current inpatients should be maintained in the patient's files on the ward. HIS will scan the document along with the admission notes when discharged. A separate copy of the PICF does not need to be emailed to HIS.

Where the PICF would not otherwise be uploaded through existing channels it can be uploaded by email to *RichmondHIS@epworth.org.au* with note '*please file in medical record*'.

Note any notes (if required) to be added to the patient's Alert Card in relation to involvement in a project must be added by the ward/study staff.