Verbal Consent Guidelines

St Vincent's Hospital Melbourne 2021

Verbal Telephone Consent

In-person, face-to-face, consenting/re-consenting should always be undertaken wherever possible.

At SVHM, consenting/re-consenting is usually undertaken in person with the Principal Investigator (PI), or Associate Investigator (AI) (if that person has HREC approval to obtain consent) to ensure that the participant has understood the information given and has had the opportunity to ask questions before signing.

ICH-GCP requires clinical trial participants to be informed of new information about a study drug or procedure that is discovered during the course of the trial. The common method for presenting this information to participants is to ask them to sign an amended PICF containing the new information Where in-person consenting/re-consenting in not possible (i.e. participant is not conscious or when it places undue burden on the participant, telephone consent may be applicable.)

Telephone consent/e-consent can be undertaken when:

- It is part of a project protocol approved by an HREC
- Additional or follow-up consent is required when there is a change to the PICF and it would place undue burden on the participant to return to the hospital to re-consent to the study on the updated PICF (e.g. Participant lives at a great distance from the hospital, their physical condition makes it a burden for them to attend the hospital to re-sign consent or when participants have completed the trial and are no longer attending the hospital.)
- There is a need to offer alternative options of consent in order to ensure the comfort and safety of participants during a civil crisis, natural disaster or public health crisis (such as the COVID-19 pandemic).

The Principal Investigator (PI) must make a **signed and dated file note** in the study file and in the patient's medical record stating why the telephone re-consenting procedure was used in the particular instance in question.

The participant is then sent (e.g. by post, email, fax) the amended Participant Information Consent Form (PICF) with a covering letter explaining that the PICF contains new information and arranging a time when the PI assistant PI, or AI will telephone them to discuss it.

The letter should have been standardised and approved by HREC, to meet the requirements many pharmaceutical companies and other research organisations may have.

The Investigator (PI), or Associate Investigator (AI) contacts the participant by telephone at the agreed time and discusses the PICF and answers any questions that the participant might have. The discussion is documented in the participant's medical records and/ or research notes and signed and dated.

If the participant is agreeable, they re-sign the consent form and date it and it is sent back to the site. Where possible participants remotely signing PICFs should also obtain the signature of a witness.

When it is received at the site, the PI or AI signs and dates the PICF. The date may be different from the date signed by the participant. The reason for the difference in the dates should be documented in the medical records and/or research notes.

A copy of the fully signed PICF is returned to the participant and the original is kept in the investigator file with a copy to be stored in the participant's medical record.

Authorized by:

Dr Megan Robertson
Director of Research