SOP 09 Participant Informed Consent Process and Documentation

1.1 Purpose

To describe procedures and documentation management relevant to the initial and ongoing informed consent process, including consenting via telehealth. The objective is to seek and retain voluntary, informed consent through ongoing communication and information exchange between a patient/participant and a clinician about the best interests of each participant. 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 Standard Operating Procedure (SOP).

1.2 Scope

This SOP applies to all relevant employees including, but not limited to, visiting health professionals, contractors, consultants and volunteers who propose to undertake, administrate, review and/or govern human research involving patients/participants and staff. All study personnel involved in the clinical study must operate within their scope of practice.

1.3 Procedure

9.1 Informed Consent Process

- In obtaining and documenting Informed Consent, all persons involved in the research must comply with the National Statement Chapter 2.2, the National Clinical Trials Governance Framework (including the Roles and Functions of Identified Positions) and applicable regulatory requirements, and adhere to ICH GCP R2 and to the ethical principles that have their origin in the Declaration of Helsinki.

Informed consent is a process of information exchange that culminates in a potential trial participant (or their legally acceptable representative) confirming willingness to participate, and to continue to participate, in a study.

For clinical trials, consent is documented using a written, signed and dated Participant Information and Consent Form (PICF).

A person's decision to take part in a trial must be voluntary and based on sufficient information and adequate understanding of both the proposed research and the implications of participation, including the risks and potential benefits of (and alternatives to) taking part.

Consent must be obtained before the first study-specific procedure or intervention is undertaken.

9.2 Establishing the Informed Consent Process

- The Principal Investigator (PI) for any research project retains overall responsibility for ensuring a participant's consent has been obtained in the correct manner prior to the participant's entry into the project. This includes where consent is obtained from participants at Satellite Sites under the responsibility of the PI. However, at their discretion, the PI can delegate the duty for obtaining consent to a suitably qualified Associate Investigator as described in *SOP 02 Investigator Responsibilities*, *SOP 03 Site Staff Qualifications, Training Records and Capability*, and the National Clinical Trials Governance Framework. Delegation of all activities must be recorded in a Delegation Log or similar. The PI remains responsible for any delegated activity.
- The Investigator must ensure that they have the relevant Research Governance approval, inclusive of approval by an appropriate HREC, for all written information and any other media used to provide information to potential participants, before these forms, information or other materials may be used to obtain consent from any participant.
- When changes have been made to approved Participant Information resources the Investigator must have the relevant HREC's written approval (and if needed the written authorisation from the local RGO) before these may be used to obtain consent or continued consent from any participant.

9.3 Process for Obtaining Informed Consent

- If a participant expresses interest in participating in a research study, the PI or delegate must ensure that the potential participant has a copy of the current version of the HREC approved Participant Information and other approved media. This can be provided in person, by telehealth or by telephone and email or weblink.
- Potential participants, or their legally acceptable representative, should be given adequate time to read any information or to watch any approved media 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 any meeting with the PI/delegate.
- Whilst delegates such as Study Coordinators/Nurses or other appropriately qualified person may initiate the process of recruitment, and provide guidance around the written information and media, all medical questions must be answered only by Medical and Dental qualified persons working within their scope of practice and appropriate to oversee the use of an unregistered medicine.
- The PI or delegate must assess the potential participant's understanding of what they are agreeing to, that they are aware of the purpose of the study, what will be involved and any risks that may exist. The participants must demonstrate that they fully understand the implications of decisions that may be made within the course of the research.
- After all questions are satisfactorily answered, potential participants who wish to participate in the research will provide a record of their agreement either through physically signing a paper copy of the consent form or electronically signing a consent form using an approved format that accurately documents the time, date and authenticity of their signature. The PI/delegate will countersign and date that the consent process has occurred. Ideally this will be done contemporaneously; however, under special circumstances related

to the nature of the study the HREC may approve this signature to occur at a later time with appropriate documentation.

- 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 translation of the Participant Information provided (see also ICH GCP Section 4.8.9). If a witness is required, the witness should sign and personally date the witness section of the consent forms.
- Once all parties have signed the Informed Consent documentation, the participant will receive a copy of this and all other written information and media provided to the participant that were used as part of the consent process. A copy of the signed consent documentation must be placed in the participant's medical record to indicate that person is participating in research as part of their medical care.
- Participants may withdraw their consent at any time without giving a reason.

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 trial has started. The PI or delegate must contact the HREC to obtain ethical approval for these changes and to discuss the need, or immediacy of need, to inform existing participants.
- 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/participants be recontacted immediately. There are potential implications for blinding of any studies and care must be taken when developing the process for recontact. If approved by the HREC, continued consent may be obtained verbally and recorded in the participant's medical records and Source Documents.
- Where there is an amendment to the PICF, this should be signed by the participant as confirmation of their willingness to continue in the trial. This must be recorded and kept in the medical records and the ISF.

Where the person giving consent is unable to read, is physically unable to sign or mark the document, or where a translator is being used for non-English speaking participants, they may give their consent orally in the presence of an impartial witness (i.e. someone not involved in the conduct of the trial). The witness signs and personally dates the consent form to attest that the information in the PICF was read and explained to the participant or legal representative and that consent was freely given.

In cases where translation is required, a professional interpreter should be accessed to facilitate the process.

Some participants (such as minors, or patients/participants with severe dementia), can only be enrolled in a clinical trial with the consent of a legally acceptable representative or guardian.

The PICF provided to participants should be revised if important new information becomes available that may impact on the participants' continued consent. Participants may withdraw their consent at any time without giving a reason. Participants should be contacted for

continued consent promptly to confirm their willingness to continue in the trial. If approved by an ethics committee, the re-consent may be obtained by telephone.

9.4 Research Involving Participants who are Unable to Give Consent

- The Investigator must ensure that the National Statement, Chapter 2.2 and ICH GCP E6 (R2) 4.8.15 are complied with, and the following is taken into consideration:
  - The Declaration of Helsinki states that research involving participants who are physically or mentally incapable of giving consent, for example, unconscious patients/participants, may be done only if the physical or mental condition that prevents giving Informed Consent is a necessary characteristic of the research group. In other words, in these cases, the study must be relevant to the physical or mental condition of the participant that prevents them from being able to consent to participate in the study.
  - Where an adult is unable to give consent to participate in a study, once the Investigator has received HREC approval, and if there is an option to do so under the relevant legislation, the Investigator may apply under the relevant jurisdictional Act to obtain consent for the adult to participate in research that involves a 'medical research procedure' or 'experimental health care' – provided the relevant legislated criteria apply.

If Informed Consent is obtained by telephone, this must be recorded on the Informed Consent form and in the participant's health and medical record, and/or Source Document, stating (as an example): "The protocol was discussed with [participant's name] via telephone on [DD/MMM/YYYY]."

Telehealth

- E-consent may be the preferable option for teletrials, as consent signatures can be obtained contemporaneously at both Primary and Satellite Sites.
- If Informed Consent is obtained by telehealth consultation, all persons who are not known to each other must produce identification to the other person to ensure verification of each person's identity and to confirm the identity of the participant who is giving valid consent.
- A description of how study procedures, visits, assessments, collection of data and medical consultations will be undertaken e.g. they may be conducted in person or via telehealth or a combination of both, are to be clearly detailed in the HREC application and the PICF and clearly described to the participant during the consent process.
- With telehealth, all measures will be taken to ensure privacy and confidentiality of the participant's identity.
- If Informed Consent is obtained by telephone, this must be recorded on the Informed Consent Form and in the participant's health and medical record, and/or Source Document. The Investigator must then sign the Consent Form on the date they received the Consent Form, NOT the date they obtained consent from the participant.

9.5 Informed Consent Documentation

Ensure the essential elements are present as described in the National Statement, Chapter 2.2 and ICH GCP E6 (R2) Section 4.8.10.

- The Master PICF is supplied by the Sponsor. Any necessary national or local adaptation will be made as required for submission to the reviewing HREC.
- Once the PICF is signed and dated by both participant and the Investigator, the original PICF is kept in the participant's health and medical record and a copy is given to the participant.
- Storage of Informed Consent documents may be at the Satellite Site, at the Primary Site or at both sites (refer to *SOP 07 The Study Master File*).
- Where consent has been obtained by telehealth or telephone, once the PICF is signed and dated by both the participant and the Investigator (and any other person present for example an interpreter), the participant is to tick the statement identifying that consent was obtained by telehealth or telephone with the name of the Investigator. Similarly, the Investigator is to tick the statement identifying that consent was obtained by telehealth or telephone with the name of the participant. The participant's original PICF is kept in the participant's health and medical record (electronic or paper), a copy is given to the participant and:
  - where paper records are kept, a certified copy of the participant's signed and dated PICF is sent to the Primary Site for filing in the participant's health and medical record with the Investigator's signed and dated original. The Investigator is to add the date the participant's PICF was received.
  - where electronic records are kept, both signed PICFs are uploaded into the participant's electronic medical record and a certified copy of the PICF is not required.
  - If the participant requests a copy of the PICF with the Investigator's signature, obtain a copy of the Investigator's signed PICF and give to the participant.

A HREC may approve a Master PICF amended with preapproved local adaptations such as:

- Involvement in this study may require the Investigators to access records involving instances where I have been transported by ambulance. These records may include information relevant to the safety and efficacy of the study material and may help improve the scientific findings. The Investigator warrants that they will treat the information with the strictest confidence and abide by all relevant privacy policies and legislation.
- By signing this consent form, I give permission for the study Investigator to obtain information from the following:

– ambulance transportation

– any admission to any hospital

– Emergency Department visits

– stays in an observation unit

– information from my local doctor

– for the term of the study period.

The information collected from these places/persons will only be requested if it is required for this study and will only be used for the purpose of this study.

- The appropriate pre-approved wording relating to the use of contraception where a site has a specific requirement.

Pre-approved statements that may be added to the PICF where consent is obtained by telehealth/telephone include the following examples:

- Consent was obtained using telehealth with “Name of Investigator”, whose identification was sighted by the participant who observed the Investigator’s signature being written.
- Consent was obtained using telehealth with “Name of participant”, whose identification was sighted by the Investigator who observed the participant’s signature being written.
- Consent was obtained via telephone with “Name of Investigator”, on [DD/MMM/YYYY]
- Consent was obtained via telephone with “Name of participant”, on [DD/MMM/YYYY].
- Participant’s signed consent form received by the Investigator on [DDMMMYYYY].
- Discussed with [participant] via telephone on [insert date] and received signed consent form on [insert date]. Signed by [Investigator].

Glossary

TERM	DESCRIPTION
ADE	Adverse Device Effect
ADR	Adverse Drug Reaction
AE	Adverse Event
AHPRA	Australian Health Practitioner Regulation Agency
AI	Associate Investigator
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
ARPANSA Code of Practice	ARPANSA Code of Practice for the Exposure of Humans to Ionizing Radiation for Research
CAPA	Corrective and Preventative Actions
CASA	Civil Aviation Safety Authority
CIOMS	Council for International Organizations of Medical Sciences
CPI	Coordinating Principal Investigator
CRA	Clinical Research Associate
CRC	Clinical Research Coordinator
CRF	Case Report Form
CRO	Contract Research Organisation
CTA	Clinical Trial Approval scheme (previously Clinical Trials Exemption (CTX) scheme)
CTN	Clinical Trial Notification scheme
CTPRG	Clinical Trials Project Reference Group
CTRA	Clinical Trial Research Agreement
CV	Curriculum Vitae
DSMB	Data and Safety Monitoring Board
EMR	Electronic Medical Record
GCP	Good Clinical Practice
HHS	Hospital and Health Service
HREC	Human Research Ethics Committee
IATA	International Air Transport Association

ICH	International Council for Harmonisation of Technical Requirements of Pharmaceuticals for Human Use
IP	Investigational Product
IMD	Investigational Medicinal Device
IMP	Investigational Medicinal Product
IVRS	Interactive Voice Response System
IWRS	Interactive Web Response System
National Statement	National Statement on Ethical Conduct in Human Research (NHMRC)
NHMRC	National Health and Medical Research Council
NMA	National Mutual Acceptance
PI	Principal Investigator
PICF	Participant Information and Consent Form
PMS	Post Registration or Marketing Surveillance Study
RGO	Research Governance Officer
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
SMF	Study Master File
SSA Form	Site Specific Assessment Form
SSI	Significant Safety Issue
SSSF	Satellite Site Study File
SUSAR	Suspected Unexpected Serious Adverse Reaction
TGA	Therapeutic Goods Administration
UR	Unit Record
USADE	Unanticipated Serious Adverse Device Event
USM	Urgent Safety Measure

○ Revision Chronology

Document History			
Version	**Effective Date**	**Summary of Changes**	**Author**
1.0	*13/11/2025*	Initial Version	Katie Ozdowska