CHAPTER TWO: GLOSSARY of the AUSTRALIAN ICH GCP (Including Teletrials) SOPs

Introduction

This Glossary forms Chapter Two of the AUSTRALIAN ICH GCP (Including Teletrials) Standard Operating Procedures (SOP) Compendium. Please refer to terms in this glossary when reading the SOPs and other chapters in this compendium.

For the intent and purpose of all SOPs in this compendium:

- the term clinical research site is synonymous with clinical study site, clinical trial site and investigational study site. This includes sites acting as a primary site or a satellite site where the teletrial model using telehealth is used
- the term trial is interchangeable with study, research, project, protocol, clinical research trial, clinical research study and clinical research project
- the term clinical research coordinator is synonymous with research nurse, study coordinator, clinical study coordinator and clinical research nurse
- the term hospital and health service is synonymous with local health district or other terminology used by different Australian states and jurisdictions
- the term independent third party provider is interchangeable with the term external service provider
- words in the singular include the plural and vice versa
- these SOPs do not cover Phase IV Post Marketing Surveillance Studies. (For Investigator Initiated Trials, local policies and procedures may be adopted; but the requirements and principles for safe and ethical conduct of these studies may be similar to that are outlined in this compendium).

By adhering to these SOPs we are striving to ensure consistency and clarity across the state. Consequently, if there are any inconsistencies, OR should an acronym be used in this Compendium which is not found in this glossary OR should a term be used which is not clear and requires a clarification please inform the Health Innovation, Investment and Research Office (HIIRO) on hiiro@health.qld.gov.au with the acronym OR the term and in which SOP/s it is used in the subject title. HIIRO will then rectify the omission/clarification in order maintain a quality compendium for all stakeholders.

Thank you for your vigilance.

Queensland Clinical Trials Coordination Unit (QCTCU)
Health Innovation Investment and Research Office (HIIRO)
Office of the Director-General (ODG)
Queensland Department of Health
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LIST OF TERMS AND ACRONYMS

Appropriately Qualified Persons

Persons qualified by professional qualifications, currently registered to practice in this field and operating within the delegated persons Professional Scope of Practice (eg Pharmacist, Nurse Practitioner or Doctor for dispensing of study medication and Doctor or Registered / Endorsed Enrolled Nurses for administration of study medication, OR holding a current "Biological Substances, Category B and/or Dangerous Goods" certificate in order to ship those substances).

Adverse Device Effect (ADE)

Adverse event related to the use of an investigational medical device.

Note: *This definition includes adverse events resulting from insufficient or inadequate Instructions for Use, deployment, implantation, installation, or operation, or any malfunction of the investigational medical device. This definition includes any event resulting from use error or from intentional misuse of the investigational medical device*.

Adverse Drug Reaction (ADR)

Any untoward and unintended response to an investigational medicinal product or device related to any dose administered. All adverse events judged by either the reporting investigator or the sponsor as having a **reasonable possibility of a causal relationship** to an investigational medicinal product or device, would qualify as adverse reactions. The expression "reasonable possibility of a causal relationship" means to convey in general that there is evidence or argument to suggest a causal relationship.

Adverse Event (AE)

Any untoward medical occurrence in a participant administered an investigational medicinal product or device and which does not necessarily have a causal relationship with this treatment. An adverse event can therefore be any unfavourable and unintended sign (for example, an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product or device, whether or not considered related to this medicinal product or device.

Associate Investigator (see Investigator)

Australian Health Practitioner Regulation Agency (AHPRA)

The Australian Health Practitioner Regulation Agency (AHPRA) is the organisation responsible for the registration and accreditation of ten health professions across Australia.

Biological Substances, Category B

An infectious substance which does not meet the criteria for inclusion in Category A. Most human or animal material ('patient specimens') including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluids, and body parts, being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention are considered Biological Substances, Category B.

Civil Aviation Safety Authority (CASA) Training

Part 92 of the Civil Aviation Safety Regulation (CASR) prescribes the minimum safety requirements for the consignment and carriage of dangerous goods by air. It includes training, documentation, record keeping and incident reporting as well as provisions for packaging, marking, labelling, loading of and stowage in aircraft. Staff involved in the preparation, safe handling and carriage of dangerous goods on aircraft, are required to undertake CASR Part 92 training

Case Report Form (CRF and e-CRF)

A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the study sponsor on each trial participant.

Certified Copy

A copy (irrespective of the type of media used) of the original record that has been verified (i.e. by a dated signature or by generation through a validated process) to have the same information, including data that describe the context, content, and structure, as the original.

Clinical Research Coordinator (CRC)

A research worker who works at a clinical research site under the immediate direction of a Principal Investigator, whose research activities are conducted in accordance with Good Clinical Practice guidelines. May also be called "Clinical Study Coordinator" or "Research Coordinator" or "Research Nurse".
Where Teletrials is engaged, the CRC at the primary site is the contact for coordinators at both primary and satellite sites. Their duties are extended to include satellite sites in all aspects of their role (these roles can be delegated to satellite site coordinators).

Clinical Trial/Study

Any investigation in humans intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product, and/or to identify any adverse reactions to an investigational product, and/or to study absorption, distribution, metabolism, and excretion of an investigational product with the object of ascertaining its safety and/or efficacy.

Clinical Trial Agreement (CTA)

A legally binding agreement that manages the relationship between sponsor and institution where the sponsor may be providing the study drug or device, the financial support and /or proprietary information and the institution may be providing data and/or results, publication, input into further intellectual property. The agreement covers matters such as confidentiality, intellectual property, ownership of data, insurance and indemnity.

Clinical Trial Sub-contract

A legally binding agreement that manages the relationship between the principal site and the satellite site where the satellite site is a separate legally entity to the principal site.

Clinical Trials Notification (CTN)

The CTN scheme is an online notification scheme run under the Therapeutic Goods Act, 1989 whereby information relating to a proposed clinical trial is submitted directly to the Therapeutic Goods Administration (TGA) by the Sponsor. Once a trial is notified to the TGA and the relevant fee has been paid, the sponsor can supply the "unapproved" therapeutic goods to be used in the trial. The institutions where the clinical trial will be undertaken are also documented on the CTN. As it is a notification scheme, the TGA does not review any data relating to the clinical trial.
CTN trials cannot commence until the trial has been notified to the TGA, the appropriate notification fee paid and acknowledgement is received.

Clinical Trials Exemption (CTX)

An *approval* process whereby a sponsor submits an application to the TGA for evaluation and comment requesting to administer an investigational agent to participants under specified conditions of a particular research study in a clinical setting such as in clinical trials.

A sponsor cannot commence a CTX trial until written advice has been received from the TGA regarding the application and approval for the conduct of the trial has been obtained from an ethics committee and authorisation from the institution at which the trial will be conducted.

Clinical Research Organisation / Contract Research Organisation (CRO)

A person or an organisation (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions

Cluster

A group of sites involved in undertaking the same study, consisting of a Primary Site who assumes overall responsibility for the conduct of the same study and one or more Satellite Sites, which conduct the study under the direction of the primary site using tele-health. A cluster can be made up of sites in the same Hospital Health Service or across different HHSs.

Co-Investigator (see Investigator)

Co-ordinating Investigator (see Investigator)

Co-ordinating Principal Investigator (see Investigator)

Curriculum Vitae (CV)

A summary of professional experience and educational background, along with other relevant information regarding the candidate's qualifications and may include publications and personal interests.

Dangerous Goods

Articles or substances which are capable of posing a risk to health, safety, property or the environment and which are shown in the list of dangerous goods in the International Air Transport Association (IATA) Regulations or which are classified according to the IATA Regulations as such.

Data and Safety Monitoring Boards (DSMB), or Independent Data-Monitoring Committee (IDMC) or (Monitoring Committee, Data Monitoring Committee)

An independent data-monitoring committee that may be established by the sponsor to assess at intervals the progress of a clinical trial, the safety data, and the critical efficacy endpoints, and to recommend to the sponsor whether to continue, modify, or stop a trial.

Delegate

A person delegated specific tasks in relation to the conduct of a clinical trial. Tasks must be appropriate to qualifications and levels of training.

Delegation Log

A list of appropriately qualified and trained persons to whom the Principal Investigator has delegated significant study – related duties and which documents study-specific roles and responsibilities assigned to each staff member on the study team. Each entry is signed and dated by the delegates and countersigned by the PI.

Device Deficiencies

Inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety or performance.
Note: *Device deficiencies include malfunctions, use errors, and inadequate labelling.*

Essential Documents

Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor and monitor with the standards of Good Clinical Practice (GCP) and with all applicable regulatory requirements. They may be subject to, and should be available for, audit by the sponsor's auditor and inspection by the regulatory authority(ies).

Essential documents for the trial should be supplemented or may be reduced where justified (in advance of study initiation) based on the importance and relevance of the specific documents to the study.

External Service provider (see Independent Third Party Provider)

Good Clinical Practice (GCP) ICH GCP E6 (R2)

An international ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that involve participation of humans. GCP provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial participants are protected.
Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

Hospital and Health Service (HHS)

Independent statutory bodies which are responsible for delivering public health services within each state and jurisdiction. In Queensland, each HHS is established under section 17 of the *Hospital and Health Boards Act 2011 (Qld)* and managed by a Health Service Chief Executive.

Human Research Ethics Committee (HREC)

A committee registered by the NHMRC and constituted under the guidance of the NHMRC National Statement on the Ethical Conduct in Human Research 2007 (Updated 2018) which reviews all research proposals involving human participants, and is responsible for assessing the scientific validity of the trial design, the safety and efficacy of the medicine or device and the ethical acceptability of the trial process, and grants approval of the trial protocol in accordance with relevant standards and national guidelines

Independent Third Party Provider

An individual or group of individuals contracted by and external to a clinical trial site to provide a service related to a clinical trial, who is/are qualified to perform those trial-related duties and functions. The individual or group of individuals provide the service under supervision of the Principal Investigator who ensures the integrity of the trial-related duties and functions performed and any data generated by them.

Informed Consent

A process by which a participant 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 participant's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.

Institution

Any public or private entity or agency or medical or dental facility where research/clinical trials are conducted. In Queensland Health, an institution is any QH facility which provides patient care. In other jurisdictions, this may have a different meaning.

Insurer

The insurer for the QH institution and personnel employed by QH, is Queensland Government Insurance Fund (QGIF).

International Air Transport Association (IATA)

An international organisation that develops the commercial standards globally, for the air transport system.

Interactive Voice Response System (IVRS)

Interactive Voice Response System is an interactive technology that allows a computer to interact with a human to detect voice and keypad inputs.

Interactive Web Response System (IWRS)

Interactive Web Response System is an interactive technology that allows a computer to interact with a human through data input using a web browser

International Council for Harmonisation (ICH)

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Registration of Pharmaceuticals for Human Use is a joint initiative involving both regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration. Conceived in 1990, ICH has gradually evolved, to respond to the

increasingly global face of drug development. ICH's mission is to achieve greater harmonisation worldwide to ensure that safe, effective, and high-quality medicines are developed and registered in the most resource-efficient manner.

International Organisation for Standardisation (ISO)14155:2011 Clinical Investigation of Medical Devices for Human Subjects

The international standard which addresses good clinical practice for the design, conduct, recording and reporting of clinical investigations carried out in human subjects to assess the safety or performance of medical devices for regulatory purposes.

Investigational Medical Device (IMD)

Medical device is any instrument, apparatus, implement, machine, appliance, implant, software, material or other similar or related article that is being assessed for safety or performance in a clinical investigation.

Note: *This includes medical devices already on the market that are being evaluated for new intended uses, new populations, new materials or design changes.*

Investigational Medicinal Product (IMP)

A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication or a new patient group, or when used to gain further information about an approved use.

Investigational Product

Investigational Medical Device or Investigational Medicinal Product.

Investigator

An individual responsible for the conduct of a clinical research study at a study site and ensures that the study complies with ICH GCP E6 (R2) guidelines. An investigator can be either a coordinating investigator, principal investigator or a sub-investigator.

- **Coordinating Principal investigator (CPI)**
  The health professional, whether or not they are an investigator at any particular site, who is assigned the responsibility for the conduct of the study and coordination of investigators at different sites participating in a multicentre trial, including coordination

of all Human Research Ethics Committee (HREC) processes throughout the study, on behalf of the individual primary and / or satellite site investigators.

- **Principal Investigator (PI)**

Assumes overall responsibility for supervising any individual or person to whom they delegate study-related duties and functions conducted at the study site.

Where the teletrial model is implemented:

- the Principal Investigator (PI) at the primary site is the contact for Sub-Investigator/Associate Investigator/ Co-Investigator
  - at both Primary and Satellite Sites and the primary contact with the Sponsor.
  - The PI provides oversight to the Satellite Site/s and their duties are extended to include Satellite Sites in all aspects of their role.
  - The PI evaluates the team's performance and is able to select the research team, including changing the research team as required.

- **Sub-Investigator (SI)/Associate Investigator(AI)/ Co-Investigator (CI)**
  - These terms are interchangeable
  - The SI ensures the study complies with GCP guidelines at their site and can be situated in either a primary site or a satellite site.
  - The SI, when located at the satellite site, will be the local contact for study related matters at the satellite site and will be under the supervision of the PI.
  - The SI, when located at the primary site, may be delegated some or all of the study related responsibilities by the PI according to their level of experience.

Investigator Brochure (IB)

- **Medicine**: A compilation of the clinical and non-clinical data on the investigational product that is relevant to the study of the product in human participants. For marketed products it may be acceptable to use the Product Information.
- **Device**: A compilation of the current clinical and non-clinical information on the investigational medical device relevant to the clinical investigation.

Investigator Initiated Study (IIS)

Research studies initiated and managed by non- commercial company researchers, such as individual investigators, institutions, collaborative study groups or cooperative groups. The researcher, or researcher's institution, is responsible for the legal and regulatory responsibilities of the trial sponsor for the conduct and management of the study as defined by all applicable laws and regulations.

Monitoring Plan

A document, developed by the sponsor that is tailored to the specific human subject protection and data integrity risks of the trial. The plan should describe the monitoring strategy, the monitoring responsibilities of all the parties involved, the various monitoring methods to be used, and the rationale for their use. The plan should also emphasize the monitoring of critical data and processes. Particular attention should be given to those aspects that are not routine clinical practice and that require additional training. The monitoring plan should reference the applicable policies and procedures.

National Mutual Acceptance (NMA)

In 2013, the Queensland Victorian, South Australian Departments of Health and, and the New South Wales Ministry of Health signed a Memorandum of Understanding (MOU) for the National Mutual Acceptance (NMA) of ethics and scientific review of clinical trials conducted in each of the participating jurisdictions' public health organisations. In December 2015, the scope of NMA was expanded beyond clinical trials to include all human research. In August 2016, the Australian Capital Territory joined the NMA and Western Australia joined in August 2017.

In order for ethics reviews of human research to be accepted under NMA, the HREC conducting the review must be under the authority of an institution certified under the NHMRC National Certification Scheme, and also be a Certified Reviewing HREC under the NMA scheme.

Participant Identification Log

A list of all participants screened and/ or recruited to a clinical trial which includes full name and contact details and hospital specific medical record number.

Post Registration or Marketing Surveillance Study (PMS)

The term "post-marketing surveillance (PMS) study" implies a scientifically rigorous study of a product that is approved for registration in Australia designed to produce reliable information about drug safety.
PMS studies are generally performed on the initiative of the sponsoring company, but may be suggested or requested by other parties. They should generally be designed to address a specific drug safety question or hypothesis (the latter often identified initially by voluntary reporting).

Primary Site

The purpose of the Primary Site is to support trial accessibility across a number of trial sites. The Principal Investigator provides oversight and has ultimate responsibility for the trial and any related Satellite Sites.

Protocol

A document that describes the objective(s), design, methodology, statistical considerations, and organisation of a trial.

Protocol Deviation

Any breach, divergence or departure from the requirements of Good Clinical Practice or the clinical trial protocol. Minor protocol deviations which do not carry significant ethical / administrative implications or consequences do not need to be reported to the HREC. However, all such deviations must be recorded in the study file and reported to the sponsor.

Protocol Violation

A protocol violation is any change, divergence, or departure from the study design or procedures of a research protocol that affects the participant's rights, safety, or wellbeing and/or the completeness, accuracy and reliability of the study data. Also Called a Serious Breach A breach of Good Clinical Practice or the protocol that is likely to affect to a significant degree:
a) The safety or rights of a trial participant, or
b) The reliability and robustness of the data generated in the clinical trial.
Note: this guidance's definition of serious breach differs from the definition in the Australian Code for the Responsible Conduct of Research and is about deviations from the requirements of
Good Clinical Practice or the clinical trials protocol

Public Health Act 2005 (application) (PHA)

The process for accessing, without patient or statutory Health Attorney consent, identifiable or potentially re-identifiable confidential health information, held by Queensland Health for approved research projects. Applications are required for the release of confidential information for the purposes of research under Section 280 of the *Public Health Act 2005* must include:

- Copy of approval letter from a HREC
- Evidence of authorisation from the relevant Queensland Health data custodians.

Queensland Civil and Administrative Tribunal (QCAT)

An independent Queensland Government tribunal established under the Guardianship and Administration Act 2000 to appoint decision makers to protect the rights of adults with impaired decision-making capacity. Impaired decision-making capacity can be as a result of an intellectual or psychiatric disability, an acquired brain injury, an illness such as dementia or a combination of these.

Queensland Government Insurance Fund (QGIF)

A part of Queensland Treasury and is the insurer of Queensland Government agencies, including Queensland Health.

Queensland Health Research Governance Office(r) (QH RGO) Standard Operating Procedures (SOPs)

A set of SOPs approved by Queensland Health for use by RGOs in Queensland Health sites undertaking research.

Queensland Health Research User Guide (QH RUG)

A guidance document providing information on how to obtain authorisation to commence a research project within or in association with Queensland Health.

Research Governance Office(r)

The Office or coordinated function within a Public Health Organisation which is responsible for assessing the site-specific aspects of research applications, making a recommendation to the Hospital and Health Service CEO / delegate as to whether a research project should be granted authorisation at that site, and overseeing that authorised research at the site meets appropriate standards (research governance).

Safety Monitoring Plan

A description of the methods, roles and responsibilities and requirements for monitoring the safety data of the trial

Satellite Site

A Satellite Site is located in a geographically separate health facility and responsibility is delegated by the Primary Site (clinical trial site) to perform activities associated with the conduct of a clinical trial and to support trial accessibility of remote participants to a clinical trial. Satellite Sites can be located in metropolitan, regional or rural settings. Delegated activities to be performed by the Satellite Site are trial specific and should be agreed and documented at the time of site selection via a delegation log and a supervision plan.

For each trial, infrastructure and training requirements for Satellite Sites are the same for both the Primary and Satellite sites.

A satellite site should have the following:

- Appropriately contracted qualified and trained investigator(s) and delegated staff to undertake trial related activities including obtaining informed consent (if required). Study staff are trained in the protocol, IB, study procedures, Adverse Event (AE)/Serious Adverse Event (SAE) reporting. A system for safety reporting duties is in place for all study staff

- Study related documentation including a Satellite Site Study File, procedures for managing the security of information and trial data and a process for managing data security or privacy breeches.
- An understanding of the process for securely and suitably storing and ensuring accountability for the Clinical Trials Investigational Medicinal Product (CTIMP).

Satellite Site Study File (SSSF)

A folder containing all the Satellite Site study relevant documents generated during the course of the trial. The content of the Satellite Site study file can be decided with the study team and the sponsor. The SSSF may be a sub-set of the SMF and should be prefaced with an index of contents as well as indicate the location(s) of all essential /source documents.

Serious Adverse Device Effect (SADE)

An adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.

Serious Adverse Event (SAE) – drug

Any untoward medical occurrence that, at any dose:

a) results in death;
b) is life-threatening

***Note**: The term 'life-threatening' in the definition of 'serious' refers to an event in which the study participant was at risk of death at the time of the event; it does not refer to an event, which hypothetically might have caused death if it were more severe*.

c) requires in-patient hospitalisation or prolongation of existing hospitalisation;
d) results in persistent or significant disability/incapacity; or
e) is a congenital anomaly/birth defect; and fits the SAE criteria as specified in the relevant clinical trial protocol.

Medical and scientific judgment should be exercised in deciding whether an AE or ADR should be classified in other situations. Important medical events that may not be immediately life-threatening or result in death or hospitalisation but may jeopardise the participant or may require medical or surgical intervention to prevent one of the other outcomes listed in the above definition, should also be considered serious.

Serious Adverse Event (SAE) - device

Serious Adverse Event for medical devices: any adverse medical occurrence that:

a) lead to a death;

b) lead to a serious deterioration in health of a study participant user or other. This would include:
- a life-threatening illness or injury.
- a permanent impairment of body function or permanent damage to a body structure.
- a condition requiring hospitalisation or increased length of existing hospitalisation.
- a condition requiring unnecessary medical or surgical intervention
- foetal distress, foetal death or a congenital abnormality/birth defect

c) might have led to a death or a serious deterioration in health had suitable action or intervention not taken place. This includes:
- a malfunction of a device such that it must be modified or temporarily / permanently taken out of service.
- a factor (such as a deterioration in the characteristics or performance) found on examination of the device.

Serious Breach

A term in a subset to the term “deviation”. A breach of Good Clinical Practice or the protocol that is likely to affect to a significant degree:

a) The safety or rights of a trial participant, or

b) The reliability and robustness of the data generated in the clinical trial.

Note: *this guidance's definition of serious breach differs from the definition in the Australian Code for the Responsible Conduct of Research and is about deviations from the requirements of Good Clinical Practice or the clinical trials protocol*.

Significant Safety Issue (SSI)

A safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial.

Source Documents

Original documents (where the data was first recorded), data, and records (e.g. medical/hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial).The principles apply to all records referenced irrespective of the type of media used.

Sponsor

An individual, company, institution or organisation which takes on the responsibility for securing the arrangements, the initiation, management, and/or financing of a clinical trial. A sponsor should be designated for all clinical trials.

Standard Operating Procedure (SOP)

Detailed, written instructions to achieve uniformity of the performance of a specific function across an organisation.

Study Master File (SMF)

A folder containing all the study related Essential Documentation / Source Documents as defined by study team and in accordance with ICH GCP E6 (R2), section 8.2, 8.3 and 8.4 that should be established at the beginning of a trial at both the primary site and at the sponsor's office. The SMF should also be prefaced with an index of contents as well as indicate the location(s) of all Essential /Source documents. The storage system used during the trial and for archiving (irrespective of the type of media used) should provide for document identification, version history, search, and retrieval. The primary site should have control of all essential documents and records generated by the investigator / institution before, during, and after the trial.

Subject Identification Log

A list of all contact details for patients included in clinical trials plus hospital specific medical record number to be stored at the patient’s site used for future reference.

Substitute decision-maker

The person who is legally entitled to give consent to health care on behalf of a patient who lacks capacity. This may be a guardian, or attorney under an Advance Health Directive or Enduring Power of Attorney or Statutory Health Attorney.

Supervision Plan

A plan that outlines processes for a PI in the supervision of any individual or party to whom he/she delegates study-related duties and functions conducted at a study site, which includes, but is not limited to, details on joint consultations using telehealth, collation and monitoring of documents, frequency of joint trial meetings across a cluster (with minutes of these meetings) and clarification of activities performed by the PI and the SI, other study staff and independent third party ie external service providers. Clear delegation and supervision of roles documented in the supervision plan will be agreed with the team and the sponsor in advance to study start.

Suspected Unexpected Serious Adverse Reaction (SUSAR)

An adverse reaction that is both serious and unexpected and possibly, probably or likely related to the drug/device

Teletrial model

The conduct of clinical trials from a Primary site utilising telehealth communication to engage access to Satellite Sites, forming a clinical trials cluster in designated regions to enhance patient reach, recruitment and management.

Therapeutic Goods Administration (TGA)

Australia's regulatory agency for therapeutic goods.

Training Log

A record of all training relating to a specific clinical trial undertaken by a trial staff member who has been delegated clinical trial related duties. The record documents date, the training undertaken, who gave the training with a signature of both trainer and trainee and is kept current for the duration of the clinical trial.

Unanticipated Serious Adverse Device Effect (USADE)

Serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report

Note: Anticipated serious adverse device effect (ASADE) *is an effect which by its nature, incidence, severity or outcome has been identified in the risk analysis report and in the Investigator Brochure.*

Urgent Safety Measure (USM)

One type of significant safety issue where sponsors or trial investigators act immediately to protect participants from an immediate hazard to their health and safety. Consequently, USMs are often instigated before the TGA and HREC are notified. In these cases, it is strongly recommended that the sponsor contact the TGA within 24 hours of the measure being taken. If this initial contact is by telephone, it should be followed-up with a written notification provided by facsimile or e-mail within 72 hours.

Validation of Computerised Systems

A process of establishing and documenting that the computer systems used can be consistently fulfilled from design until decommissioning of the system or transition to a new system. The approach to validation should be based on risk assessment that takes into consideration the intended use of the system and the potential of the system to affect human participant