GVHealth	**TITLE:**	**Standard Operating Procedure (SOP) - Abbreviations and Terms**	
Document Type:	Procedure	**Approved by:**	CMO & EDMS
Directorate:	CMO & Medical Services	**Section:**	Research
Author/Prepared by:	Dr Ainsley Robinson	**Position:**	Clinical Trials Coordinator

DO NOT USE THIS STANDARD OPERATING PROCEDURE IN PRINTED FORM WITHOUT FIRST CHECKING IT IS THE LATEST VERSION.

The definitive versions of all Goulburn Valley Health (GVH) Clinical Trial Standard Operating Procedures (SOPs) appear online, not in printed form, to ensure that up to date versions are used. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the GVH website or Prompt.

Document Details

Document Title:	Abbreviations and Terms
Document ID:	GVHREU_CT-SOP-Abbreviations and Terms
Version Number:	2.0
Effective Date:	16 June 2023
Review Date:	16 June 2025

Document Approval

Name:	Dr John Elcock
Position:	Executive Director of Medical Services and Chief Medical Officer
Date:	16 June 2023

Amendment History

Version	Effective Date	Review Date	Author(s)	Amendment Details
1.0	12 Nov 2020	16 June 2023	Dr Ainsley Robinson Research and Ethics	Reviewed and updated to v2.0

GVHealth	**TITLE:**	**Standard Operating Procedure (SOP) - Abbreviations and Terms**	
Document Type:	Procedure	**Approved by:**	CMO & EDMS
Directorate:	CMO & Medical Services	**Section:**	Research
Author/Prepared by:	Dr Ainsley Robinson	**Position:**	Clinical Trials Coordinator

1. ABBREVIATIONS:

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	International, non-governmental, non-profit organisation representing the biomedical scientific community
Code	Code of Practice - Exposure of Humans to Ionizing Radiation for Research (2005) published by ARPANSA
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
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 for Registration of Pharmaceuticals for Human Use
IMD	Investigational Medical 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
SERP	Single Ethical Review Process
SI	Sub-Investigator
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

2. TERMS:

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)
In the Australian context, an adverse event (AE) is any unfavourable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. An adverse event is an incident that results, or could have resulted, in harm to a patient/participant or consumer. An unintended near miss is a type of adverse event.

Associate Investigator (AI)
Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions e.g. associates, residents, research fellows.

Where the teletrial model is implemented:

- the SI when located at a Primary Site may be delegated some or all of the study related responsibilities by the PI according to their level of experience
- the SI when located at the Satellite Site is the local contact for study related matters at the Satellite Site and will be under the supervision of the PI.

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.

Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)
The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) is the Australian Government's primary authority on radiation protection and nuclear safety. ARPANSA regulates Commonwealth entities using radiation with the objective of protecting people and the environment from the harmful effect of radiation.

Blue Card
An Adverse Reaction reporting form to report suspected adverse reactions to vaccines and prescription, over the counter and complementary medicines.

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 certified copy is a copy of an original document that has been verified to be a true copy by an authorised witness after they have sighted the original document.

CIOMS form
A form used to report Serious Adverse Reaction reports that occur in Australia and sent to the TGA.

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.

Clinical Research Associate (CRA)
An individual designated by a sponsor or Contract Research Organisation to monitor the sites conduct in a clinical trial.

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 Approval (CTA)
In the CTA scheme, the TGA has a direct role in the review of trial scientific data and must give an 'approval' for the proposed trial program to go ahead; however, HREC review is still required.

Clinical Trial Coordinator
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 "Trial 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 Research Agreement (CTRA)
Medicines Australia Standard form.

Clinical Trial Sub-contract
A legally binding agreement that manages the relationship between the Primary Site and the Satellite Site where the Satellite Site is a separate legally entity to the Primary site.

Clinical Trial 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.

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 Hospital Health Services.

Code of Practice for the Exposure of Humans to Ionising Radiation for Research Purposes (2005) ARPANSA (Code)
This Code of Practice is designed to ensure that researchers proposing to expose research participants to ionizing radiation provide the participants and the Human Research Ethics Committees with information that allows consent to be properly considered by the research participants and approval considered by the Human Research Ethics Committee.

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.

Contract Research Organisation (CRO)
An organisation contracted by the sponsor to oversee the conduct of the clinical trial.

Curriculum Vitae (CV)
A resume of academic and professional training, work history and other qualifications.

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 Board (DSMB), or Independent Data Monitoring Committee (IDMC) or Monitoring Committee or 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.

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 Principal Investigator.

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.

FDA 1572
A form that must be filed by an Investigator running a clinical trial to study a new drug or agent. The Investigator agrees to follow the United States Food and Drug Administration (FDA) Code of Federal Regulations for the clinical trial and verifies they have experience and background needed to conduct the trial. The Statement of Investigator, Form FDA 1572 (1572), is an agreement signed by the investigator to provide certain information to the sponsor and assure that he/she will comply with FDA regulations related to the conduct of a clinical investigation of an investigational drug or biologic.

Financial Disclosure Form (FDF)
A statement form in compliance with the U.S Code of Federal Regulations for which clinical investigators are required to disclose to the study sponsor their financial interests for the period of time they participated in the study and for one year following the end of the study.

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.

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.

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. These can be accessed via telephone. Users respond/provide their responses via touch-tone keypad of telephone. This system is used to proactively manage the key aspects of their clinical trials which includes enrolment/randomisation, dosing/drug dispensation, clinical supplies, drug inventory management and unblinding.

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. Users respond/provide their responses via the internet site. This system is used to proactively manage key aspects of their clinical trials which includes enrolment/randomisation, dosing/drug dispensation, clinical supplies, drug inventory management and unblinding.

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. 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 trial 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 Principal Investigator, Principal Investigator or an Associate Investigator.

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.

Institutional Review Board (IRB)
An independent ethics committee.

Monitoring
The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures (SOPs), GCP, and the applicable regulatory requirement(s).

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 emphasise 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 Health and Medical Research Council (NHMRC)
The Council established to develop and maintain health standards and is responsible for implementing the National Health and Medical Research Council Act 1992.

National Mutual Acceptance (NMA)
NMA provides the framework for single scientific and ethical review of multi-centre human research projects in publicly funded health organisations of participating jurisdictions.

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 a Certified Reviewing HREC under the NMA scheme. There will be some exceptions to single scientific and ethical review and details can be found on jurisdictional health websites.

Participant screening log
To document identification of participants who entered pre-trial screening.

Participant enrolment log
To document chronological enrolment of participants by trial number.

Participant identification list
To document that investigator/institution keeps a confidential list of names of all participants allocated to trial numbers on enrolling in the trial. Allows investigator/institution to reveal identity of any participant and to make future contact if required.

Participant Information and Consent Form (PICF)
The ethically approved document used for providing written patient information about a specific clinical trial and the documentation of Informed Consent in the form of the patient and the investigator signatures and date.

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 Primary Site coordinates the trial across a cluster to enhance patient reach, recruitment and management. The Principal Investigator located in the Primary Site has full responsibility of conducting the clinical trial under ICH GCP.

Principal Investigator
Takes responsibility at their own site for the conduct, management, monitoring and reporting of a research project. Where the teletrial model is implemented, the Principal Investigator at the Primary Site assumes overall responsibility and provides oversight to Satellite Site(s) within a cluster.

Protocol Deviation
A deviation is any breach, divergence or departure from the requirements of Good Clinical Practice (GCP) or the protocol that does not have a significant impact on the continued safety or rights of participants or the reliability and robustness of the data generated in the research project.
GCP requires all deviations to be reported to the trial sponsor.

Research Governance Officer (RGO)
The RGO is the individual appointed within an organisation who is responsible for the management of applications for site authorisation and administrative oversight of authorised research projects. Research Governance considers legal compliance, financial management, accountability and risk management associated with research at a participating site.

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 breaches.

An understanding of the process for securely and suitably storing and ensuring accountability for the Investigational Medicinal Product (IMP).

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 Study Master File (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:
- results in death;
- is life-threatening;
- requires inpatient hospitalisation or prolongation of existing hospitalisation;
- results in persistent or significant disability / capacity;
- is a congenital anomaly / birth defect.

Serious Adverse Event (SAE) – device
Serious Adverse Event for medical devices: any adverse medical occurrence that:
- lead to a death;
- 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.
- 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 breach of Good Clinical Practice (GCP) or the protocol that is likely to affect to a significant degree the safety or rights of a research participant or the reliability and robustness of the data generated in the research project. A serious breach must be notified to the reviewing Human Research Ethics Committee (HREC).

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. Source documents substantiate the existence of the participant and integrity of trial data collected.

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.

Study Master File (SMF) or Investigator Site File (ISF)
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 both at the Investigator / Institution's 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. Where the teletrial model is implemented the Primary Site should have control of all essential documents and records generated by the Investigator / Institution before, during, and after the trial.

Supervision Plan
A plan that outlines processes for a Principal Investigator 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 Sub Investigator, other study staff and independent third party i.e. 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
Teletrials are defined as follows: A teletrial uses TeleHealth technology to communicate between the Primary Site and Satellite site/s for all aspects of a clinical trial. This support a Principal Investigator to supervise Sub-Investigator/s to conduct a clinical trial at a Satellite Site geographically remote from the Principal Investigator's Primary Site. The Principle Investigator remains responsible for the trial. A detailed Supervision Plan is required, in addition to a Delegation Log required by ICH GCP. Trial participants may have trial visits at both the Primary and Satellite Sites, as determined by the protocol. The conduct of the trial is detailed under 'head agreement', being using a Clinical Trial Research Agreement/Clinical Trial Agreement between the Sponsor and the Principal Investigator's institution and a Sub-Agreement between the Primary Site and the Satellite Site institutions.

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 log 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.

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.

ABBREVIATIONS AND TERMS:

Please refer to GVH_CT-SOP-Abbreviations and Terms.

KEY ALIGNED DOCUMENTS:

GV Health Procedures:

- GVH_CT-SOP-03 Site Staff Qualifications, Training Records and Capability

REFERENCES:

Nil.

Contributors to the document

	Name	Position	Department
Document Owner:	Dr Ainsley Robinson	Clinical Trials Coordinator	Research and Ethics
Document Author:	Dr Ainsley Robinson	Clinical Trials Coordinator	Research and Ethics
Contributor:	Dr Md Rafiqul Islam	Director of Research	Research and Ethics
Committee:	Executive Committee – Safety, Quality & Performance		
	Dr John Elcock, Chief Medical Officer/ Executive Director, Medical Services		