Terms

Please refer to terms in this section when reading the National Standard Operating Procedures for Cancer Decentralised Clinical Trials (DCT), in New Zealand and other associated documents.

Adverse Drug Reaction (ADR)

Any untoward and unintended response to an Investigational Medicinal Product 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 New Zealand 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.

Clinical Trial (or Research) or Study Co-ordinator (CTC or CRC)

Any individual member of the clinical trial team designated and supervised by the Principal Investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions.

Their 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 the DCT Model is implemented:

- An CTC when located at a Primary Site may be delegated some or all of the study-related activities by the PI according to their level of experience and documented in the Delegation Log.
- An CTC 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 at the Primary Site.

Audit

An audit is a systematic and independent examination of trial activities to determine whether a trial is conducted in accordance with applicable requirements. This may be scheduled periodically at sites to confirm protocol compliance, adherence to GCP and regulatory requirements. Routine audits often involve an opening meeting and are conducted according to a pre-prepared plan, which may be revised based on initial findings as the audit proceeds. Audits normally include interviews with the trial team, supporting department staff and the research office, document review, and facility tours.

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. The data collected in the CRF is used as the basis of the trial report and any publications, as well as making up part of the data for regulatory approval for the unapproved therapeutic goods.

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

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

Clinical Trial Research Agreement (CTRA)
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 or input into further intellectual property. The agreement covers matters such as confidentiality, intellectual property, ownership of data, insurance, and indemnity. NZACRes has the recommended Standard form.

Clinical Trial Team
The clinical trial team includes individuals, identified by the Co-ordinating Investigator, who are responsible for study co-ordination, data collection and data management. Members of the clinical trial team may include: the research coordinator, study coordinator, research nurse, study nurse, the Co-ordinating Investigator, the Primary Investigator, the Sub-Investigator, and clinical trial pharmacist. They may have roles in the clinical trial as per the Delegation Log, including:

- Participant recruitment and enrolment
- Obtaining consent from prospective participants, meeting with research participants, and collect and record information from research participants
- Maintain consistent implementation of the protocol
- Data management, to ensure the integrity of data
- Dispensing and administering the Investigational Product
- Compliance with regulatory and reporting requirements.

Cluster
A group of sites involved in undertaking the same study, consisting of a Primary Site that 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. A cluster can be made up of sites in the same region or across different regions.

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.

Co-ordinating Investigator (CI)
In New Zealand, this term is used to describe the health professional, who is the Investigator at one of the Primary sites, who is assigned the responsibility for the conduct of the study and co-ordination of Investigators at different sites participating in a multicentre trial. This includes co-ordination of all Health and Disability Ethics Committees (HDEC) processes, such as the initial submission and any required notifications throughout the trial, on behalf of the individual Primary and/or Satellite Site Investigators.

Credentialing
Credentialing is the formal process used by a health service organisation to verify the qualifications, experience, professional standing, competencies and other relevant professional attributes of clinicians, so that the organisation can form a view about the clinician's competence, performance and professional suitability to provide safe, high-quality healthcare services within specific organisational environments.

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

Dangerous Goods
Articles or materials 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 (or the Institution acting as 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. The composition and operations of the IDMC must be approved as part of the ethical review process by a HDEC.

Decentralised Trials Compendium
Set of documents for DCT that includes National Standard Operating Procedures developed and approved through the Cancer National DCT Steering Committee of Aotearoa New Zealand intended to support nationally consistent and high-quality implementation of the Oncology DCT Model in New Zealand.

Decentralised Trials 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 legal entity to the Primary Site.

Delegation Log
A list of appropriately qualified and trained persons to whom the Co-ordinating Investigator has delegated significant study-related duties and functions. The Log details related duties and documents which study-specific roles and responsibilities are assigned to each staff member on the study team. Delegation Logs should be actively maintained (not constructed retrospectively) so there is evidence of appropriate delegation before any trial activities are undertaken. Each entry is signed and dated by the delegates and countersigned by the Principal Investigator.

Deviation
A deviation is any breach, divergence or departure from the ICH Good Clinical Practice (GCP), the approved Protocol, SOPs or applicable regulatory requirements 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 Investigator and trial Sponsor.

Essential Documents
Documents that 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.

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 clinical trial participants are protected.

Compliance with this standard provides public assurance that the rights, safety and well-being of trial participants are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data generated from the clinical trials are credible. These SOPs rely upon the carefully considered Clinical Trials Governance Framework which uses ICH GCP as an objective international minimum standard for clinical practice.

Health and Disability Ethics Committee (HDEC)
The Health and Disability Ethics Committees review research proposals involving human participants to ensure that they are ethically acceptable and in accordance with relevant standards and guidelines. As a general principle, research originating in a tertiary educational institution will normally be reviewed by an institutional ethics committee (IEC) within that institution. However, particular types of research proposals an IEC receives may also come into the scope of a Health and Disability Ethics Committee (HDEC), under section 11 of the New Zealand Public Health and Disability Act 2000. The Ministry of Health administers HDECs.

The function of an HDEC is to secure the benefits of health and disability research by checking that it meets or exceeds established ethical standards. An HDEC's scope of review is set out in its standard operating procedures (Health and Disability Ethics Committees 2018).

In addition, HDEC considers other guidance material including The Treaty of Waitangi and the standards. Three principles derived from the Treaty of Waitangi, rangatiratanga (partnership), whai wāhi (participation) and kaitiakitanga (protection) should inform the interface between Māori and research (Royal Commission on Social Policy 1988):

- rangatiratanga: researchers, iwi, hapū, whānau and Māori communities working together to ensure Māori individual and collective rights are respected and protected
- whai wahi: involving Māori in the design, governance, management, implementation and analysis of research, especially research involving Māori
- kaitiakitanga: actively protecting Māori individual and collective rights, Māori data, Māori culture, cultural concepts, values, norms, practices and language in the research process.

The Treaty partnership provides an opportunity to design together an advanced national health and disability research ethics platform that encompasses two world ethical views: that of western ethics and that of tikanga Māori (Māori ethics).
Other guidance material may also be referred to including, but not limited to: Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) and the Consolidated Standards of Reporting Trials (CONSORT).

HDECs also consider relevant national and jurisdictional legislation including guardianship legislation and the roles of civil and administrative tribunals for the participation of people without the capacity to provide consent. HDECs also monitor compliance with the approved Protocol during the conduct of the trial and provide advice on strategies to promote awareness of the ethical conduct of clinical trials and research more broadly.

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
Informed consent is a process of communication between a patient/participant and a clinician about options for treatment, care processes or potential outcomes. This communication results in the patient/participant's authorisation or agreement to undergo a specific intervention or participate in planned care. The communication should ensure that the patient/participant understands the care they will receive, all the available options, and the expected outcomes, including success rates and side effects for each option.

Informed Consent may be expressed orally, in writing, or by some other means depending on the nature, and complexity of the research, and the participant's personal and cultural circumstances.

Research is 'low risk' where the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk. The greater the risks to participants in any research for which ethical approval is given, the more certain it must be both that the risks will be managed as well as possible, and that the participants clearly understand the risks they are assuming.
Potential participants who wish to participate in 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.

Inspection
An official review of trial related activities by a regulatory authority that has rights conferred by regulation (e.g., to enter premises and to request documents) to determine whether a trial is conducted in accordance with applicable requirements. May be scheduled periodically at sites to confirm Protocol compliance and adherence to GCP and regulatory requirements. Regulatory inspections normally require more extensive planning and input from the organisation than routinely conducted trial audits.

Inspections often involve an opening meeting and are conducted according to a pre-prepared plan, which may be revised based on initial findings. Inspections normally include interviews with the trial team, supporting department staff and research office, document review, and facility tours.

Institutional Ethics Committee (IEC)
Research originating in a tertiary educational institution will normally be reviewed by an ethics committee within that institution. In New Zealand, ethics committees determine their own scope of review, based on the level of risk posed to participants in individual situations. The Health Research Council Ethics Committee has a formal approval process to review and monitor institutional ethics committees.

Institutional Review Board (IRB)
A term used to refer to an independent research ethics committee used in some countries, particularly the United States. In NZ, this term is not used. Each NZ hospital and university has its own institutional review committee – which usually includes a Māori research assessment. See also IEC and Locality Review/Authorisation

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 the touch-tone keypad of a telephone.

This system is used to proactively manage the key aspects of their clinical trials which includes enrolment/randomization, dosing/drug dispensation, clinical supplies, drug inventory management, and un-blinding.

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/randomization, dosing/drug dispensation, clinical supplies, drug inventory management and un-blinding.

International Air Transport Association (IATA)
An international organisation that develops the commercial standards globally, for the air transport system. In the context of this document, IATA sets the standards for training personnel in the packing and shipping of Dangerous Goods including Dry Ice, e.g. packing and shipping of biological samples in clinical trials.

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)
The ICH is a joint initiative involving both regulatory authorities and the pharmaceutical industry to discuss scientific and technical aspects of pharmaceuticals and develop ICH guidelines. Since its inception in 1990, ICH has gradually evolved, to respond to increasingly global developments in the pharmaceutical sector and the increasingly global face of drug development, and these ICH guidelines are applied by a growing number of regulatory authorities.

ICH's mission is to achieve greater harmonisation worldwide to ensure that safe, effective, and high-quality medicines are developed, registered, and maintained in the most resource-efficient manner whilst meeting high standards.

Harmonisation is achieved through the development of ICH Guidelines via a process of scientific consensus with regulatory and industry experts working side-by-side. Key to the success of this process is the commitment of the ICH regulators to implement the final Guidelines.

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 Brochure (IB)
A compilation of the clinical and non-clinical data available on the experimental products intended for use in the clinical trial in question. It provides trial organisers and staff with an understanding of the rationale of the trial, in order to inform their compliance with the Protocol requirements. The information enables a risk/benefit assessment of the appropriateness of the proposed trial, of vital importance to HDEC considerations.

Investigational Medicinal Device (IMD)
A 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 authorisation 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/participant group, or when used to gain further information about an approved use.

Investigational Product
The Investigational Product (IP) includes any product, or intervention being investigated, tested, or used as a placebo or reference point in a clinical trial. This includes 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 authorisation when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use. The Sponsor or their delegate, is responsible for the provision and maintenance of the IP.

Investigator
An individual engaged in 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 Investigator, Principal Investigator, a Co-Investigator or a Sub Investigator.

It should be noted that in ICH GCP the term Sub Investigator is used to refer to an individual member of the clinical trial site who is delegated to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, resident's research fellow).

The Cancer DCT Steering Committee, and in accordance with ICH-GCP, the Principal Investigator is the Investigator responsible for all aspects of the clinical trial at a site and within a cluster if relevant. A Co-Investigator cannot be responsible for trial conduct at a site but may be delegated duties according to expertise and scope of practice.

The term Coordinating Investigator (CI) is a term used in New Zealand in the to describe the Investigator responsible for coordinating the ethics application and related notifications associated with a trial, and so this role has been included in these SOPs.

Legally acceptable representative

For children and young people under the age of 16, consent may be given by a parent, guardian or other person acting in the place of a parent. Depending on the child's age, they will be involved as much as possible, and information will be given to them in a way that they can understand.

Consent for people who are incompetent may be given by their welfare guardian or a person who holds an enduring power of attorney in respect of personal care and welfare for that person. Where there is no person able to provide lawful consent for that person, a Court Order may be needed.

Locality Review/Authorisation

This is given by an individual appointed within an organisation who is responsible for the assessment of applications for site authorisation and who provides administrative oversight of authorised research projects. Locality authorisation focuses on locality-specific research governance issues, (such as locality-specific insurance and indemnity arrangements) and must be obtained before a study commences at that locality. This usually includes a local Māori research review. One locality review can cover multiple sites (for example hospitals or departments) within a single locality.

The granting of ethical approval by HDEC does not oblige an approving authority to grant authorisation at their site as the site may not have the capacity or capability to undertake the trial based on the Protocol requirements. As part of the process to confirm whether authorisation should be granted, the person who gives locality approval confirms the clinical trial has undergone HDEC review and received approval prior to commencement.

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 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 Ethical Standards
The National Ethical Standards are the principal ethical guideline setting out the requirements for the ethical design, review and conduct of human research in New Zealand (including clinical trials). It is authored by the National Ethics Advisory Committee (NEAC). Its full name is the National Advisory Committee on Health and Disability Support Services Ethics, and it is also known by its Māori name; Kāhui Matatika o te Motu, which translates as 'National Ethics Group'. This is a committee set up under New Zealand legislation to advise the Minister of Health on ethical issues in health services and research and determine national ethical standards for the health sector. NEAC issues guidelines that set out the ethical standards that must be met by researchers when they undertake health and disability research. These guidelines are also used by ethics committees that review research study proposals – they are responsible for checking that each study meets the ethical standards set out in NEAC's guidelines.
These ethics committees include those run by universities and the four statutory health and disability ethics committees that must follow the procedural rules (ethics.health.govt.nz) issued by the Ministry of Health. Unlike these ethic committees, NEAC does not have a role in considering or approving individual proposals for research.

New Zealand Radiation Safety Act 2016, Radiation Safety Regulations 2016, and Codes of Practice.
Section 21 of the Radiation Safety Act 2016 (the Act) requires a natural person to hold a use licence to use radiation sources. Training requirements in the relevant codes of practice issued under the Act set out the basic level of radiation safety knowledge an applicant must demonstrate to be granted a licence.
Use licences may be granted for the following medical purposes: medical diagnosis – including cardiology, nuclear medicine, endocrinology, sentinel node biopsy general practice; medical therapy – including ophthalmology, nuclear medicine, endocrinology and blood irradiation; other medical purposes – including research on humans, podiatric, chiropractic, and medical physics.

Participant
A participant is a clinical trial subject, patient/participant or consumer who is enrolled to participate in a clinical trial.

Participant screening log
A document used to record the identification of participants who entered pre-trial screening.

Participant enrolment log
A document used to record the chronological enrolment of participants by trial number.

Participant identification list
A confidential document that the Investigator/Institution keeps of the names of all trial participants linked to their corresponding unique clinical trials identifier code. It allows an Investigator/Institution to reveal the identity of any participant and to make future contact if required.

Participant Information and Consent Form (PICF)
The written information approved for use to provide information to potential participants and to record their decision to participate. The PICF must be approved by an HDEC prior to use.

Primary Site
Under the DCT Model, the Primary Site coordinates the trial across a cluster to enhance participant reach, recruitment, and management. The Principal Investigator located at the Primary Site has full responsibility for conducting the clinical trial at their site and any Satellite Site within their cluster under ICH GCP.

Principal Investigator
The Principal Investigator (PI) is the Investigator responsible for the conduct, management, monitoring and reporting of a trial at their own site. Where the DCT Model is implemented, the Principal Investigator at the Primary Site assumes overall responsibility and provides oversight to Satellite Site(s) within a cluster. Sub-Investigators at Satellite Site(s) operate under the direction and responsibility of the Principal Investigator at the Primary Site. The co-investigators at satellite sites can be delegated responsibility just as if they were based at the same site.

Protocol
A detailed clinical trial plan that includes the purpose and procedures of the research and who can be part of the trial. The Protocol provides the rationale, design, methodology for the trial conduct, who may participate in a trial, the length of a trial and the schedule of tests, procedures, medications and dosages, method of analysis, monitoring of data safety and quality. The Sponsor of the trial is responsible for the Protocol. The Protocol must be formally approved by the HDEC prior to trial commencement.

Protocol Amendment
A written description of a change(s) to or formal clarification of a Protocol. The Protocol amendment must be formally approved by an HDEC prior to being enacted, except where participant safety is threatened.

Risk Assessment
Risk assessment is the assessment, analysis, and management of risks. It involves recognising which events may lead to harm in the future and minimising their likelihood and consequence.

Risk Management
Risk management is the design and implementation of a program to identify and avoid or minimise risks to patients/participants, employees, volunteers, visitors, and the organisation.

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 trial activities are delegated by the Primary Site (clinical trial site) to the Satellite Site, to enable the performance of activities associated with the conduct of a clinical trial at the Satellite Site and to support trial accessibility of remote participants to a clinical trial.

A Satellite Site can be located in metropolitan, regional, or rural settings. Delegated activities to be performed by a Satellite Site are trial and Satellite Site specific. The Primary Site must consider a Satellite Site's personnel and facilities in developing a Delegation Log and Supervision Plan suitable for a trial. The proposed delegation of duties and Supervision Plan must be agreed at the time of site selection and must be documented before the study is initiated at each Satellite Site.

For each trial, infrastructure and training requirements 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 delegated trial-related activities including obtaining informed consent (if required). Study staff are trained in the Protocol, IB, study procedures and 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).

Scope of Clinical Practice
Scope of clinical practice is the extent of an individual clinician's approved clinical practice within a particular organisation, based on the clinician's skills, knowledge, performance and professional suitability, and the needs and service capability of the organisation.

Serious Adverse Event (SAE)
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
- results in or is associated with a congenital anomaly/birth defect.

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 HDEC.

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.

Standard Indemnity and Compensation Agreement for Clinical Trials in New Zealand Public Health Organisations (sICA)
This Guidance Document relates to the standard Indemnity and Compensation Agreement that is pre-approved for use in clinical trials that are sponsored by pharmaceutical and medical device companies and conducted in NZ public health organisations.

It applies to each clinical trial sponsored by a manufacturer of a pharmaceutical or medical device and conducted in NZ public health organisations. These must be covered by an Indemnity and Compensation Agreement between the site and the trial sponsor.

The sICA can be used by all NZ DHBs without modification to speed the process of approval of clinical trials and remove the need for a lengthy and difficult negotiation. The sICA has been developed for use in all industry-sponsored clinical trials that take place in NZ DHBs.

The sICA does not cover clinical trials that are:

- sponsored by collaborative clinical trial groups,
- are investigator-initiated; as compensation for injuries caused to participants as a result of their participation in these clinical trials is covered by NZ's statutory no-fault compensation scheme (*Injury Prevention, Rehabilitation, and Compensation Act 2001*).

Source Data
All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source Data are contained in Source Documents (original records or certified copies). Collection of accurate Source Data (contained in Source Documents) is essential for compliance with GCP.

The format used (whether paper or electronic) should permit the reconstruction of the clinical care given to the participant and describe any significant participant-related events that may occur during the conduct of the trial. Source Data should be attributable, legible, contemporaneous, original, accurate, and complete.

Source Documents
Original documents (where the Source 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 that takes responsibility for the initiation, management, and financing arrangements of the study.
An overseas pharmaceutical company wishing to market a medicine or related product in New Zealand needs to have a New Zealand-based subsidiary or appoint a local individual or company as a New Zealand agent to act for them in New Zealand as sponsor for the product concerned.

Each clinical trial sponsored by a manufacturer of a pharmaceutical or medical device and conducted in NZ public health organisations must be covered by an Indemnity and Compensation Agreement between the site and the trial sponsor.

The ultimate responsibility for the quality and integrity of the clinical trial data resides with the trial Sponsor. The trial Sponsor retains overall responsibility for all delegated functions in accordance with the Guideline for Good Clinical Practice and the International Organisation for Standardisation for trials under the CTN or CTA schemes. This also applies when a non-commercial trial Sponsor delegates activities to a Coordinating Principal Investigator, trial coordinating centre or clinical research organisation.
The Sponsor is also responsible for ensuring that appropriate approvals are obtained prior to the commencement of the clinical trial, that conditions of any approvals are adhered to during the

course of the clinical trial, and that the ethical principles of research merit, integrity, justice, beneficence, and respect are applied to the conduct of clinical trials.

Study Coordinator (SC)/ Clinical Trial Coordinator (CTC) see Clinical Trial (or Research) or Study Co-ordinator (CTC)

Study Master File (SMF) or Investigator Site File (ISF)
A folder containing all the study related Essential Documentation/Source Documents as defined by the 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 DCT 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.

Standing Committee on Therapeutic Trials (SCOTT)
Clinical trials that involve the use of a new medicine require approval under Section 30 of the Medicines Act 1981. The Health Research Council's Standing Committee on Therapeutic Trials (SCOTT) undertakes a scientific assessment of applications to conduct trials and makes recommendations to the Director-General of Health on whether or not trials should be approved.

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 Satellite 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.

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.

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 the date, the training is undertaken, who gave the training with a signature of both trainer and trainee and is kept current for the duration of the clinical trial.