Clinical Trials Coordinator

CTSU Orientation Manual

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INTRODUCTION

This orientation manual aims to provide coordinators baseline information about the clinical trials environment, and an introduction of the expectations of the role. Ongoing education and support will be provided during the coordinators employment within SWSLHD/Ingham and this will become a significant component of career development within the specialty area. The application of our training program also strives to improve operational quality and trial outcomes for all stakeholders involved in clinical research.

SECTION 1: CLINICAL TRIALS SUPPORT UNIT (CTSU)

1.1 OUR TEAM

Since early 2015 the South West Sydney Local Health District, together with the support of the Ingham Institute established a Clinical Trials Support Unit (CTSU). This unit provides support to our dynamic research culture and provides a network for all our clinical trials teams and supporting departments.

The CTSU has achieved this through working closely with our supporting departments such as the Ethics Office and Governance Office, Pathology and Pharmacy departments. We also place high emphasis in working with Sponsors, Investigators and clinical trial staff in all areas of clinical trial development and delivery.

Within South Western Sydney Local Health District, we have as significant number of clinical trials teams that cover more than 25 different specialty areas. This footprint that covers Liverpool, Campbelltown, Bankstown, Bowral and Fairfield Hospitals. The largest teams work directly from the Ingham Institute with close ties to with University of New South Wales, and the Western Sydney University.

At any given time, we have over 550 trials open in a broad range of specialty areas. At the Ingham Institute and in South West Sydney Local Health District, through the work of our dedicated clinical trials units we have improved health outcomes for our community.

1.2 CTSU TEAM AND CONTACT INFORMATION

The CTSU comprises of a team of dedicated support staff including;

Acting Executive Director of Clinical Trials – Ms. Victoria Willacy

Clinical Trials Manager(s) – Mr. Erfan Jaberiyanfar

Clinical Trials Education Manager – Ms. Kirsty Kubik

Startup Manager – Ms. Nacha Han

Finance Officer – Mr. Masud Anwar

Administration support – Ms. Belinda Kleut & Ms. Shivani Mani

Contact Details:

Email: SWSLHD-ClinicalTrialsSupportUnit@health.nsw.gov.au

Website: https://www.swslhd.health.nsw.gov.au/ethics/CT.html

https://inghaminstitute.org.au/

Relevant access required for all staff (Ask your department Manager/Lead Coordinator to assist)

- District –Clinical Trials (Share drive) – Access to generic information across the LHD for Trial management
- eMR (Powerchart) and or Mosaiq – Medical Records
- Veeva Site Vault – Investigator Site File for trial management
- REGIS – Ethics and Governance submission platform

1.3 CTSU MONTHLY MEETINGS

On a monthly basis the CTSU hosts a team meeting for all Clinical Trials Coordinators across SWSLHD and the Ingham Institute. The meeting provides an opportunity for Coordinators from all specialty areas to come together and discuss relevant concerns and work towards overcoming barriers. The meeting also provides relevant updates regarding regulatory processes, accreditation requirements and other important information relevant to the specialty area.

1.4 SWSLHD CLINICAL TRIAL DEPARTMENTS

Cardiology	Immunology	Endocrine and Diabetes	Interventional Radiology
Interventional Neurology and Neurovascular	Neurology and Multiple Sclerosis	Women's Health	Emergency Medicine
Respiratory and sleep medicine	Limb Preservation/ Diabetes	Rheumatology	Dermatology
Intensive Care	Drug Health	Orthopedics	Gastroenterology/ IBD and Hepatology
Medical Oncology	Brain Injury and Rehabilitation	Mental Health	Hematology
Radiation Oncology	Pediatrics	Renal Medicine	Palliative Care

1.5 SUPPORTING DEPARTMENTS

- The SWSLHD Ethics and Governance office is a key supporting department that provides each trial department support and guidance. This department is currently located at the Eastern Campus at Liverpool Hospital. The team consists of the following people:
  - Ethics and Governance Manager
  - Ethics and Governance Coordinator
  - Administration support

It is highly recommended that you review the Ethics and Governance website here

- Dependent on the clinical trial protocol site may require the support of internal departments such as Pharmacy and Radiology. Please review the protocol and determine the site requirements needed to successfully action the schedule of events. Please be mindful that if you are requesting the support of these department that they are required to be involved in the feasibility process, and more importantly the budgeting process.

1.6 EXTERNAL PROVIDERS

Please note that if an external provider is required to support the clinical trial a Service Level Agreement (SLA) is required. Please refer the SWSLHD Policy located here. Most external venders will have this agreement already in place please confirm this during the startup/feasibility process. Some external providers are listed below:

1. NSW Pathology
2. Slade Pharmacy
3. Radiology (Spectrum, I-Med, South West Radiology)

SECTION 2: WHAT IS A CLINICAL TRIAL?

Clinical trials are research investigations in which people volunteer to test new treatments, interventions or tests to prevent, detect, treat or manage various diseases or medical conditions. Some investigations look at how people respond to a new intervention and what side effects might occur. This helps to determine if a new intervention works, if it is safe, and if it is better than the interventions that are already available.

Clinical trials might also compare existing interventions, test new ways to use or combine existing interventions or observe how people respond to other factors that might affect their health (such as dietary changes).

The World Health Organization (WHO) definition for a clinical trial is;

'Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.'

Clinical trial interventions include, but are not restricted to:

- experimental drugs
- cells and other biological products
- vaccines
- medical devices
- surgical and other medical treatments and procedures
- psychotherapeutic and behavioural therapies
- health service changes
- preventive care strategies
- educational interventions

Researchers may also conduct clinical trials to evaluate diagnostic or screening tests and new ways to detect and treat disease.

Why do we need clinical trials?

Clinical trials are essential to the development of new interventions. For example, without clinical trials, we cannot properly determine whether new medicines developed in the laboratory or by using animal models are effective or safe, or whether a diagnostic test works properly in a clinical setting. This is because computer simulation and animal testing can only tell us so much about how a new treatment might work and are no substitute for testing on a living human body.

Clinical trials also permit testing and monitoring of the effect of an intervention on many people to ensure that any improvement as a result of the intervention occurs for many people and is not just a random effect for a one person.

Most modern medical interventions are a direct result of clinical research. New interventions for most diseases and conditions — including cancer, heart disease, high blood pressure and asthma — have been developed through clinical research.

Clinical trials often lead to new interventions becoming available that help people to live longer and to have less pain or disability.

Additionally, clinical trials can also help to improve health care services by raising standards of treatment. Doctors and hospital staff involved in clinical trials are continually trained to provide best practice patient care. Australian clinical trials are recognised internationally for including very high-quality patient care.

SECTION 3: CLINICAL TRIAL COORDINATOR COMPETENCY TRAINING

3.1 GOOD CLINICAL PRACTICE (GCP) TRAINING

Our SPHERE partners offer an online GCP program coordinated by Sophie Mepham. These programs are tailored to all staff involved in clinical research and their supporting departments such as Pathology, Nursing and Pharmacy. The course content promotes a depth of understanding about conducting research involving humans within the Australian environment.

All Researchers are ethically responsible to conduct clinical research of the highest quality. This includes the collection of high quality, credible data that contributes to the answering of specific scientific questions, while protecting the rights, safety and well-being of clinical trial participants. These principles have their origin in the World Medical Association's Declaration of Helsinki.

GCP standards exist to provide a benchmark of clinical research quality that can be relied upon throughout the world.

As endorsed by SWSLHD Chief Executive, GCP training is a mandatory requirement for all staff

involved in clinical trials in South Western Sydney. Please ensure that you complete this requirement within the first week of employment. GCP training also needs to be updated every three years.

3.2 STANDARD OPERATIONG PROCEDURES and FORMS

The expectation is for all staff to review and acknowledge that they have read each Standard Operating Procedure within 2 months of starting the role and each time the SOP is amended. Acknowledgment notification can be sent via email to the CTSU.

Please find the list of SWSLHD/Ingham SOPs via the following links:
http://www.thespot.inghaminstitute.org.au/clinicaltrials

https://www.swslhd.health.nsw.gov.au/ethics/CT.html#SOP

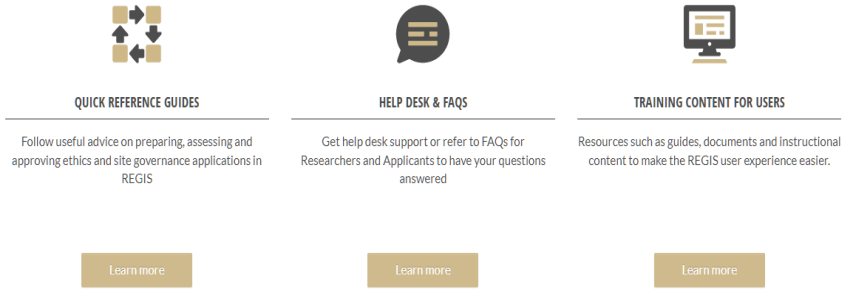
3.3 CLINICAL TRIAL COMETENCY TRAINING

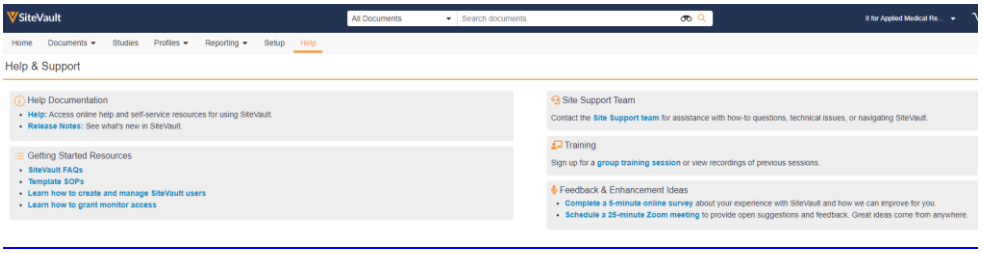
To assist with initial understanding of the fundamental requirements of a Clinical Trials Coordinator, the following online training sessions currently available and are an essential part of the initial CTSU orientation program and ongoing competency training. Please also complete the FM_029 Core Competency Form and email back to the CTSU for filing.

Please contact the CTSU for the training schedule. The schedule is frequently updates and will vary in subjects in accordance to educational requirements of the clinical trials team.

For a current overview of training please see below table:

Topic	Overview
Overview of Ethics and Governance **SOP_CTSU_03 Communication with Human Research Ethics Committee, Trial Sponsor and Insurer**	All research involving humans conducted within the NSW public health system must be ethically and scientifically reviewed and approved by a Human Research Ethics Committee (HREC) in accordance with the National Health and Medical Research Council National Statement on Ethical Conduct in Human Research (2007). In addition, all human research that takes place in NSW Public Health Organisations, or that requires support from a NSW Public Health Organisation in the form of access to participants, tissue or data requires site authorisation. Site authorisation must be reviewed and authorised by the Chief Executive or their delegate before commencement For further education regarding the REGIS system please review the REGIS website for training and FAQ sheets for guidance. https://regis.health.nsw.gov.au/

	
Feasibility, site Initiation and start up **SOP_CTSU_01 Risk Assessment for Clinical Trials** **SOP_CTSU_02 Investigator Responsibilities** **SOP_CTSU_04 Clinical Trials Start Up** **SOP_CTSU_08 Documentation of Training and clinical trial handover** **SOP_CTSU_10 Site Initiation and activation**	It is critical that researchers conduct a thorough feasibility assessment of any prospective clinical research studies, whether they be single site, collaborative or sponsored by commercial industry partners. There are a great number of considerations that must be weighed up before making a determination as to whether a specific study should be conducted. Studies that do not have the potential to be successfully completed are unethical and waste both time and resources The session also provides an overview of what is required prior to site initiation and study start up
Informed consent **SOP_CTSU_02 Investigator Responsibilities** **SOP_CTSU_14 Informed Consent**	Understanding the responsibilities of the consent process under the guidance of ICH-GCP and all other regulatory requirements
Non Compliance – Reporting **SOP_CTSU_02 Investigator Responsibilities** **SOP_CTSU_20 Non Compliance** **SOP_CTSU_22 CAPA Completion**	This session explains Non-compliance and the consequences. Non-compliance with the protocol, International Council for Harmonisation (ICH) Good Clinical Practice (GCP) or regulatory requirements can compromise participant's rights, safety and well-being and can invalidate a clinical trials contractual obligations, insurance/ indemnity. Events of non-compliance are generally identified by the Sponsor of the clinical trial during a site monitoring visits, an internal or external audit or during a Regulatory inspection. This session has a case study which will be reviewed to enable the completion of a Corrective and Preventative Action (CAPA) document
Safety Management in clinical trials **SOP_CTSU_02 Investigator Responsibilities**	This session explains and defines clinical trial safety management in accordance with the approved study protocol and all regulatory guidelines Describes the Investigator's role and responsibilities regarding Subject Safety and reporting requirements for Serious Adverse Events.

SOP_CTSU_19 Safety Assessment, Data Monitoring and Reporting requirements **NHMRC Guidance Documents**	Improved understanding of Adverse Event identification and reporting by Investigators and their staff working directly with study subjects, as well as enhanced subject safety.
Monitoring Audit and Inspections – What to expect **SOP_CTSU_02 Investigator Responsibilities** **SOP_CTSU_11 Monitoring Visits** **SOP_CTSU_23 Sponsor Audits and Regulatory Inspections**	This session reviews the necessity for quality in trials management to save time, resources and maintain site reliability By understanding the purpose and the routine activities of monitoring and auditing the Investigator and study staff will better understand how they can prepare for all site activities when conducting a clinical trial
Clinical Trials Contracts **SOP_CTSU_03 Communication with Human Research Ethics Committee, Trial Sponsor and Insurer**	This session is a discussion about clinical trial contract, indemnity and confidentiality requirements in the Australian environment.
Budget Negotiation **SOP_CTSU_03 Communication with Human Research Ethics Committee, Trial Sponsor and Insurer**	An overview of the standard fees for Industry Sponsored clinical trials and budget negotiation tips and tricks for reviewing a budget.
Veeva eISF Training – Self Directed Learning **SOP_CTSU_09 Investigator Site File and essential documents**	Electronic Investigator Site File training available via the eISF site or via the SWSLHD District Share drive; Veeva ISF – District Share Drive 

SECTION 4: ADDITIONAL TRAINING

4.1 INTRODUCTION TO BASELINE OBSERVATIONS – NON NURSING

Clinical trials training requirements for non-nursing Coordinators can now require additional professional development in the field of vital sign understanding and measurement. The online course offered by the Centre for Professional Development offers this course via the following link:

Vital Signs - Introduction to baseline observations: Learning Outcomes

The course provides the Coordinator with the following professional development components:

1. Identify what are normal vital signs
2. Recognise the client's physiological health of their vital organs

An additional requirement will be to perform and document two site vital sign measurements including Blood Pressure, Pulse and Respirations witnessed by a Registered Nurse/Educator or equivalent

Once complete, please provide the FM_033 Vital Sign Measurement form to the CTSU via email: SWSLHD-ClinicalTrialsSupportUnit@health.nsw.gov.au as a record of your ongoing training and development.

4.2 IATA DANGEROUS GOOD TRAINING/REGULATIONS

The purpose of the IATA Dangerous goods regulations is to provide consistent technical requirements for the transport of dangerous goods across Australia. If you are responsible for packing or supervising an individual who packs dangerous goods for transport by air (including enclosing the goods in packaging, marking or labelling the consignment or preparing a shipper's declaration) then you are required by both the International Air Transport Authority (IATA) and Civil Aviation Safety Authority (CASA) to ensure that you have received the appropriate dangerous goods training on an approved course certified by CASA.

Please contact CTSU via email: SWSLHD-ClinicalTrialsSupportUnit@health.nsw.gov.au to arrange the IATA Safe Transport of Dangerous Goods course.

SECTION 5: FURTHER INFORMATION - CLINICAL TRIAL START UP

5.1 FEASIBILITY

Conducting clinical trial feasibility is one of the first steps in clinical trial process. This includes assessing internal and environmental capacity, alignment of the clinical trial in terms of study design, Investigational product/device or other requirements. The site is required to also

review recruitment capabilities that align with capabilities and ensure a clinical trial budget is reviewed and negotiated with the named Sponsor as appropriate.

A robust feasibility assessment by the site also ensures a realistic capability to conduct the clinical trial which includes the capability of local supporting departments and external stakeholders.

5.2 CLINICAL TRIAL RESEARCH AGREEMENTS (CTRA)

The NSW department of health together with Medicines Australia have developed a standard template for use by Industry sponsored and collaborative group clinical trials. See website for the current version - https://medicinesaustralia.com.au/policy/clinical- trials/clinical-trials-research-agreements/ any additional clauses to schedule 4 and or 7 must be pre-approved by the NSW department of health under SEBS approval. If you are unsure please contact the Ethics Office and or CTSU department for advice.

Additionally, please refer to the Ethics and governance website for information such as:

- Ethics committee closing dates for applications
- Correct institutional address for CDA, CTRA and Indemnity documents
- Multicenter Cover (MC) letter templates
- Ethics and Governance Fees
- Essential contact details

5.3 UNDERSTAND BUDGETS – Key points

SWSLHD Site fees are available here. These fees can be provide to the Sponsor (Industry) when negotiating a budget.

HREC Preparation Fee: The activities associated with the preparation and submission of the human research ethics committee (HREC) application form (or equivalent) and supporting documentation which includes the protocol, participant information and consent form (PICF), recruitment and advertising materials, etc. Also includes revisions to applications in response to ethics committee requests for additional information and forwarding copies of relevant approvals (once obtained) and associated documentation to the trial funder/sponsor.

Site Specific Preparation Fee: The activities associated with the preparation and submission of the Site Specific Assessment (SSA) form (or equivalent) by the PI or project team, which include completion of the form, following up authorizing signatures, liaising with inter-institutional Departments (e.g. radiology, pathology, pharmacy, etc.), adapting the Lead HREC approved master PICF(s) with site specific letterhead and contact details; and liaison with sponsor including forwarding copies of relevant authorisations (once obtained) and associated

documentation to the trial funder/sponsor. Also includes responding to RGO queries and/or requests for additional information and forwarding copies of relevant authorisations (once obtained) and associated documentation to the trial Sponsor.

Protocol Amendments: The activities associated with the preparation and submission of protocol amendments to the HREC and RGO including amendments to the PICFs, investigator brochures and any other trial information which has been updated/amended. Also includes responding to HREC and/or RGO queries and/or requests for additional information and forwarding copies of relevant authorisations (once obtained) and associated documentation to the trial funder/sponsor.

Site Establishment and yearly Administration Costs: The activities associated with ongoing operation of the trial at the trial site that occur post initiation of the trial. Includes liaison with investigators and/or sponsor (including the monitors), preparing materials for, and involvement in, monitoring visits, eCRF completion, data collection and entry, endpoint recording, accrual reporting, safety and adverse event reporting, review of SAE reports, managing clinical trial documentation, retrieving medical and/or clinical records, invoicing, and annual reporting including annual ethics report and final report.

Archiving Fee: The activities associated with archiving the trial records for the required period.

Institutional Overhead: This covers the cost of running the Institution and applied to the per participant fee. SWSLHD charges 30% overhead.

Participant Screening/Screen Failure: The activities directly linked with clinical trial cohort identification which includes:

- database and medical records review
- the development of recruitment plans including suggested strategies, timelines and costs;
- the development and execution of a consultation plan to support study recruitment as well as provide opportunities to increase awareness about clinical research and opportunities to participate;
- Interviewing potential participants which includes asking questions to address the specific inclusion/exclusion criteria for the study and other issues of suitability (either by telephone or face-to-face); and documenting pre-screening trial activity (irrespective of eligibility).

Abandonment Fee: The CTRA should contain the following clause “In the event the clinical trial is abandoned any costs incurred by the clinical trials unit will be recovered by invoice”

SECTION 6: GLOSSARY

Adverse Event (AE) – Any untoward or unfavorable medical occurrence in a clinical research study participant, including any abnormal sign (e.g. abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the participants' involvement in the research, whether or not considered related to participation in the research.

Australian Clinical Trials Website – http://www.australianclinicaltrials.gov.au/

Baseline – The initial time point in a clinical trial that provides a basis for assessing changes in subsequent assessments or observations. At this reference point, measurable values such as physical exam, laboratory tests, and outcome assessments are recorded.

Bias – A point of view or preference which prevents impartial judgment in the way in which a measurement, assessment, procedure, or analysis is carried out or reported.

Case Report Form (CRF) – A printed, optical, or electronic (eCRF) document designed to capture all protocol-required information for a study.

Coordinating Center (CC) – A group organized to coordinate the planning and operational aspects of a multi-center clinical trial. CCs may also be referred to as Data Coordinating Centers (DCCs) or Data Management Centers (DMCs).

CTRA – Clinical Trial Research Agreement. An agreement or contract between the Site and the sponsor indicating expectations, guidelines and payment schedules. **https://medicinesaustralia.com.au/policy/clinical-trials/clinical-trials-research-agreements/**

Concomitant Medication – Prescription and over-the-counter drugs and supplements a study participant has taken along with the study intervention. This information may be collected as a history item as well as during the study. Some studies may collect only those medications that may interact with the study or intervention or that may exclude an individual from participating in a study.

Conflict of Interest – A conflict of interest occurs when individuals involved with the conduct, reporting, oversight, or review of research also have financial or other interests, from which they can benefit, depending on the results of the research.

Control Group – The group of individuals in a clinical trial assigned to a comparison intervention.

Data Management – The processes of handling the data collected during a clinical trial from development of the study forms/CRFs through the database locking process and transmission to statistician for final analysis.

Data and Safety Monitoring Board (DSMB) – A DSMB is a multidisciplinary group established by the trial sponsor to review, at intervals, accumulating trial data, to monitor the progress of a clinical trial. Its role is to provide advice on data integrity, safety and/or trial conduct issues by making recommendations to the sponsor, or their Trial Steering Committee, on whether to continue, modify or stop a trial for safety or ethical reasons.

For more information on DSMBs, see **https://www.nhmrc.gov.au/guidelines-publications/eh59.**

Efficacy – Indication that the clinical trial intervention produces a desired therapeutic effect on the disease or condition under investigation.

Eligibility Criteria – List of criteria guiding enrollment of participants into a study. The criteria describe both inclusionary and exclusionary factors.

International Committee on Harmonization (ICH) – Good Clinical Practice (GCP) - Is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials of medical interventions that involve the participation of human beings. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

ICH-GCP has been largely adopted in Australia by the Therapeutic Goods Administration (TGA); however, the TGA has recognised that some elements are, by necessity, overridden by the National Statement (and therefore not adopted) and that others require explanation in terms of 'local regulatory requirements'. Compliance with ICH-GCP is a condition for all trials conducted under the Clinical Trials Notification (CTN) or Clinical Trials Application (CTA) schemes.

The complete text of the 1996 ICH-E6 GCP document is available at:

http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf

An amendment to ICH-E6 GCP was published in 2016 and can be found at:

http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2_Step_4_2016_1109.pdf

In February 2018, the TGA issued a revised version of the GCP with TGA annotations incorporating the 2016 amendment. This can be found at: **https://www.tga.gov.au/publication/note-guidance-good-clinical-practice**

Governance review and authorisation - A process used by an organisation for the oversight, assessment, and authorisation and monitoring of research conducted at one or more of its sites or a site under its auspices. Research cannot commence at a site until the governance review process is completed and the research has received the necessary authorisation.

Indemnity - Security or protection against a loss or other financial burden.

https://medicinesaustralia.com.au/policy/clinical-trials/indemity-and-compensation-guidelines/

Insurance certificate – A certificate provided by the Sponsor providing the dates for insurance period for the named clinical trial.

Informed Consent – A process by which a participant or person responsible 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 take part in the clinical trial. Informed consent is usually documented by means of a written, signed, and dated informed consent form, which has been approved by an Ethics Committee**.**

Informed Consent Form – A document that describes the rights of a study participant and provides details about the study, such as its purpose, duration, required procedures, and key contacts. Risks and potential benefits are explained in the informed consent document.

Human Research Ethics Committee (HREC) - Human Research Ethics Committees (HRECs) play a central role in the Australian system of ethical oversight of research involving humans. HRECs review research proposals to ensure that they are ethically acceptable and in accordance with relevant standards and guidelines.

The National Statement on Ethical Conduct in Human Research, 2007 (National Statement) consists of a series of guidelines made in accordance with the National Health and Medical Research Council Act 1992. The purpose of the National Statement is to promote ethically appropriate human research. Fulfilment of this purpose requires that participants be accorded the respect and protection that is due to them. It also involves the fostering of research that is of benefit to the community. The National Statement can be found via the following link https://www.nhmrc.gov.au/guidelines-publications/e72d

Intervention – A procedure or treatment such as a drug, nutritional supplement, gene transfer, vaccine, behavior or device modification that is performed for clinical research purposes

Blinding – A procedure in which the investigator administering the assessments and intervention as well as the participants in a clinical trial are kept unaware of the treatment assignment(s). Single blinding usually refers to the study participant(s) being unaware, and double blinding usually refers to the study participant(s) and any of the following being unaware of the treatment assignment(s): investigator(s), monitor, and data analyst(s).

Clinical Trial Notification (CTN) or Clinical Trial Application (CTA) - There are two schemes under which clinical trials involving therapeutic goods may be conducted, the Clinical Trial Application (CTA) Scheme and the Clinical Trial Notification (CTN) Scheme. These schemes are

used for clinical trials involving:

- any product not entered on the Australian Register of Therapeutic Goods; or
- use of a registered or listed product in a clinical trial beyond the conditions of its marketing approval.

Clinical trials in which registered or listed medicines or medical devices are used within the conditions of their marketing approval are not subject to CTN or CTA requirements but still need to be approved by a Human Research Ethics Committee (HREC) before the trial may commence.

Clinical Trials Management System (CTMS) is an essential database to effectively plan, manage and track a department's clinical study portfolio. It is a specialised, comprehensive project management application that takes the study team from startup, through enrollment and monitoring, to study close.

HREA – Human Research Ethics Application

Open-Label Trial – A clinical trial in which investigators and participants know which intervention is being administered.

Pharmacokinetics – The process (in a living organism) of absorption, distribution, metabolism, and excretion of a drug or vaccine.

Clinical trial phase - Many clinical trials to develop new interventions are conducted in phases. In the early phases, the new intervention is tested in a small number of participants to assess safety and effectiveness. If the intervention is promising, it may move to later phases of testing where the number of participants is increased to collect more information on effectiveness and possible side effects.

Clinical trials of biomedical interventions typically proceed through four phases:

Phase I clinical trial Phase I clinical trials are done to test a new biomedical intervention for the first time in a small group of people (e.g. 20-80) to evaluate safety (e.g. to determine a safe dosage range and identify side effects).

Phase II clinical trial Phase II clinical trials are done to study an intervention in a larger group of people (several hundred) to determine efficacy (that is, whether it works as intended) and to further evaluate its safety.

Phase III clinical trial Phase III studies are done to study the efficacy of an intervention in large groups of trial participants (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions (or to non-interventional standard care). Phase III studies are also used to monitor adverse effects and to collect

information that will allow the intervention to be used safely.

Phase IV clinical trial Phase IV studies are done after an intervention has been marketed. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use over longer periods of time. They may also be used to investigate the potential use of the intervention in a different condition, or in combination with other therapies.

Other clinical trials Researchers may also conduct exploratory studies, sometimes referred to as **'Phase 0 trials'** or 'pilot studies. These come before Phase I trials and are used to test how the body responds to an experimental drug.

In these studies, small doses of the new drug are given once or for a short time to a very limited number of participants

Placebo – A placebo is an inactive pill, liquid, powder, or other intervention that has no treatment value. In clinical trials, experimental treatments are often compared with

placebos to assess the treatment's effectiveness. Also defined as a method of investigation in which an inactive substance/treatment (the placebo) is given to one group of participants, while the test article is given to another group. The results obtained in the two groups are then compared to see if the investigational treatment is more effective in treating the condition.

Principal Investigator (PI) - the lead researcher at the site for a clinical trial. Holds the overall responsibility for the conduct of the trial under the auspices of ICH-GCP

Protocol – A document that describes the objective(s), design, methodology, statistical consideration, and organization of a trial.

Protocol Amendments – A written description of a change(s) to or formal clarification of a protocol. The amendment requires both Ethical approval and Governance acknowledgement prior to implementation at the site.

Non-Compliance – Failure to conduct a study as described in the protocol. The failure may be accidental or due to negligence and in either case, the protocol deviation should be documented. This also includes failure to comply with federal laws and regulations, the institution's commitments and policies, and standards of professional conduct and practice.

Examples of noncompliance include:

- Failure to obtain/maintain approval for research,
- Failure to obtain informed consent when required,
- Failure to file adverse event reports,
- Performance of an unapproved study procedure,

- Performance of research at an unapproved site,
- Failure to file protocol modifications and
- Failure to adhere to an approved protocol.

Quality Assurance (QA*)* – Systematic approach to ensure that the data are generated, documented (recorded), and reported in compliance with the protocol and good clinical practice (GCP) standards.

Quality Control (QC) – The internal operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of trial related activities have been fulfilled (e.g., data and form checks, monitoring by study staff, routine reports, correction actions, etc.).

Randomization – The process of assigning clinical trial participants to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.

Recruitment Plan – The plan that outlines how individuals will be recruited for the study and how the study will reach the recruitment goal.

REGIS –Online platform for the submission of Ethics and governance projects in NSW and ACT Register your account via the link **https://regis.health.nsw.gov.au/**

For further REGIS support contact the SWSLHD Ethics and Governance office on 02 8738 8304 E: **SWSLHD-Ethics@health.nsw.gov.au** or review the webinars via the following website **https://www.swslhd.health.nsw.gov.au/ethics/training.html**

Retention Plan – The site plan that details the methods in which the study will use in order to retain study participation in the clinical trial.

Safety Monitoring Plan – A plan that outlines the oversight of a clinical trial formulated by the named Sponsor/Clinical Research Organisation.

Satellite Site - The satellite site is a study site that is linked to an existing parent site where the parent site and the satellite site share the same principal investigator. Participants are seen by the same principal investigator and visit both the parent site and the satellite site.

Screening Log – An essential document that records all individuals who entered the screening process. The screening log demonstrates the investigator's attempt to enroll a representative sample of participants.

Screening Process – A process designed to determine individual's eligibility for participation in a clinical research study.

Serious Adverse Event (SAE) – Any adverse event that:

- Results in death
- Is life threatening

- Requires or prolongs hospitalization
- Causes persistent or significant disability or incapacity
- Results in congenital anomalies or birth defects

Please refer to the clinical trial protocol for specific reporting requirements

Source Document – Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, participant diaries, recorded data from automated instruments, x-rays, etc.) that are used in a clinical trial.

Significant Safety Issues (SSI) A safety issue that could adversely affect the safety of participants or materially impact the continued ethical acceptability or conduct of the trial.

Standard Operating Procedure (SOPs) – Detailed written instructions to achieve uniformity of the performance of a specific function across studies and patients at an individual site.

Stratification – Separation of a study cohort into subgroups or strata according to specific characteristics such as age, gender, etc., so that factors which might affect the outcome of the study.

Study Coordinator (SC) A person responsible for conducting clinical trials under the supervision of the Principal Investigator. They are involved multiple essential duties that encompass the management of a Clinical Trial. The Study Coordinator ensures compliance with the protocol and adheres to ICH-GCP guidelines. Although not inclusive, some of the SC responsibilities include preparing the HREC and/or Governance Submissions, communication with International

Sponsoring Companies/Local Collaborative groups or local Investigators in relation to study start up, daily management as well as performing close out procedures. They are also involved in subject recruitment, patient care, adverse event reporting, data capture and all other procedures that are involved the ongoing ethical management of a clinical trial.

Sub Investigator (SI) Any member of a clinical trial team—e.g., associate, resident,

Research fellow—who is supervised by the investigator at a trial site and allowed to perform critical trial-related procedures and/or to make key trial-related decisions.

TGA –Therapeutic Goods Administration is Australia's regulatory authority for therapeutic goods.

Unmasking/Unblinding – A procedure in which one or more parties to the trial are made aware of the treatment assignment(s). This process is mapped out within the clinical trial protocol.

SECTION 6: REFERENCES AND USEFUL LINKS

https://www.australianclinicaltrials.gov.au/useful-links

https://www.tga.gov.au/clinical-trials

https://mrctcenter.org/clinical-trial-competency/

https://www.nhmrc.gov.au/about-us/publications/safety-monitoring-_and-reporting-clinical-trials-involving-therapeutic-goods

https://www.australianclinicaltrials.gov.au/researchers

https://www.nhmrc.gov.au/about-us/publications/competencies-australian-academic-clinical-trialists