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Glossary of terms for anaesthesia research co-ordinators

August 2025

Purpose of document:

This document offers a list of common research terms and abbreviations for research staff and research co-ordinators working in anaesthesia clinical trials.

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The development of the Anaesthesia Research Coordinator Network (ARC�) and ANZCA CTN toolkit is being led by the CTN office team, in collaboration with the ARC� sub-committee and the CTN executive. We gratefully acknowledge the contributions of the ANZCA CTN members, CTN office, ARC� sub-committee, and CTN executive committee in the creation, preparation, development, and review of this document.

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Glossary of terms for anaesthesia research co-ordinators

Term	Definition
ANZCA	Australian and New Zealand College of Anaesthetists
ANZCA CTN	Australian and New Zealand College of Anaesthetists Clinical Trials Network
AAPM	American Academy of Pain Medicine
ABA	American Board of Anesthesiology
ABPM	American Board of Pain Medicine
A-CTEC	Australian Clinical Trials Education Centre – offers free, TransCelerate-compliant GCP training and regular webinars on clinical trial activities.
AE	Adverse Event: Any untoward medical occurrence in a patient or clinical trial participant administered a medicinal product and that does not necessarily have a causal relationship with this treatment or study. All adverse events must be recorded in the case report form, even if the event is commonly observed. An AE can be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporarily associated with the use of a medicinal (investigational) product, whether or not related to the medicinal(investigational) product. (Note also see AR)
AHPRA	Australian Health Practitioners Regulatory Board
AMA	Australian Medical Association
ANZCTR	Australian New Zealand Clinical Trials Registry
ANZICS	Australian and New Zealand Intensive Care Society
ANZICS CTG	Australian and New Zealand Intensive Care Society Clinical Trials Group
ANZICS PSG	Australian and New Zealand Intensive Care Society Paediatric Study Group
AR	Adverse Reaction: Any untoward and unintended response to an investigational medicinal product (study drug) related to any dose administered. If an adverse event has a reasonable causal relationship with treatment. (Note also see AE)
Archiving records	Storage of trial study documents once the trial has closed. There are local and institutional guidelines for the archiving of research records. Please refer to these for information on the method and length of retention required for your centre.
ARCN	Anaesthesia Research Co-ordinator Network
ASA	Either Australian Society of Anaesthetists or American Society of Anesthesiologists . This could also refer to ASA 1-6 which is the American Society of Anesthesiologists Physical Status Classification System.
Assent	A process whereby minors may agree to participate in clinical trials it is distinct from consent, which must be obtained from a parent or legal guardian.
ATSI	Aboriginal and Torres Strait Islanders.
Audit trail	An audit trail is the documentation that allows reconstruction of the course of events i.e. the patients pathway in a trial. Therefore, any change or correction to a paper Case Record Form (CRF) should be crossed out, dated, initialled and explained if necessary, new value should be included and should not obscure the original entry. "Whiteout" should never be used. Electronic CRF's usually have an electronic audit trail operating in the background of the program.

Term	Definition
Beneficence	A concept in research ethics that researchers should have the welfare of the research participant as a goal of any research study including clinical trials.
Bias	Any intentional or unintentional adjustment in the design and/or conduct, analysis or evaluation of a clinical trial.
Blinding	A procedure in which one or more parties to the trial are kept unaware of the treatment they have been allocated to. Single blinding usually refers to the participant(s) being unaware, and double-blinding usually refers to the participant(s), investigator(s), monitor and in some cases, the data analyst or statistician being unaware of the treatment assignment(s).
CAG	Consumer Advisory Group: is a structured group of consumers (patients, carers, or community representatives) who provide input and advice and helps ensure that projects are patient-centered, ethically sound, and aligned with the needs and values of the target population.
Comparator/Control	An investigative or marketed product (i.e. active control/study drug) or placebo, used as a reference in a clinical trial.
Confidentiality	Prevention of disclosure, to other than the authorised individuals, of a sponsor's proprietary information or of a participant's identity or identified health information.
Conflict of interest	Any circumstance that creates a risk that professional judgement or actions will be influenced by a secondary interest.
Consumer engagement	Meaningful involvement of patients, families, caregivers, or community members, in the planning, conduct, and dissemination of research. These individuals bring lived experience and help ensure the research is relevant, ethical, and impactful.
Contract	A written, dated and signed agreement between two or more parties that sets out any arrangements on delegation and distribution of tasks and obligations, and if appropriate, on financial matters. (See Clinical Trial Research Agreement (CTRA)).
Consent	See Informed Consent.
Consent to continue	Also known as delayed consent, is where the initial treatment or intervention begins without prior informed consent and then consent is obtained as soon as possible afterwards.
CPI	Coordinating Principal Investigator: an investigator who has the overall responsibility for the coordination of the study trial and investigators at different study sites for a multicentre trial.
CPD	Continuing Professional Development: education activities to maintain professional certification.
CRF	Case Record/Report Form: a subject specific document used to collect data about each participant in a clinical trial. Can be printed, optical or electronic.
Critical appraisal	A careful and systematic assessment of evidence to judge its trustworthiness, value and relevance in a particular context.
CRO	Contract Research Organisation: an organisation (commercial, academic or other) contracted by the sponsor to perform one or more of a sponsor's trial- related duties and functions.
CTEP	Clinical Trials Exemption Scheme : a Therapeutic Goods Administration (TGA) approval pathway used in special circumstances in Australia.
CTN	Clinical Trial Notification : an application made to the TGA in Australia to notify that a clinical drug trial is being conducted at sites listed on the form.
CTMS	Clinical Trial Management System: an online system that manages clinical trials such as data input, randomisation, study reports, payments.
CTRA	Clinical Trial Research Agreement: a contract that is signed between the sponsor of a trial and the site trial which outlines arrangements/responsibilities for the clinical trial at the site level and the sponsor level. There are standardized templates available and used across Australia and adapted in New Zealand for sponsor-site contracts. Medicines Australia Standard contracts are advised for use in Australia and can be adapted in New Zealand. .
Data checking	Review of collected research data against any source documents that are available.
Data cleaning	The detection and removal/correction of errors and inconsistencies in a data set or database. Incomplete, inaccurate or irrelevant data is identified and then either replaced, modified or deleted.
Data integrity	Data should be complete and accurate.

Term	Definition
Data linkage	Bringing information about the same person from different sources (birth records, vaccination records) together.
DSMC/DSMB	Data Safety Monitoring Committee/Board. an independent and multidisciplinary group of experts established to review at preset intervals the accumulating trial data (usually unblinded) in order to monitor the progress of a trial and to make recommendations on whether to continue, modify or stop the trial for safety or ethical reasons.
Deidentified data	Research data which has no identifying information such as participant name, date of birth or medical record number attached.
Delegation log	A document completed by the investigator which shows the study related duties of all study staff members assisting with running the trial at a site.
Double blinding	Neither the participant nor the investigators know which treatment a participant has been randomised to.
eCRF	Electronic Case Record/Report Form.
eGCP	Electronic Good Clinical Practice training: digital formats of GCP education.
Efficacy	The ability to achieve or produce the intended result.
EMR	Electronic Medical Record.
ERM	Ethical Review Manager an online system that enables users to complete ethics and governance applications in Victoria and Queensland in Australia.
Electronic data capture	Information Technology (IT) system to collect clinical and research data.
Eligibility	Guidelines, detailed in the protocol for who can and cannot take part in a study.
Ethical conduct	Adhering to ethical standard when conducting research.
Exclusion criteria	Reasons outlined in the protocol for a potential participant being ineligible to partake in a research study e.g. comorbidities, ages, gender, etc.
FANZCA	Fellow Australian and New Zealand College of Anaesthetists.
FFPM	Fellow of the Faculty of Pain Medicine.
FPM	Faculty of Pain Medicine
FICANZCA	Fellow of the Faculty of Intensive Care, Australian and New Zealand College of Anaesthetists.
GCP	Good Clinical Practice: a standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of the subjects are protected.
GLCC	Good Clinical Learning Centre: New Zealand based provider of accredited GCP training.
GLP	Good Laboratory Practice: a quality management system that generates high quality and reliable test data.
GMP	Good Manufacturing Practices: a system of regulations and guidelines that ensures manufactured products like pharmaceuticals, food and cosmetics are consistently produced and controlled according to set quality standards.
HDEC	Health and Disability Ethics Committees – New Zealand’s national ethics committee.
HDU	High Dependency Unit.
Helsinki Declaration	A set of medical principles established by the World Medical Association, first published in 1964 following a General Assembly of the World Medical Association in Helsinki. It provides protection for trial participants. https://www.wma.net/policies-post/wma-declaration-of-helsinki/
HRC	Health Research Council of New Zealand : the main research funding body in New Zealand.
HREA	Human Research Ethics Application : Australia’s ethics submission form.
HREC	Human Research Ethics Committee.
Human research	Research conducted with or about people, their tissue or their data.

Term	Definition
Hypothesis	A supposition or proposed explanation made on the basis of limited evidence as a starting point for further investigation.
ICH	International Council for Harmonisation: a process which has generated guidance documents for the stages of drug development from non-clinical to human studies. https://www.tga.gov.au/resources/publication/publications/ich-guideline-good-clinical-practice
ICU	Intensive Care Unit.
Identifiable data	Data which could potentially identify a research participant e.g. name, medical record number, date of birth or email address.
Inclusion criteria	Criteria outlined in the protocol for a potential participant being eligible to partake in a research study e.g. type of procedure, age, gender, etc.
Informed consent	A process by which a subject 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 subject's decision to participate. Informed consent is documented by means of a written, signed and dated consent form.
Interventional research	Research designed to investigate a particular intervention e.g. device, drug, procedure.
IP	Investigational Product: 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 unapproved indications, or when used to gain further information about an approved use.
ITT	Investigator Initiated Trial: a trial designed and managed by a non-commercial investigator.
ITT analysis	Intention-to-treat analysis: a method in clinical trials where all participants are analysed in the groups to which they were originally assigned (randomised to), regardless of whether they completed the intervention as planned.
Investigator	A person responsible for the conduct of a clinical trial at a trial site.
Investigator's brochure	A document containing a summary of the clinical and non-clinical data relating to an investigational medicinal product that are relevant to the study of the product in humans.
IRB	Institutional Review Board: equivalent of a HREC in the USA.
IRCIG	Intensive Care Research Coordinators Interest Group
ISO	International Organization for Standardization
Locking a database	Once all data has been completed, entered, checked and cleaned with data queries as much as possible the database should be locked so that no changes or additions can be made and statistical analysis of the data can commence.
Low risk research	Research where the only foreseeable risk to a participant is mild discomfort or inconvenience.
MAPI	Māori and Pacific Islander.
MedSafe	New Zealand's medicines and medical devices regulatory authority.
MIA	Multi-Institutional Agreement: this document outlines the responsibilities and obligations of multiple institutions involved in a trial.
Mixed methods research	Research that involves both qualitative (interviews, focus groups) and quantitative (experiments, trials) elements.
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 requirements.
Monitor	The monitor in accordance with the sponsor's requirements ensures that the trial is conducted and documented properly.
MR	Mutual Recognition: a system allowing GCP training to be accepted by multiple sponsors (TransCelerate model).
MRFF	Medical Research Future Fund : long term investment supporting Australian health and medical research via grant applications.
Multicentre Trial	A clinical trial conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator/research team.

Term	Definition
Multivariate analysis	Statistical analysis which considers more than one statistical outcome variable at a time.
NEAF	National Ethics Application Form: a web-based tool for submitting human research ethics proposals in Australia. Note this has been replaced by the HREA.
NMA	National Mutual Acceptance: is a scheme used in Australia, in public health organisations within ACT, NSW, QLD, SA, VIC and WA. Under the NMA all multi-centre research projects being conducted at public health organisations within the participating jurisdictions must be ethically and scientifically reviewed only once by a National Health and Medical Research Council (NHMRC) Certified Lead HREC.
National Statement (Australian Document)	The National Statement on Ethical Conduct in Human Research (NHMRC 2007, updated 2018) outlines an agreed set of principles and guidelines to promote ethically good human research which respects and protects participants and ensures that research is beneficial to the community. The National Statement is designed to clarify the responsibilities of: institutions and researchers for the ethical design, conduct and dissemination of results of human research; and review bodies in the ethical review of research. https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023
NHMRC	National Health and Medical Research Council in Australia.
NICU	Neonatal Intensive Care Unit.
Nonclinical study	Biomedical studies not performed on human participants.
Northern Territory Health	Northern Territory Health provides research ethics review for all health related research conducted in the Northern Territory in Australia.
Observational research	Research without an intervention or change to the care of participants which simply observes and records data.
Outcome	The end result of research.
PACU/Recovery	Post-Anaesthesia Care Unit or recovery area.
PHARMAC	Pharmaceutical Management Agency of NZ : manages funding of subsidised medicines.
PICF	Participant Information and Consent Form.
PICOT	Population: who should be in the study Indicator: intervention or exposure of interest Comparator: baseline or gold standard Outcome: what outcome measurements interest you Time: over what time period are we interested
PICU	Paediatric Intensive Care Unit.
PHA	Public Health Act Application: is made only in Queensland when a researcher wishes to use information held by Queensland Health.
Phase I clinical trial	Testing of drug on healthy volunteers for safety.
Phase II Clinical trial	Testing of drug on patients to assess efficacy and side effects.
Phase III Clinical trial	Testing of drug on patients to assess efficacy, effectiveness and safety.
Phase IV clinical trial	Post marketing surveillance of a study drug.
Pilot study	A small study to test the research design and allow refinement of the protocol prior to a larger study. May be useful in determining intervention effect and therefore sample size.
PISCF	Participant Information Sheet and Consent Form.
Placebo	Placebos are often used as a control in research to help determine how much of any observed effect is due to the intervention itself and how much is due to participants or other factors.
PP	Per Protocol Analysis: focuses on participants who strictly adhered to the study protocol, excluding those who didn't comply with the treatment or protocol requirements.
Preclinical study	In vitro and animal experiments conducted to obtain preliminary efficacy, toxicity and pharmacokinetic information.
Principal Investigator	An investigator responsible for the conduct of a clinical trial at a trial site.

Term	Definition
PREMs	Patient Reported Experience Measures: are standardised tools that are used for patients to provide feedback on their experience of the service provided.
PROMs	Patient Reported Outcome Measures: validated scales that ask the patient to rate their own health, clinical outcomes and quality of life.
Protocol	Describes all the procedures of a study/trial to be followed by the investigator. They may vary in structure and format but should include: <ul style="list-style-type: none"> · The aims of the study · Which subjects are to be recruited, using inclusion and exclusion criteria · How and when the investigational project or intervention is to be administered · How and when evaluations are to be performed · What to do if adverse events occur · How all study data will be collected and analysed
Protocol amendment	A written description of changes(s) to or formal clarification of a protocol which has already obtained ethical approval.
Protocol deviation	An accidental or unintentional non-compliance with the study protocol.
Protocol major violation	A deviation that has an impact on subject safety or may have an effect on data integrity.
Qualitative research	Research which involves focus groups and interviews to gather impressions and opinions rather than gathering clinical data or exact figures. It does not involve statistical data.
Quantitative research	Systematic investigation by gathering quantifiable data.
Randomisation	The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.
RCT	Randomised Controlled Trial: a study that randomly assigns participants into experimental or control groups.
REGIS	Research Ethics Governance Information System used in NSW and TAS to apply for ethics and governance approval of research.
Recruitment log	A document or program which records details of all participants recruited to a study.
Regulatory Authorities	Bodies having the power to regulate, sometimes referred to as competent authorities.
Research GEMS	Research GEMS – is an electronic system to apply for ethics and governance approval of research in South Australia.
RGO	Research Governance Office.
RGS	Research Governance Service :an electronic system to apply for ethics and governance approval of research in Western Australia.
Risk analysis	Assessing identified risks and their potential affects on the study.
Risk identification or assessment	Identifying any risk to a research study. These identified risks should be analysed and managed appropriately.
SAE	Serious Adverse Event: an adverse medical event that: <ul style="list-style-type: none"> · results in death · is life-threatening · requires in-patient hospitalisation · prolongs existing hospitalisation · results in persistent or significant disability/incapacity · is a congenital anomaly/birth defect. <p>Must be reported to the sponsor within 24 hours of learning of the SAE.</p>

Term	Definition
SAR	Serious Adverse Reaction: an adverse reaction to a study drug that: <ul style="list-style-type: none"> · results in death · is life-threatening · requires in-patient hospitalisation · prolongs existing hospitalisation · results in persistent or significant disability/incapacity · is a congenital anomaly/birth defect. Must be reported to the sponsor within 24 hours of learning of the SAR.
Sample size	The number of study participants or observations required in a study.
SCAM	An acronym used to describe how to ensure that study equipment is adequate: Suitable, Calibrated and Checked, Available and Maintained.
Screening log	A record of subjects screened for a study regardless of whether they were subsequently enrolled or recruited.
Single Ethical Review	NHMRC system enabling recognition of a single ethical and scientific review of multi-centre human research within and/or across Australian jurisdictions. Note see also NMA.
Site file	Collection of essential trial documents kept together either in an electronic or hard copy file.
Site Principal Investigator	The person responsible for the conduct of a trial at a particular site.
SIV	Site Initiation Visit: a visit (via teleconference or in person) of a site where the running and protocol of the clinical trial is explained to the trial team. There is also time for the site team to ask questions. This happens before a site becomes active to recruit to a trial.
SOP	Standard Operating Procedure: detailed, written instructions to achieve uniformity of the performance of a specific function.
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 verification	Comparing entries in CRFs with data recorded in subject files and other source documents. This could also be cross checking the database with the CRF to ensure the data has been entered correctly. This can help to ensure that all data is recorded correctly and reliably.
Source documents	The place where data is recorded for the first time. It must be kept as a record of the participants journey in the trial.
Sponsor	Is the organisation, institution, or company that takes overall responsibility for the initiation, management, and financing of a research study, such as pharmaceutical companies, other commercial organisations and non-commercial organisations such as universities.
SSA	Site specific assessment: (governance) conducted by a research governance office to determine if a study should be approved for a particular site. Involves assessment of legal issues, finances and risk management.
SSI	Significant Safety Issue: a safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial.
Stage 1 Clinical Trials	Also called Phase 1, these are conducted to test a new intervention for the first time in a small group of people to evaluate safety.
Stopping criteria	Predefined guidelines on when a study should be halted due to safety or potential harm to study participants.
Study number	A unique number assigned to each study participant.
Study file	Collection of essential trial documents.
Study Personnel Log	A log of all personnel with significant trial-related duties. This should list each individual's name, job title, dates of involvement in the study and their specific roles.

Term	Definition
Sub-investigator or AI	Associate Investigator: 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.
Subject/Trial Subject/Participant	An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.
SUSAR	Suspected Unexpected Seious Adverse Reaction: an adverse reaction that is both serious and unexpected.
Te Whatu Ora (Health NZ)	New Zealand's national health authority formed in 2022.
TGA	Therapeutic Goods Administration : the regulatory body for Australia for therapeutic goods including prescription medicines, vaccines, sunscreens, vitamins and minerals, medical devices, blood and blood products.
Trial Master File	A study file that is held at the sponsor site.
TransCelerate	A non-profit organisation that standardises and streamlines clinical trial practices globally and runs GCP courses.
UAR	Unexpected Adverse Reaction: an adverse reaction, the nature or severity of which is not consistent with the Reference Safety Information of a study drug/device.
UMR	Unique Medical Record Number.
USM	Urgent Safety Measure: a measure required to be taken in order to eliminate an immediate hazard to a participant's health or safety.
Vulnerable Persons	Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of groups with hierarchical structures such as medical, dentistry, pharmacy and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces and persons kept in detention. Other vulnerable persons include patients with incurable diseases, ethnic minority groups, homeless persons, nomads, refugees, drug effected, minors and those incapable of giving consent.
VSM	Victorian Specific Module: an ethics module that needs to be completed for all trials conducted in Victoria, Australia.
WAHEAF	Western Australia Human Ethics Application Form.
Waiver of consent	A waiver of consent occurs when researchers seek approval from a HREC to conduct research without obtaining explicit consent from participants. This is typically done when it's deemed impractical or impossible to obtain consent due to various reasons, such as the age of records, characteristics of the cohort, or other factors.
WASM	Western Australia Specific Module: must be completed if sites in Western Australia are taking part in a study/trial.
Withdraw Consent	Withdrawing consent means revoking or cancelling a previously given permission or agreement, where a participant no longer wishes to take part in the clinical study. No further data should be collected and no further contact made with the patient. The PICF should outline whether the already collected data can be used in the study analysis.