AlfredHealth

Glossary to Accompany the Archive Record

Archivist
The person responsible for archiving the study material. This will typically be a person in the research department.

Blinding/Code Break Envelopes
A sealed document which reveals the treatment or treatment sequence of a single participant or all participants involved in the study. For sponsored studies - these will usually be returned to the sponsor at the end of the study.

Clinical Trial
Pre-planned, usually controlled, clinical study of the safety, efficacy, or optimum dosage schedule (if appropriate) of one or more diagnostic, therapeutic, or prophylactic drugs, devices or interventions in humans selected according to predetermined criteria of eligibility and observed for predefined evidence of favourable and unfavourable effects.

Correspondence
All incoming and outgoing letters, faxes, emails, file notes relating to the study.

CRF/Worksheets, Clinical Data/Other Test Results/Data/Assay Data
A printed, optical, or electronic document designed to record all of the protocol required information on each trial subject.

CTX/ or CTN
Regulatory documentation for the trial of new drugs, drugs for new indications, and devices.

Interventional Research Study
Research in which at least some participants will be subject to a medical intervention, such as a drug, device, surgical procedure, behavioural treatment, process-of-care change, and the like.

NATA/Alfred Pathology Accreditation
ISO 17025 Quality System Accreditation (internationally recognised system now used by NATA (National Association of Testing Authorities) or other Regulatory documents, required by ALL pathology laboratories to certify they are accredited to conduct Medical Testing. An authorised, signed copy of the certificate is usually required to be kept with other trial documentation.

Pharmacy Folder
If relevant, Pharmacy will provide a Pharmacy Folder. Discard from the folder only documentation that is already archived.

Randomisation Schedule
A list which clearly shows which treatment/treatment sequence each participant received (must be present for all randomised trials both blinded and unblinded). In some cases, at the conclusion of a study the blinding/code break envelopes may become the randomisation schedule.

Lab Reports, Normal Reference Ranges
These are a list of the tests conducted at a specific lab (i.e. Alfred Pathology services) with the normal reference ranges and units used by the lab. If a various number of labs are used to obtain test results, an authorised, signed copy of ALL these different laboratory normal ranges & units must be obtained and stored with the trial documentation.

Screening Log
A list of all participants and whether they have been included in the study or not.

Site Personnel
For sponsored studies, CVs of personnel as requested by the study sponsor. For other studies, CVs of key site study personnel.

Subject Identification List
A confidential document, maintained by the investigator in the investigator file, which lists the names of all subjects who have provided informed consent, the allocated patient number, date of birth, gender, date enrolled and whether they were enrolled/randomized. It may also list the hospital UR number or other identifying General Practice number for the purpose of cross-referencing patient information. It allows investigators to reveal the identity of any subject consented for the trial.