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## ALFRED ETHICS COMMITTEE GUIDELINES: ARCHIVING / STORAGE OF RESEARCH RECORDS

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### PURPOSE AND SCOPE

The purpose of this document is to inform researchers of the process for archiving research studies undertaken at Alfred Health. This is to ensure that all materials associated with a study are securely stored in such a manner that the study details can be reconstructed at any time.

These guidelines should be read in conjunction with the:

- NHMRC [Australian Code for the Responsible Conduct of Research](#)
- [Alfred Health Policy on Research Conduct](#)

### GUIDELINES

All research studies conducted at Alfred Health must be archived in accordance with these guidelines.

All documentation for **interventional** research studies - involving drugs, devices or medical interventions - is to be kept **indefinitely**. If, at some stage in the future, the Ethics Committee (in consultation with the Ethics Unit) deems that storage is no longer required, all materials will be destroyed in a secure manner. This would not occur until *at least* 15 years after completion of the study.

Research documentation for **non-interventional** studies, such as social science research, studies involving standalone surveys or questionnaires, or as deemed by the Ethics Committee, is to be kept for **7 years** after completion of the study (taken from the date at which the Final Report is submitted to the Ethics Committee) and then destroyed in a secure manner.

### PROCEDURES

#### Preliminary procedures before archiving

- Provide Health Information Services (HIS) with a list of the UR numbers of the patients involved, so that appropriate medical records can be kept for the required period.
- Submit a Progress Report for your study, taking care to fill out the *Final Report* section. Download the latest version from [www.alfredresearch.org/ethics/monitor.htm](http://www.alfredresearch.org/ethics/monitor.htm)
- Notify all hospital departments such as Health Information Services, Pathology, Pharmacy, Radiology etc. according to the study closure requirements of the specific departments. Fees for retention of hospital medical records will be applicable.
- Research information may need to be stored for some time following completion of the study and prior to archiving. Secure storage must be provided during this period to prevent unauthorised access to the information.

#### Archiving instructions

- Place all documents in heavy-duty Recall archive boxes. Ask the sponsor to supply the boxes or order them from Supply (eReq) for bulk orders or the Ethics Office (Alfred Health researchers only). Email [Emily Bingle](#) with the number of boxes required. Emily will send an ICAN invoice by return email.
- Complete the Archive Record, available from the [Archiving](#) page of our website. The Archive Record lists the types of documents that require archiving. This list can be amended to suit the study. A glossary of terms is provided at the end of these guidelines.

- Pack archive boxes, wherever possible, so that individual participant documentation is not divided between boxes. Should this occur, record the details on the Archive Record.
- Boxes must not be overfilled nor weigh more than 16kg.
- Ensure lids fit properly and are securely fixed to the box with strong tape.
- Email the completed Archive Record to [Anna Parker](#) at the Office of Ethics and Research Governance. A copy of the Archive Record with box identification numbers, study identification stickers, barcodes and corresponding instructions, will be sent to you via internal mail.
- Store a copy of the Archive Record in the department responsible for the study in a folder labelled "Record of Archived Materials". This can be used to identify specific boxes that may need to be accessed in the future. The Office of Ethics and Research Governance will retain the Archive Record with the Ethics Office project file.
- Electronic data can be stored in the same boxes as paper documents. Boxes containing electronic media must be identified in the table labelled *Electronic Media* on the last page of the Archive Record.
- The address of the off-site storage location is listed on our website at [www.alfredresearch.org/ethics/archiving.htm](http://www.alfredresearch.org/ethics/archiving.htm)

## **GLOSSARY**

### **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.

### **Reports Lab. Normal Reference Ranges**

These are a list of the tests conducted at a specific lab (ie. 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.