

---

## **ALFRED ETHICS COMMITTEE GUIDELINES: ACCESS TO MEDICAL RECORDS**

---

### **ACCESSING MEDICAL RECORDS FOR RESEARCH PURPOSES**

If researchers plan to conduct research that involves access to medical records or databases, they will need to provide relevant details of the planned research to the Ethics Committee as part of their ethics application.

External research personnel (non-Alfred staff members) cannot access patients' identifiable medical information (patient records) without patient consent. In addition, external researchers should name an Alfred Health staff member in their ethics application as the person who will arrange access to medical records and provide them with the required medical information.

Researchers must include a completed Health Information Services Resource Centre Declaration form with their ethics application. They should contact Chrisa Alexiou at Health Information Services (phone: 9076 2009 email: [c.alexiou@alfred.org.au](mailto:c.alexiou@alfred.org.au)) beforehand to complete the form and gain an estimate of the costs involved in accessing records.

### **ACCESS TO PAPER MEDICAL RECORDS**

All researchers should observe the Medical Records Access, Borrowing and Return [Guidelines](#) and [Policy](#).

Once ethics approval has been granted, researchers must show Health Information Services the ethics approval certificate whenever they need to access records.

If they need to access multiple medical records they should complete the [Multiple Medical Record Requisition Form](#).

### **ACCESS TO ELECTRONIC MEDICAL RECORDS**

#### **Alfred Health researchers:**

Alfred Health researchers may access, collect, use and disclose patient information in accordance with their ethics applications and the conditions of approval imposed by the Ethics Committee. Instructions describing how to gain access to Alfred Health electronic patient records are available on the Alfred Health [intranet](#).

#### **Researchers/auditors/monitors external to Alfred Health:**

External research personnel may require access to electronic medical records for the purposes of collection of patient information or auditing or monitoring of research activities.

In order to do this, they will need to contact a **Research Study Coordinator (RSC)** to gain access to the required records. Each research project that requires access by external personnel must have its own RSC. This person would be an Alfred Health staff member, typically the coordinator of a departmental research team, a Research Project Coordinator, an Alfred Principal Researcher or a Contact Person (for external Principal Researchers).

## GUIDELINES

- The relevant Alfred Health Head of Department is to appoint a RSC from amongst his/her staff.
- The external researcher/auditor/monitor is to contact the RSC and provide the required details for access to the electronic records. They can be advised who the RSC is through their contact in Alfred Health.
- Once ethical approval has been granted, the RSC is to complete the [Alfred Health Information Systems New Account for External Researcher/Auditor/Monitor form](#) and submit it to the ITS Helpdesk along with the ethics approval certificate and the required signatures of the relevant Head of Department and the Researcher/Auditor/Monitor.
- The Researcher/Auditor/Monitor account details, including username and password will be notified to the RSC and the relevant Alfred Health Head of Department within five working days of receipt of the form.
- The RSC, using his/her own username and password, is to use the electronic system to add the required patient information to the Researcher/Auditor/Monitor's account.
- The Researcher/Auditor/Monitor will only be able to access their account from within Alfred Health under the supervision of the RSC. Accounts are active for 12 months from creation.
- The RSC is to train the Researcher/Auditor/Monitor in the use of the electronic system. [Training](#) for RSCs is available on the Alfred Health intranet
- The RSC is to inform/remind the Researcher/Auditor/Monitor of their obligations in accordance with the conditions of ethics approval and Alfred Health and regulatory and legal requirements. Researchers/Auditors/Monitors must not print any patient information or use screen prints, use USBs or other forms of data transfer to take information off-site. The RSC reserves the right to check that these devices have not been used. The RSC may print certain documentation and de-identify patient information. The RSC should also remind the Researcher/Auditor/Monitor that an audit trail of all their access to the electronic system and internet usage can be monitored by Alfred Health.

Sponsors may require a Representation Form regarding Sites' Computerised System. This can be requested from Alfred Health. The Alfred Health Clinical Information System complies with the requirements outlined in a [generic checklist](#) though sponsors may provide their own form for completion, if required.

## FURTHER INFORMATION

Ethics Office

w: [www.alfredresearch.org](http://www.alfredresearch.org)

e: [research@alfred.org.au](mailto:research@alfred.org.au)

t: +613 9076 3619

f: +613 9076 8841

Last reviewed: September 2010
-------------------------------