

Alfred Ethics Committee Newsletter

February 2010

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Farewell and welcome

2010 sees us bidding farewell to a number of Ethics Committee members. We will miss the diverse talents of Dr Stephen Duffy who expertly chaired the Research Review Committee and then the Health & Social Sciences group of the main Committee. We also thank A/Professor Victor Kalff, Ms Fiona Ellis, Ms Fran Westmore, Rabbi Gersh Zylberman, Professor Graeme Ryan and Mr Andrew Kauler for their many years of service and commitment to promoting the highest standards of ethical research conduct at Alfred Health. Dr Tracey Caulfield and Ms Marta Ago are moving from the main committee to the General Ethical Issues Subcommittee

We have been busy recruiting new members to the Committees and wish all the new volunteers a rewarding time with us.

Which application form should I use?

CAF, NEAF, SERP?

There are now many different ways to submit an application for ethical review. We have been redesigning the [Applications](#) page of the website to try and simplify this process for you.

CAF

In the beginning there was the CAF or 'Common Application Form', comprising modules developed by the Victorian Department of Human Services. We still recommend using the CAF as an alternative to 'NEAF National'.

If you plan to conduct your research at other institutions, you should check with those institutions' HRECs to see if they will accept the CAF modules and to obtain their submission instructions.

NEAF National

These forms are suitable for research to be conducted at Alfred Health alone, or Alfred Health and other sites in Victoria and/or interstate. If the research is to be conducted at more than one site, you should also consult those institutions' HRECs about their submission requirements.

NEAF National is suitable for projects using the National Ethics Application Form (NEAF) but not using SERP, now called the Victorian Government Streamlining Ethical Review of Multi-Site Clinical Trials or the 'NEAF Streamlined' system (see below). NEAF National is an alternative to the CAF. The research may be a clinical trial, but typically will not be commercially sponsored and is more likely to be conducted by a student, or involve epidemiological or allied health research or surveys, focus groups or program evaluations.

NEAF Streamlined

The Victorian Government Streamlining Ethical Review of Multi-Site Clinical Trials (NEAF Streamlined) system is suitable for multicentre clinical trials that are eligible to undergo a single review by a CCHRE accredited HREC. www.health.vic.gov.au/cchre/

These trials are typically commercially sponsored or sponsored by a collaborative group. Researchers will normally be approached to submit under this system by a commercial sponsor or a collaborative group, who will provide instructions about the application process.

Before embarking upon your applications, you will need to consult [Angela Henjak](#), Ethics Officer, Alfred Hospital on 9076 8825 about your eligibility to use this system at Alfred Health and, if eligible, to obtain submission instructions.

Please see our revamped [Applications](#) page on our website for further information and all the forms.

Templates and PICFs

How much should I change?

There are a range of Participant Information and Consent Form (PICF) templates available on our website. They contain recommended wording for specific types of studies. They are designed to help you develop a PICF that is easy for anyone to understand.

The presentation of the PICF to the potential participant, alongside a discussion with the researcher, is a crucial part of the consent process and helps participants to become informed about the research activity and able to consider whether or not they would like to become involved.

We see many PICFs where the key messages are obscured as researchers are reluctant to leave out any of the template wording. Please consider your audience and alter, delete, amend and modify the templates as necessary. When reviewing your draft PICF, ask yourself whether the research aims, procedures and risks are clearly and unambiguously stated? Is all the information absolutely relevant to your specific study? If not, then please remove it or adapt it! Some text, such as compensation wording and injury clauses shouldn't be changed. Either keep those clauses (if applicable to your study) or delete them.

Monitoring research at Alfred Health

The Ethics Office conducts a number of audits of research projects every year, in line with the monitoring requirements set out in the [National Statement on Ethical Conduct in Human Research](#). We aim to visit each department at least once every two years in order to check that you are conducting your research as approved and to provide you with an opportunity to ask questions about any ethical compliance issues you might need help with. This is also an opportunity for us to seek feedback about our services.

Some of the issues raised by audits in 2009 included:

- projects conducted without ethics approval
- key documents missing from study files
- incorrect or out-of-date PICFs used to consent participants
- identifying information visible on CRFs (ie. hospital sticker or UR)
- 'person responsible' consent used inappropriately
- unapproved amendments, though activities carried out
- incomplete data in CRFs and in medical record.

We are moving

The Ethics Office will be moving to the Linay Pavillion, Ground Floor in March 2010.

This will enable all Ethics Office staff to be located in the same place for the first time in many years.

We will notify you of the date via the Weekly Information Pack and our website.

Some of these constitute research misconduct and may have serious ramifications for the researchers involved.

Please make sure you familiarise yourself with the [National Statement on Ethical Conduct in Human Research](#), the [Australian Code for the Responsible Conduct of Research](#) and the [Alfred Health Policy on Research Conduct](#).

Fees for 2010

Please remember to use the latest version of Module 6 and take note of the additional fee categories for 2010.

For further details see the [Fees](#) page of our website.

Low risk final reports

It is expected that most projects approved via the low risk review stream will have been completed 12-24 months after approval. Once you have completed your project you are required to submit a brief [final report](#). We are currently sending reminders for projects approved in 2008 or 2009.

Website updates

The website has recently been updated to include:

- New [Applications](#) pages and Alfred Specific Form
- Updated compensation wording in the [Participant Information and Consent Form - Clinical drug/device](#)
- Updated information on the [Radiation Safety Reporting](#) page

Don't let this be you!



"And what if I did doctor the documents?
I'm a doctor."