

Alfred Ethics Committee Newsletter

October - December 2010

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To subscribe, email
a.parker@alfred.org.au

Alfred Hospital Ethics Committee
Research & Ethics Unit
Ground Floor, Linay Pavilion
The Alfred
55 Commercial Road
Prahran Vic 3181
Melbourne, Australia
t: 9076 3619
f: 9076 8841
e: research@alfred.org.au
w: www.alfredresearch.org

Farewell to Eve

We will miss you...

We are sad to announce that after ten years, the much-valued and ever-reliable Eve Kovesdy is leaving us. We are not quite sure how life will be without her here. We ask for your patience and understanding while we try to learn the intricacies of handling the enormous volumes of paper that pass through here.

She is planning to enjoy her retirement with an action-packed program of camping, overseas travel, cookbook writing and much more. Eve will leave us in early December.



2010 snapshot

We have reviewed 415 projects so far this year, comprising:

- 149 projects reviewed by the Drugs and Interventions Group of the Ethics Committee, including 40 through the new streamlined review process.
- 96 projects reviewed by the Health and Social Sciences Group
- 166 Low risk projects
- 4 cross approvals.

In addition, the seven administrative staff in the Ethics Office and the 52 Ethics Committee members have reviewed 720 amendments, 138 Investigator's Brochures and 608 progress reports.

VMIA Research Governance Toolkit Training

Free training sessions for all researchers

The [Research Governance Toolkit](#) has recently been developed by the hospital's insurer, the Victorian Managed Insurance Authority (VMIA). It has been developed to assist Victorian public entities, such as Alfred Health, to conduct quality clinical research. The toolkit was launched here during Research Week.

Five training modules are being developed to reinforce the information contained in the toolkit and improve the quality of research applications and governance across Victoria. The topics comprise:

1. Research Governance and Ethics
2. Induction, Training, Accreditation
3. Research Finance Management
4. Data, Tissue Banking and Radiation
5. Legal & Insurance, Risk Management, IP and Publications

Alfred Health staff are invited to attend the free training sessions here (or at other Victorian public hospitals) next year. The dates at The Alfred will be:

- Module 1 - 22 Feb @ 1.30pm
- Module 2 - 19 Apr @ 1.30pm
- Module 3 - 28 Jun @ 1.30pm
- Module 4 - 30 Aug @ 1.30pm
- Module 5 - 26 Oct @ 11.00am

The sessions in the AMREP Seminar Room, will last two hours, with a focussed presentation of the content in the first hour and the second hour reserved for structured questions and answers. Participants are tested and receive a certificate on completion of the training module.

From mid-2011, the modules will be available online, through our website.

It is hoped that better training will lead to quality applications, faster approval, more research activity and more resources for research. Research output will be increased and risk reduced.

2011 meeting dates

Next year's dates have been posted on our [website](#), so you can get organised!

January 2011 Meeting of the Ethics Committee

There has been some demand for ethics applications to be reviewed in January 2011 and in response the Ethics Committee has decided to convene an extraordinary meeting for **Tuesday 25 January 2011**.

Any researcher wishing to submit an application for review at this meeting will need to:

- Submit a full electronic version of their application
- Justify why their application should be accepted for review at this meeting
- Agree to pay \$300 for assessment of their justification and application (there will be no refund, even if the application is disallowed)
- Be available for interview at the meeting if required. The meeting begins at 4pm.

The ethics application and response to the other points above are to be emailed to research@alfred.org.au by Monday 10 January 2011. The Committee will use its own discretion in deciding whether to accept applications or not. Any application not accepted will be held over until the February meeting.

Handy hints for the perfect PICF

The Participant Information and Consent Form is integral to the consent process...

- Choose the [template from our website](#) that is appropriate for your study
- Remove any text that is not relevant for your project
- The PICF should not be overly long
- Avoid repeated information, 'cut and pasted' text from protocols, and information that merely pads out the PICF and obscures the key messages of what is to take place and the risks involved
- Check that the level of detail provided is appropriate to the risk-level and complexity of the study
- Make sure the formatting is consistent throughout, eg. headings all the same size and font; paragraph spacing consistent; sections numbered consecutively
- Ensure the consent section is embedded within the document, before the contact section.
- Collection of human samples needs to be a separate section within the consent section
- Provide direct contact phone numbers for researchers rather than the main switchboard numbers.

- Use the [recommended wording](#) we provide if appropriate
- The information about consent for future use of data and/or human samples needs to be clear, i.e. types of future research; that this research would be ethically approved; that only the applicable check boxes in the template are retained (and/or adapted as appropriate)
- Ensure the PICF is developed with close reference to the [Guidelines for research that potentially involves legal risks for participants and researchers](#) when the research may have potential legal risks for participants and/or researchers
- Information and Consent forms for third parties need to be checked to ensure that they address the third party (i.e. the third party is the person referred to as 'you' in the form) and refer to the participant/patient/ relative using a consistent term. This includes amending the various sub-heading in the form, which are often overlooked.
- Thoroughly check the entire document for clarity, sense, applicability, spelling and grammar.

People often forget to mention the following when appropriate:

- if the research will contribute towards a student's qualifications
- if information is being collected from the participants' medical records and when (at what time points)
- if information from the medical record will be accessed by someone who is not an Alfred Health staff member.

Season's Greetings



We wish all participants, researchers, ethics committee members and sponsors a safe and restful festive season.

We thank all researchers for their cooperation and valuable feedback throughout the year and the Ethics Committee members who have donated their time to reviewing research at Alfred Health.

We will be closed for the period between Christmas and New Year.

