January – February 2014

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Alfred Health Ethics Newsletter

A new ERA

We would like to take this opportunity to announce a new 'era', changing the way Alfred Health will manage ethics applications and review. After going paperless in January 2012 the next stage is a web-based ethics application management system named 'ERA' (Ethics Research Admin).

The Office of Ethics & Research Governance has developed ERA in collaboration with a software design company. At this stage the aim of ERA is to facilitate the submission and review of all new ethics applications via a web-based portal.

Instead of submitting the full ethics application by email, researchers will be able to upload the documents onto ERA. The Ethics Committee (EC) will review the applications and upload their comments via ERA. The system will automatically send email notifications to researchers and the EC, alerting them when their next action is required. Amendments will be managed similarly.

ERA is set to go live in April 2014 and be utilised for all ethics applications for consideration at the April EC meeting, i.e. for applications submitted for registration on 24 March 2014.

The process is the same for project registration (initial submission, no signatures). Please send the application for initial submission to research@alfred.org.au.

All relevant ERA information and instructions will be sent to after your application has been received. There is no need to contact us in advance to register for the new system.

More information and instructions on how to use ERA will be available on our website around mid March.

While ERA has been primarily developed for the purposes of the Ethics Committee and the Research Review Committee, we hope that the system will be user-friendly to researchers and that it will make the submission and review of ethics documentation more efficient.

New requirements for full submission

In a response to a directive from Alfred Health we are going to implement strategies to help reduce the time to approval of ethics applications presented to the Ethics Committee. Please note that these strategies will be **implemented** for applications going to the April EC meeting, i.e. for project registration on **24 March 2014**.

To facilitate the timely review and approval of new projects we require the following documents to be included:

- a. For project registration
- Sign-off for any 'pre-ethics' assessments (Caulfield, NRAC, Health Informatics)

For the Nursing Research Committee and Health Informatics please include the relevant signed Resource Centre Declaration at project registration.

For Caulfield Hospital, either one of the following at project registration:

- A copy of the Notice of Intention with the "Authority to Proceed" section signed; or
- An email from Nicole Austin confirming that the project is authorised to proceed.
- b. For the full submission

All application forms, associated documents and the following items, which previously were not mandatory at full submission:

- Finalised legal documents (contract, indemnities, CTN, insurance certificate) electronically and in hardcopy (insurance certificate electronically only)
- Finalised budget
- Completed Medical Physicist report
- Fully signed Resource Centre Declarations

New arrangements

Please note that the management of the Office is now shared between Rowan Frew, (now working two days a week) and Angela Henjak, who has been appointed Co-Manager. Angela will be working in this position for two days a week. Please direct manager-relevant enquiries to either Rowan or Angela.

The remainder of the week (three days) Angela will continue her work for the Drugs & Intervention sub-committee. If Angela is not available you may contact Katja with urgent enquiries.

Please make an appointment with any staff member you wish to meet with to allow us to manage our time efficiently and address your enquiries in a timely manner.

Please deliver documents for Angela, Nicole or Katja in their respective trays. Documents to be collected can be picked up from Angela's or Katja's collection trays.

On the funny side...

The link between cooking and participant confidentiality; from a PICF:

"The information will be stored securely with access restricted only to registry staff, each of whom is committed to *marinating* confidentiality."

Did you know that the probability of guessing your project number correctly is approximately 1:18,000?

Your odds of randomly guessing your project number right are far better than winning the lottery (1:8,145,000). But you are less likely to get your number right than to hit a hole in one (1:5,000) or finding a four-leaf clover on the first try (1:10,000). Our database includes projects from 1990 to 2014. To make our work easier it would be greatly appreciated if you could clearly state your project number in any correspondence. Thank you.

(We do not take any responsibility for our attempts at statistics.)

Reminder

Please remember to liaise with the Office regarding any streamlined application (SERP or NMA) prior to your submission to check that the proposed research meets the scope.

Further instructions for NMA submissions are available on our website.

Please note:

- Studies involving consent via the Guardianship and Administration Act 1986 are outside of the scope for this review process.
- Projects cannot be converted to NMA retrospectively.

of is Updates to

a) DOCUMENTS

• Fee schedule and fee payment form

The fee schedule and fee payment form have been amended. Please refer to the website for the updates. The completed fee payment form must be included with every submission, even if no fee is applicable for a study. The information provided is assessed in relation to the ethics application to ascertain that the correct fee category has been nominated. Please contact Emily Bingle if you have any questions.

• Health Informatics Resource Centre Declaration

A Resource Centre Declaration for Health Informatics is now available on our website. Please obtain sign-off from Health Informatics before submitting your application for project registration.

Liaising with Health Informatics is relevant for all applications involving Clinical Quality

b) ETHICS WEBSITE

Dates

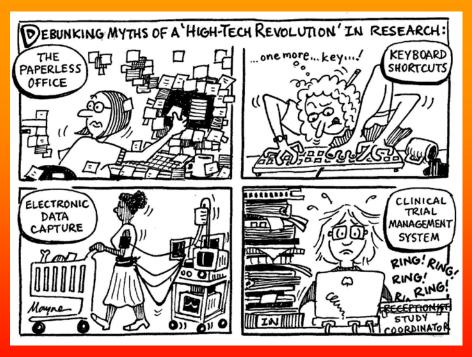
Registries.

The new requirements for full submission will be included on the 'Dates' page.

If you require advice regarding mandatory documents applicable to your ethics submission, please contact the Office in advance before submitting.

Guidelines

Please refer to the website for an updated 'Conflicts of Interest in Research - Researchers and Institution' guideline.



The Research Review Committee: Interview with A/Professor Kate Cherry

What made you decide to become an RRC member?

I was invited to join the RRC when Jenny Hoy became the Head of HIV services and left the Committee. And as I liked being on the RRC, I stayed.

Since 2010 you are also an EC member. How would you say the two Committees differ from a members/reviewers point of you?

The most obvious difference would be that the RRC is a scientific committee. Projects are reviewed by researchers and clinicians. The membership on the Ethics Committee is much broader. You also have lawyers, a minister of religion and lay people. The problems discussed at the EC are more general, while the RRC concentrates on scientific and medical issues. I enjoy both committees in different ways.

What do you enjoy most about working on the RRC?

One of the key things is that I got to know some really great people here at AMREP, some of them I had not had a chance to meet in person before joining the Committee. I also enjoy learning something new from the studies we review. It is a good way to keep up with current research.

Well, the rest of the RRC would say they enjoy your baking most of all. Where do you get your inspiration from? What is your favourite recipe? I like eating and I like cooking. This is my once a month opportunity to try a new recipe. And my favourite recipe would be cranberry-pistachio biscotti.

After the positive – what do you find challenging about the RRC?

The time commitment is definitely the most challenging aspect of it.

When you review ethics applications what is the most common error you come across? What annoys you most? Poorly completed applications are without a doubt the most annoying. You often get the sense that the person who filled out the application documents has not actually read the protocol.

You have completed your PhD in the field of sensory neuropathy in HIV. What research are you currently involved in?

I am still involved in HIV neuropathy research in South Africa. As a part-time researcher in Australia I mostly help out on other people's projects, for example with their data analysis. I am involved in a broad range of different projects, which is a lot of fun. Who knows what I will be working on in a couple of years time!?

And which recent HIV research do you find most exciting?

I think that would be the emerging research towards a cure of HIV. It would be truly amazing to see a disease of this magnitude emerge and disappear within one's life time. I am not sure whether that will happen, but there is some promising early data.

Which projects outside your area of expertise do you enjoy reviewing? I enjoy reading any well thought through and well written applications; anything where I can learn something.

I have read that you collaborate with the University of the Witwatersrand in South Africa. Have you had a chance to visit South Africa? What has made a lasting impression on you?

I visited South Africa last year and I am going again in May. Two things made a lasting impression on me. One was to see first hand the challenges involved in providing medical care and conducting research in South Africa (Can you believe patients must walk several kilometres in the hot sun to get from the pharmacy to where their blood is taken? And these are patients with neuropathy, so their feet hurt!). The other was that I was fortunate to see unspoilt areas, untouched by tourists, and animals in the wild. For example, my colleagues took me along on a field visit to an animal behaviour research project in the Karoo district of the Cape. After driving for four hours on a dirt road we arrived at the site, where monkeys had become habituated to the presence of researchers who have spent months with them. The researchers now observe the monkey colony throughout daylight hours to understand their behaviour. Obviously the monkeys were not used to my presence, but after sitting quietly for an hour, they started to ignore me and pick fleas off each other. While I was there I also saw all kinds of other beautiful

animals in the wild, too: giraffes, elephants, rhinos, various antelope species and even a deadly puff adder at close quarters!

You are a member of the Australian Doctors Orchestra. Which instrument do you play and where can our readers enjoy a performance?

I play the viola. Our next concert 'To Russia with Love" to raise funds for Lung Cancer Services at The Royal Melbourne Hospital takes place at the Melbourne Recital Centre 5 pm on the 9th of March. This will be Corpus Medicorum (Melbourne-based medical orchestra).



Being a cat person myself (don't tell my dog I said that), can you share a funny story about your cat Harvey with us?

Harvey wanders off to the local primary school quite often, because he likes the children there. When I was participating in the 2013 MS Readathon as a volunteer, "his" primary school initially was not going to take part. When it became known to them that Harvey would be involved, they changed their mind and decided to participate since (quote): "Harvey is the school community." He sat purring in his own chair in front of the assembly the whole time I was there speaking with the children! The children asked very good questions and the school ended up being one of the top fundraising schools in the Readathon. At the end of our visit, the vice-principal asked all children with a cat allergy and the ones who did not wish to pet Harvey to return to their class - about 20 children left. The remaining ~300 children lined up to pet Harvey, who did not mind at all. Harvey is very good with children. Would you believe that he is a pound rescue?

The interview was conducted by Katja Loewe.