# Alfred Health Ethics Newsletter

January – February 2015

## Inside this issue



**To subscribe, email**
**k.loewe@alfred.org.au**


Alfred Hospital Ethics Committee
Ethics & Research Governance
Ground Floor, Linay Pavilion
The Alfred
55 Commercial Road
Prahran Vic 3181
Melbourne, Australia
t: 9076 2281
f: 9076 8841
e: research@alfred.org.au
w: www.alfredresearch.org


## Addition of Opt-Out Approach to National Statement

Chapter 2.3 of the National Statement has been updated to incorporate guidance for the use of an opt-out approach to recruiting participants into research. An opt-out approach refers to a recruitment method where potential participants are provided with information about the research as well as their involvement and where their agreement to be included in the research is assumed unless they object.
This alternative to consent has, for some time now, been accepted by Ethics Committees for certain research. Positioning opt-out before the guidance on waiving the requirement for consent in chapter 2.3 the NHMRC suggests researchers and ECs may prefer opt-out over a waiver in research where participants can be reached for the purpose of enabling them to decline participation in research if they wish to do so. The opt-out approach respects people's right to autonomy by giving them the opportunity to make their own decisions; a feature absent when a consent waiver is requested.

The National Statement outlines the following criteria that need to be satisfied when considering an opt-out approach (please see chapter 2.3 for more information):
• The research carries no more than low risk
• The public interest in the research outweighs the public's interest in the protection of privacy
• 'Near complete' participation is essential for valuable outcomes to be generated by the research
• Strategies are in place to disseminate relevant information to prospective participants as well as to enable them to obtain further information and to opt-out
• The time period between information being distributed and participants' data being used must be reasonable
• Data is managed and maintained securely
• Governance processes are established outlining responsibility for the project and for data management

## Updates to…

**a) PROCESSES**

- **Radiation – changes to reporting to regulatory authority**
  All projects that involve ionising radiation additional to standard-of-care had to be sent to the Radiation Section of the Department of Health and Human Services previously, for notification or approval, depending on whether or not dose constraints of the ARPANSA Code were exceeded.
  The requirements for reporting have changed in January 2015. The Department now only has to be notified of projects where the dose of radiation is above dose constraints. For these studies the radiation license holder notifies the Department after ethics approval has been given. The Ethics Office will take care of notifications for Alfred Health studies. Studies conducted by external organisations (e.g. Baker IDI, Monash University Nucleus Network) have their own radiation license. Notification is therefore organised by these organisations.
  It is worth noting that projects may commence prior to the notification being submitted to the Department.

**b) DOCUMENTS**

- **Victorian-Specific Module**
  The VSM and the VSM guidelines have been updated to incorporate the changes to reporting requirements regarding projects involving ionising radiation. Please ensure to use the January 2015 version.

- **CTN form**
  The Clinical Trial Notification (CTN) Form has been updated. Please ensure to use the latest version (July 2014) with your ethics application.

- **Resource Centre Declaration**
  The forms for 'Pharmacy' and 'Lung Function' have been updated. These can be downloaded from the 'Resource Centre Declaration' page. Turn-around times for Pharmacy is at least 7 business working days and up to 2 weeks for lung function (refer to relevant request form for more information).

• An opt-out approach is not prohibited by state, federal or international law

The opt-out approach may be appropriate for clinical registries, epidemiological studies or other kinds of low risk research that involve collecting and using data from a very large number of people.

To fulfil the requirement to provide participants with relevant information, different strategies may be employed, e.g. media announcements or a brochure may be given to potential participants.

It is important to note that an opt-out approach does not constitute consent as per the Privacy Act 1988 for the use of identifiable information.

While not contained in the Privacy Act, information on opt-out is included in the Australian Privacy Principles guidelines (March 2014), published by the Office of the Australian Information Commissioner. It is highlighted that these guidelines are neither legally binding nor do they constitute legal advice.

When considering whether consent, opt-out or a waiver should be sought for a particular study, it might be worthwhile to note that a mix of these 'approaches' might be appropriate for different elements of the research project.

# Welcome and Goodbye

We welcome Dr. Penny Mayes to the Ethics & Governance Office and look forward to working with her.

We had to say goodbye to Kath Frowen in November last year. Kath has been invaluable in looking after low-risk applications. Luckily she is still around, working in Dermatology, which softened the blow. That she is abandoning us to spend more time with this cute lady is hard to take though! ;)

Emily is now looking after low-risk projects. If you wish to submit a low-risk application please refer to the Low Risk Guide first to establish whether your study fits into this category.

# Eligibility for Expanded Scope of SERP

The scope for the types of research eligible for the Victorian Streamlined Ethical Review Process (SERP) has expanded to health and medical research. However, it will be a requirement for all researchers intending to submit a SERP application that they have either already prepared one previously or have attended a streamlined process training session (see below). We are also in the process of modifying application forms to capture information for non-clinical trials. Therefore, please contact the Office prior to submitting or being included in a SERP application.

# Education sessions for Alfred Health/ AMREP researchers

The office is offering training for researchers on different topics. Please see the table below for more information and register your interest by contacting Emily (9076 3619).

ARCS Australia is offering GCP Training for coordinators in Melbourne on 12-13 March and 15-16 May. Different e-learning courses are also available.

| Title | Date | Time | Location |
|---|---|---|---|
| Streamlined Ethics Review Process – Reviewing Site Applications | 17/Feb/2015 | 10:30AM - 11:15AM | AMREP Education Centre Classroom 3 |
| Streamlined Ethics Review Process – Accepting Site Applications | 18/Mar/2015 | 10:30AM - 11:15AM | AMREP Education Centre Classroom 1 |
| Legal and Regulatory Documents | 22/Apr/2015 | 10:30AM - 11:15AM | AMREP Education Centre Classroom 3 |
| Low risk Applications or Reviewing Site Applications (TBC) | 20/May/2015 | 10:30AM - 11:15AM | AMREP Education Centre Classroom 1 |
| PICFs for streamlining or Accepting Site Applications (TBC) | 18/Jun/2015 | 10:30AM - 11:15AM | AMREP Education Centre Classroom 3 |
| Registries | 15/Jul/2015 | 10:30AM -11:15AM | AMREP Education Centre Classroom 2 |
| Streamlined Ethics Review Process – Reviewing Site Applications | 19/Aug/2015 | 10:30AM - 11:15AM | AMREP Education Centre Classroom 1 |
| Streamlined Ethics Review Process – Accepting Site Applications | 17/Sep/2015 | 10:30AM - 11:15AM | AMREP Education Centre Classroom 3 |
| Legal and Regulatory Documents | 14/Oct/2015 | 10:30AM - 11:15AM | AMREP Education Centre Classroom 3 |

# The Research Review Committee: Interview with Professor Flavia Cicuttini

**What made you decide to become an RRC member in 2013?**
There are a number of reasons. As a researcher, I have experienced the amount of work that goes behind the scenes regarding the ethics for research projects. Although this can feel frustrating when you are trying to get a study going, it is central to making sure that studies are undertaken in accordance with current community expectations. This is a lot of work. I was happy to be able to contribute…plus I got a call by Colin Johnston….hard to refuse!

**What do you enjoy most about working on the RRC?**
It is a great team of people to work with….very dedicated. The studies we are asked to review are very interesting. Each of us works in our own area. It is interesting to see the extent and breadth of work that is currently being undertaken across the field of health. This ranges from 'first in human' studies through to post marketing surveillance. The extent of the innovation in tackling different clinical conundrums is very impressive and reassuring.
…and one cannot fail to mention the amazing cakes Kate Cherry bakes for each meeting!

**And what do you find challenging about reviewing projects for the RRC?**
As a consequence of the huge variety of research work that is being undertaken, the studies are often very challenging to get your head around. The new molecules being targeted are almost always in pathways that were unknown not that long ago…it is not dissimilar to reviewing NHMRC grants every month.

**Which projects outside your area of expertise do you enjoy reviewing?**
I find the development of new devices/ new approaches to treating diseases very interesting, particularly when studies are presented that explore therapies for diseases where we have little or no treatment, compared to the ones where it looks as if they represent minor advances over currently available treatments.

**You are the daughter of Italian migrants. Which Italian dish is your favourite? Do you cook a lot of Italian meals?**
Pasta marinara is definitely my favourite. I would love to say 'yes, I cook lots of Italian food and I am a great cook.' The problem will be that Kit, my husband, may see this piece (and he does a lot of the cooking at home), as may Jess, my daughter, who now also works at the Alfred, and also does a lot of the cooking. I can say, however, that when I cook it is usually Italian food, and my cooking is not bad.

**Osteoarthritis, one of your research interests, affects an estimated 1.6 million Australians. What new treatments are in sight for patients? Do you think a cure is likely to become available in the near future?**
I think there will be effective treatments soon. Cures are not around the corner. One of the big problems in dealing with osteoarthritis (OA) is that, although clinically it is still thought of as one disease 'osteoarthritis,' this is not the case. The reality is that we are dealing with a very complex set of diseases. For example, in the first instance, not all joints behave in the same way. So, for example, knee OA, hip OA, hand OA, back OA etc. are all very different diseases. Therefore, the treatments are unlikely to be the same, so we need to look at each joint separately. If we then turn to one joint e.g. knee OA, we now know that you need to consider knee OA as a disease of a joint that has 'failed,' but the pathways, and thus the mechanisms, may be very different in different patients. This means that treatments will not be the same for everyone. There is currently no disease-modifying treatment available for OA. However there are a number of studies currently underway examining new treatments. For example, we are currently doing two NHMRC funded studies examining very different pathways for knee OA. One is examining the bisphosphonate, zoledronic acid, to see if it will act as a disease-modifying agent in knee OA, while the other is examining a statin. These studies are examining very different disease pathways in knee OA. OA has come a long way over the last two decades and I am confident that we will have disease-modifying treatment approaches soon.

**You also teach at Monash University. Which topic do you find challenging to teach and why?**
I have a long history of teaching epidemiology. I first learnt epi at the University of London as a post-doc, having completed a PhD in immunology. I found the subject very interesting and useful. I remember my first teaching job was to teach epi, many years ago, to second year med students in the old curriculum. This task was about as hard as it gets! It was very difficult to teach epi when it was in direct competition with the huge amounts of anatomy in the curriculum at the time. Students could easily accept that the large swags of anatomy were important, but less so with epidemiology. The curriculum has changed a lot since then with a more integrated teaching model. In contrast, post grad teaching is much easier.

**You completed your PhD at The Walter & Eliza Hall Institute and worked for the institute afterwards. What made you change from the bench to clinical research?**
I loved my time at the WEHI. However I felt that as a clinician I could make a bigger contribution by doing clinical research. The experience at the bench, however, set me up well for the work I ended up doing. I remember when I first started exploring the use of MRI to examine knee cartilage I was told it was not possible. I soon found out that measuring was very tedious and laborious, but definitely possible. It was really a matter of sitting there, doing very boring, repetitive measures carefully and realising that it could be done. Having trained in lab work where my project involved selecting stem cells from cord blood 3 times a week

(starting at 7 am so the cells were ready for sorting at 2 pm), sorting for 3 hours and then starting the final experiments at 5 pm, the tedious MRI analyses work was a breeze!

**You are also a member of the Epworth Human Research Ethics Committee. Are there differences in working for different Ethics Committees?**
I have a somewhat different role at the Epworth HREC. There my task is to review the grants from a methodological view point, as the epidemiologist on their Committee. My role at the Alfred is broader. However my experience with the Epworth HREC is also very positive, with a great team working there as well.

**If you are not busy with research, clinical work, teaching or reviewing – what do you enjoy doing in your spare time?**
I love gardening. I fit that into my spare time. Weekends have a lot of social activities both with family and friends. I think life outside work is important as it allows us to put everything we do in perspective.

# Belated Christmas Quiz

After some (justified) grumbling that there was no December newsletter and thus no Christmas Quiz, we hope to make amends by publishing a Christmas Quiz that the Ethics Committee had the pleasure/frustration of completing at the December EC meeting:

1. Which is not part of the NHMRC's PICF templates (only choose one)?
   a. Informing participants that their medical records will be accessed
   b. Stating a contact person for complaints
   c. Specific wording when HIV/hepatitis/TB testing is performed
   d. Requiring a male participant to inform his partner(s) of his trial involvement

2. Which country celebrates Christmas on the 25th of December (only one answer)?
   a. Italy
   b. Germany
   c. Iceland
   d. Romania

3. What is the average number of amendments reviewed per primary reviewer in 2014 (EC and Research Review Committee; up to 15 Dec)?
   a. ca. 10
   b. ca. 15
   c. ca. 20
   d. ca. 25

4. Which statement regarding section 42T (procedural authorisation) of the Guardianship and Administration Act is incorrect (only choose one)?
   a. The procedure is a medical research procedure.
   b. The procedure is necessary, as a matter of urgency to save life, prevent serious damage to health or prevent significant pain or distress.
   c. A person responsible cannot be identified and contacted in time.
   d. After the procedure has been performed, the supervising registered practitioner must forward the relevant certificate to the ethics committee and the Office of the Public Advocate.

5. Which country won the soccer World Cup in Brazil in 2014?
   a. Brazil
   b. Argentina
   c. Germany
   d. Netherlands

6. Which statement derived from the National Statement is incorrect (only choose one)?
   a. 'Human biospecimens' refers to any biological material obtained from a person including tissue, blood, urine, sputum, any derivative from these including cell lines and biological material such as micro-organisms that live on or in a person.
   b. An opt-out approach to participant recruitment in research may be appropriate when, unlike a waiver, it is feasible to contact some or all of the participants, but where the project is of such scale and significance that using explicit consent is neither practical nor feasible.
   c. The National Statement avoids the term 'de-identified data', as its meaning is unclear.
   d. The expression 'low-risk research' describes research in which the only foreseeable risk is one of discomfort.

7. Which Echidna fact is false (only choose one)?
   a. The spines are made of keratin.
   b. The baby teeth are shed early and replaced by rooted adult teeth.
   c. Its pointy snout can sense electrical signals from insect bodies.
   d. Echidnas can be found all over Australia and in New Guinea.

8. Who is responsible for ensuring that any research conducted at Alfred Health or approved by our EC involving ionising radiation complies with the ARPANSA (Australian Radiation and Protection and Nuclear Safety Agency) Code of Practice?
   a. The Medical Physicist
   b. Radiation Advisory Committee (Department of Health)
   c. Researcher
   d. Ethics Committee

Please see the answers to the quiz' questions here:

1D, 2D, 3C, 4B, 5C, 6A, 7B, 8D

Some explanations:
Question 4: The second statement relates to Section 42A of the GAA for which no consent is required. The medical research procedure can be performed on the patient.
[Medical research procedure cannot be conducted if there is a relevant refusal of medical treatment under Medical Treatment Act (S. 42P(5).]

Question 6: Biological material such as micro-organisms that live on or in a person are of non-human origin and therefore not classified as 'human biospecimens' – see recently revised chapter 3.4 of the National Statement.

Most importantly – question 7:
Echidnas do not have teeth. They have horny pads in their mouths and on the back of their tongues which grind the prey. Hedgehogs on the other hand have 36-44 teeth in a long, pointy snout.