AABHL Conference 2014 Perth - How should we decide?

By: Simon Gill, Laywer

Held in the grounds of the University of WA, Perth, the 2014 AABHL conference in bioethics and health law was an extensive conference over 3 days covering a diversity of topics and fields from around the world. The difficulty was in choosing which sessions to attend. The following is a summary of my recollections of a few papers presented which I suggest is a taste for Bellberry members to follow up anything of interest. Information about the program can be found here: http://www.conferencedesign.com.au/aabhl2014/program.html
and conference papers are available online to members of the association.

The conference also provided a good opportunity to meet members of other HRECs from around Australia and to discuss topics of interest, share knowledge, learn from other practices and discuss areas of difficulty. Also, it is good to hear practitioners speaking freely of their own personal and professional experiences in attempting to innovate and experiment while staying focused on treating patients.

There was a theme through many papers about innovation in practice and the pressures placed on that by institutional and legal frameworks. For example, in an inspiring talk, **Dr Elmi Muller** (Cape Town) spoke about her battle with institutional and regulatory structures and practices to bring innovation to healthcare (kidney transplantation) for HIV patients. In dealing with a patient group that is often denied treatment and simply sent home to die, Dr Muller proceeded alone to harvest and transplant organs between patients with HIV. Dr Muller takes the view that medical situations must be dealt with using rules of 'maximum possibility', that a doctor is to treat patients at maximum ability/capacity which may sometimes be in conflict with institutional processes and rules and even laws. Dr Muller described a period of years in the wilderness, during which disciplinary action was taken against her and after which she has successfully brought reform that now allows transplantation of organs between patients with HIV.

Other papers looked at difficulties with consent processes and offered solutions. **Dr Alastair McDonald** spoke of a survey of Resident medical Officers in NZ and found that there are major issues in the hospital environment with getting consent of patients and with assessing competence, both of which are requirements of law. He found that most hospitals are not set up for the process of obtaining consent (a lack of a quiet space or sufficient time) and the focus has become on getting signatures, rather than giving information and promoting understanding. In the survey 60% of respondents said that they are unable do it properly. Furthermore, while 90% of respondents said that they were confident to assess a patient's competence to consent, less than 60% were actually assessed as able to properly do this. Dr McDonald called more education and, at times, for regulators to be placed in hospitals and follow junior doctors to see such matters are limited in practical circumstances.

Dr Rebekah McWhirter from the Menzies Institute for Medical Research has, in her research with Indigenous women in Arnhem Land, explored other ways to obtain consent from participants while satisfying the requirements of the National Statement. In considering drawbacks of common lengthy, technical written PIS documents and considering that 46% of Australians are functionally illiterate, Dr McWhirter sought to try a different approach to consent that does not rely on literacy so much and that can be effectively tailored to an audience and can be modern. In a research project they developed a consent process that used interactive Q&A, an iPad app and video presentations. While the cost of the project was high (for app development) they considered this an effective way to promote understanding in participants rather than just information disclosure. We may see some of these apps in the near future at Bellberry as the app may be licensed for use in other areas.

Dr Lisa Eckstein raised certain concerns about data safety monitoring boards (DSMBs), such as wide discretion and commercial confidentiality, and suggested that there should be more oversight of such boards which may be provided by HRECs. In support of this argument she referred to a breast cancer prevention trial in which a DSMB authorised the continuation of a placebo arm in circumstances where statistical results raised concerns. In that trial 65 women in the placebo arm developed cancer and were not able to switch over to active drug. She suggested a number of avenues for reform including proactive HREC monitoring.

Dr Bernadette Richards spoke about innovation in surgery and the issues faced by surgeons when seeking to try new surgical techniques for established procedures. A number of high profile cases in the UK had resulted in the *Medical*

Innovation Bill (UK)("the Saatchi Bill") drafted to encourage *responsible innovation*, whereby a practitioner could depart from standard care 'if responsible', which was defined to include peer review, consent of the patient etc. This type of innovation may be done without the need of a trial protocol and the approval of an HREC and would extend to experimental drug supply.

Professor Christobel Saunders gave the Kirby Oration on breast cancer screening and postulated that too much screening was taking valuable time and resources away from treating the seriously ill. Professor Saunders, while acknowledging benefits and successes of screening, queried whether actual survival in breast cancer is affected. She referred to a study where 2000 women were screened over 10 years: 1 life was saved, 200 false alarms created, 10 pseudo cancers treated unnecessarily. Furthermore she stated that as a result of thyroid cancer screening, the reported incidence of thyroid cancer increased 200% while mortality form the condition has remained the same. Negatives of screening include overdiagnosis of indolent cancer, radiation risks, hospitalisation, false positives and stress. She believes that self-examination can be just as effective and that screening is not necessarily going to make a difference in the case of lethal, fast-growing cancer. Less can be more and psychological well-being, which can be unnecessarily interrupted by a false positive, is also important to consider when deciding who, and whether, to screen.

Justice Endlemen gave a very thorough and interesting analysis of the law of property and how it relates to ownership of human bodies and parts of human bodies when separated from the body. His paper in full can be found on the WA Supreme Court website and is well worth a read. He was motivated to present on this topic after dealing with a case in which he had to rule on the removal of sperm from a deceased male on the application of the deceased's wife. In that case, Justice Endlemen made an order using a power of the court to deal with the preservation of property. He concludes that while the law is equipped to deal with questions of removal of body parts such as organs, through the decision of authorised persons located in hospitals , the removal of gametes, as in the case he had to decide, is more problematic with very difficult policy questions and is not properly articulated in statute, while the common law will be of great assistance. A further reference was provided: Goold et al, Persons, *Parts and Property* (2014).

http://www.supremecourt.wa.gov.au/_files/Australian%20Association%20of%20Bioethics%20and%20Health%20Law%20Conference%20by%20Edelman%20J%203%20Oct%202014.pdf

Sid Baxi (left) and Simon Gill (right) with Dr Michael Anderson, Chair of Ramsay Health Joondalup Hospital HREC 2014 AABHL Conference, Perth

AABHL Conference 2014 Perth

By: Dr Siddhartha Baxi, Radiation Oncologist

From 2-4th October the Health Law and Ethics community met at UniWA, Perth to listen, discuss and debate many of the contemporary ethical dilemmas facing society with overseas delegates from South Africa, China and Taiwan. From an oncologists perspective it was great to meet and debate topics without the need for p values and response rates - a refreshing change indeed!

Keynote speaker Dr Elmi Muller, transplant surgeon in South Africa described her 5 year journey and ethical dilemmas faced in pursuing the concept of HIV positive kidney donors to transplant into HIV positive end stage kidney failure patients as a form of providing a transplant pool for these patients. In a population where 10% of the 50M people are HIV positive, the health resource dilemmas, who was responsible for policy application and ethics of the greater good were significant challenges. 5 years on she is overseeing a HIV positive donor program with wide acceptance - a courageous journey rewarded with an extended applause.

Some interesting topics that caught my eye were:

- the stem cell debate continues - with insurance companies in Australia bowing into the debate by supporting these therapies
- A very insightful talk by Ms Lin from UWSyd on the topic of the 18000 health workers in Chinese hospitals that are injured as a result of upset patients and families seeking better communication and a "sorry" over adverse outcomes. Comparatively, the culture of sorry in Australia is a form of empathy / sympathy while in China it is a sign of acceptance of fault, and therefore is not advocated for resulting in animosity. Well described in this reference -http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(14)61436-7/fulltext
- Dr Jane Wilson of USyd argued that in the informed consent process, we had swung too far and that it was time to swing the balance back towards paternalism again
- Dr Viki Xafis of UniSA discussed an interesting study of how education around the data linkage concept to patients had resulted in increased rate of consent for linkage and an increased trend to accept non-consent for data linkage, indicating how an educational program might be implemented at a population level to achieve a opt out program.
- The classic futility in health care debate rages on with doctors being studied - an interesting study by Prof Ben White form QUT identifyied that doctors felt the key drivers of treatments deemed to be futile, were driven by doctor and institutional factors with patient driven decisions coming in at last place.....food for thought there...
- The e-cigarette debate and its impact on society was discussed by Prof Roger Magnusson from Syd Law School - that there is a greater public harm in its current form where non-nicotine e-cigarettes might encourage the social habit of the smoking act in "never to be" smokers which leads to then smoking later on - a reason why the cigarette companies might be getting into this market and placing the marketing in parallel with their traditional marketing campaigns to align future smokers into the habit with e-cigarettes initially.

It was a diverse group of registrants and certainly very informative and a good networking opportunity. For those interested AAHB will be in Wellington next year (your harrowing landing at Wellington Airport in included in your registration!)

Sid Baxi, Margaret River

The Monash Centre for the Study of Ethics in Medicine and Society

Intensive Research Ethics Course November 2014

By: Anne Ozdowska, Community Representative

Presenters:

Paul Komesaroff
Ian Kerridge
Colin Thomson
Kandy White
Jeanne Daly
Bernie Slagtman – Aids survivor
Suresh Sundram
Martin Delatycki
David Isaccs
Lilon Bander

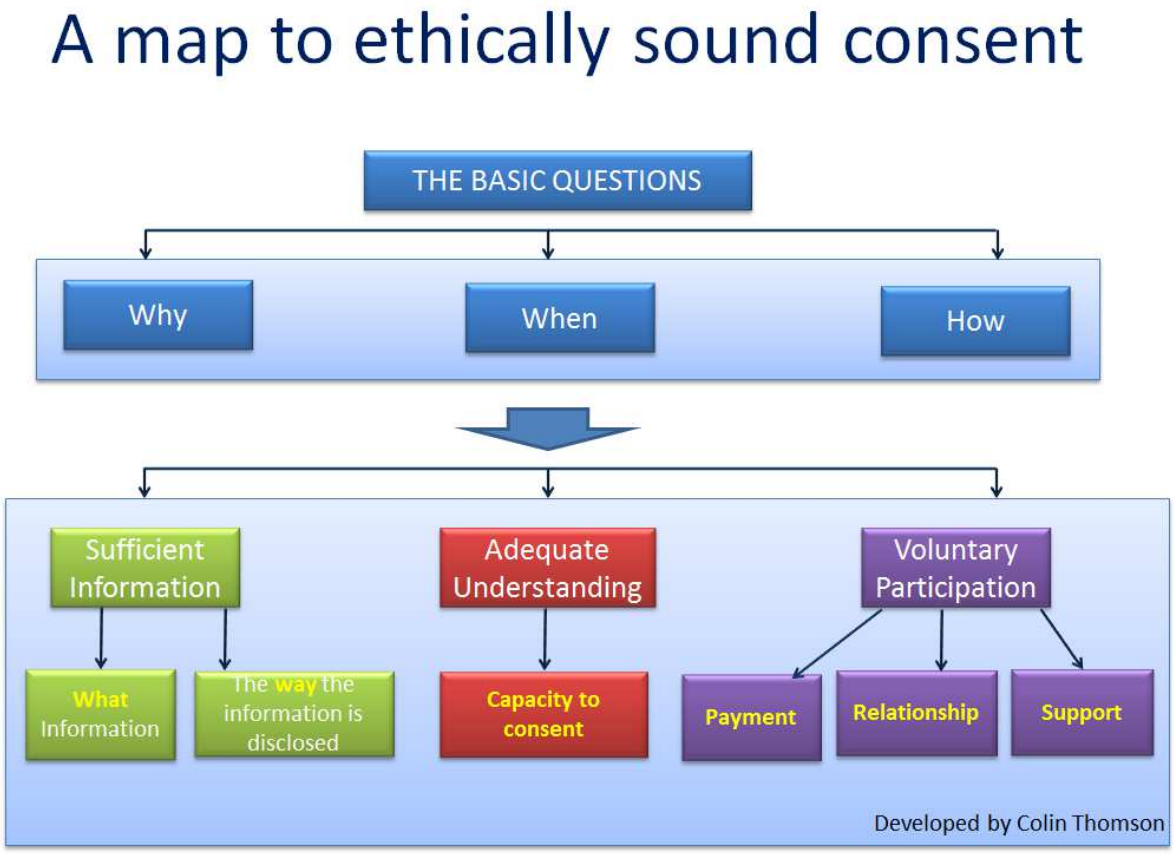
The intensive research ethics course was held over 5 days at Hepburn Springs (around an hour from Melbourne) in November 2014. Cathy asked me to write a one page summary of the course however there was just so much information that I thought I would just pick out the points that really interested me. Here is my attempt at a one page summary (yes, it is 4 pages). If you prefer to watch the YouTube video of my summary it is at: https://www.youtube.com/watch?v=8edABVDhovk&feature=youtu.be&hd=1

While the course was an intensive introduction to ethics in medical research some interesting areas for consideration were highlighted. These areas were **1. Updating and improving the process of consent, 2. Participant Experience, 3. Managing dualities and conflicts of interest (COI), 4. Genetic Testing, 5.Confidentiality or Privacy, 6. Witnesses.**

1. Improving the consent process – Interactive consent and multiple means of content delivery

Colin Thomson and Paul Komesaroff spoke about the process of consent. They both acknowledged that participants find it difficult to synthesize all the relevant information from a 20-30 page PIS.

Colin Thomson showed a map for developing ethically sound consent (I updated the graphics a little bit).



While the 20-30 page PIS may contain the relevant information the content is not often accessible for participants because the method of delivery doesn't always match a participant's literacy.

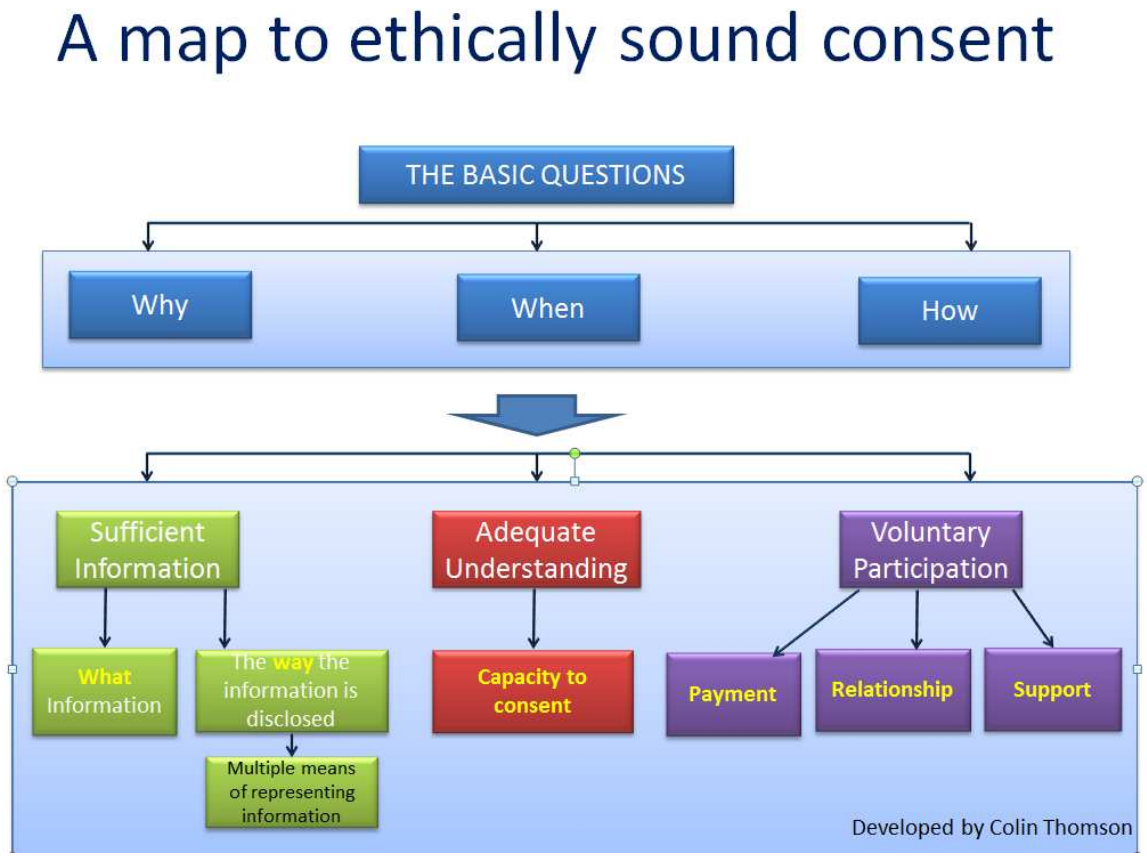
Paul Komesaroff suggested that the process be updated. One suggestion was that a better way to consent patients would be to provide a more interactive process. He suggested an online consent process. This online interactive process could contain text, video and sound recordings and could also test participants understanding of key points to determine whether they have understood the material.

This idea fits in with commonly cited teaching principle of Universal Design for Learning (UDL). UDL is a framework for guiding educational practice that:

> (a) provides flexibility in the ways information is presented, in the ways students respond or demonstrate knowledge and skills, and in the ways students are engaged; and
>
> (b) reduces barriers in instruction, provides appropriate accommodations, supports, and challenges, and maintains high achievement expectations for all students, including students with disabilities and students who are limited English proficient. http://www.udlcenter.org/aboutudl/udldefined

I found this interesting recent paper which supports Paul's idea. ***Rowbotham, Michael C (2013). "Interactive informed consent: randomized comparison with paper consents". PloS one , 8 (3), p. e58603.***

I would like to see a minor change to Colin's map, and suggest that Paul's ideas be included. The map should perhaps explicitly state that information should be delivered to participants effectively and in a suitable way.



Paul also suggested that generic brochure which provides participants with general research information may be beneficial in attempting to reduce the length of a standard PIS which also contains this information. Because the PIS is often written by a combination of doctors and lawyers and there is a huge variability in quality. By having a document which sets out the concepts like what research is, what randomisation is, what a clinical trial is and other common aspects which are included in PICS. By doing this the language can be clear, and common aspects of

research which are included in the PIS can be included in this doc rather than in PIS. The PIS can then concentrate on the critical data points without generic explanations being included.

2. Participant experience

One of the suggestions during the course was that the experience of the participant was not well understood. It was suggested that there is little data on whether the participant's initial understanding (at the point of consent) matched the individual's reality of the trial experience. It was suggested that surveys could be given to 1/3rd of the participants at the completion of the study to sample the participant experience.

I did a little bit of research and found this paper where it sets out that participant's felt that the experience of being on a trial was an important aspect to convey to trial organisers.

Holmberg, C., Karner, J. J., Rappenecker, J., & Witt, C. M. (2014). Clinical trial participants' experiences of completing questionnaires: A qualitative study. BMJ Open, 4(3), e004363-e004363. doi:10.1136/bmjopen-2013-004363

This is possibly something that is not always captured in studies because it isn't clinically relevant, but it was suggested that it may cross into the area of ethics (There are obviously issues with who should write and hand out the possible survey, who should receive the results and what should be done with them.)

3. Managing dualities and conflicts of interest (COI) – Paul Komesaroff
The disclosure of a COI is essential but it is not sufficient. The management of COI's should be systematic and non-punitive. Resolution of problems should involve discussion with the relevant communities and particular problems may require complex strategies.

A five step process

1. Individuals dualities, financial and non-financial are disclosed
2. These are considered by the relevant community
3. An assessment is made of whether they constitute a potential or actual conflict
4. If a conflict of interests is likely strategies are devised to separate the pursuit of the conflicting interests
5. The decisions and practical outcomes are communicated to the constituency affected

4. Genetic testing

Genetic testing can be offered as part of trials however it was suggested that pre-test counselling be encouraged because the outcomes of genetic tests may not be fully anticipated at the time of consent.

5. Confidentiality or Privacy

There was discussion about the terms confidentiality and privacy being used in a variety of settings. These terms are often used interchangeably, however their meanings are different.

Privacy
Privacy in Australia is regulated by the Privacy Act 1981 (Cth) ("the Act") and the Australian Privacy Principles ("APPs"). The Act and APPs apply to individuals and commonwealth government agencies. Each State and Territory has its own legislation in relation to privacy obligations of its government departments and agencies.

Privacy laws regulate the handling of personal information about individuals, whether or not that information is publicly available. In other words, if an individual has provided his or her personal details to a person in return for a particular service, privacy laws may prevent those personal details being used by the recipient for any unrelated purpose (such as the direct marketing of unrelated products).

Confidentiality
On the other hand, the legal duty of confidentiality obliges people or entities for example in a commercial transaction, to protect another person or entity's trade secrets or other information, which has been conveyed in confidence and which is not readily available to the public.

There is no specific confidentiality legislation in Australia, so it is governed by the 'common law'. So it is important to have an appropriate confidentiality clause in any agreement or contract, where you require certain information to remain confidential.

From: http://www.crhlaw.com.au/aged-services/difference-privacy-confidentiality/

6. Witnesses

Consent forms are increasingly requiring a witness' signature. However, the only section in the National Statement which refers to witnesses is Section 2.2.12.

2.2.12 Where a potential participant lacks the capacity to consent, a person or appropriate statutory body exercising lawful authority for the potential participant should be provided with relevant information and decide whether he or she will participate. That decision must not be contrary to the person's best interests. Researchers should bear in mind that the capacity to consent may fluctuate, and even without that capacity people may have some understanding of the research and the benefits and burdens of their participation. For implications of these factors, see *Chapter 4.2: Children and young people*, *Chapter 4.4: People highly dependent on medical care who may be unable to give consent*, and *Chapter 4.5: People with a cognitive impairment, an intellectual disability, or a mental illness*.

Being competent to make a decision is highly contextual. Competency is a state that you are in, it is whether an individual has the ability to make the decision required.

Aside from what is set out above, consent forms do not require witness signatures.

Australasian Ethics Network Conference

December 2014 University of Sydney

By: June Challen, Pharmacist

Approximately 280 people were registered for the conference and the 3 associated workshops that were held on Day 1. Workshop 1 was for new committee members and administrators, Workshop 2 for experienced members and administrators & Workshop 3 addressed clinical trial review in a university setting.

I attended Workshop 1 which was facilitated by Prof Colin Thomson and Ian Pieper. Colin is Professor of Law and Academic Leader for Health Law & Ethics in the Graduate School of Medicine at the University of Wollongong and would be no stranger to those from our committees who have attended the Monash Intensive Research Ethics Course. Ian has recently begun running Ethical Futures, a human research ethics and governance consulting service. The aim of this workshop was to help less experienced HREC chairs, committee members and administrators become familiar with the ethical review of research in the Australian context. The workshop provided participants with a set of questions that may be useful to reviewers when attempting to apply the principles of ethical conduct (as set out in National Statement) to research protocols. Workshop participants, working in small groups, were then able to apply this to a case study. The workshop provided a valuable lead-in to the conference which was conducted over the remaining 2 days.

Each day of the conference was opened by keynote speakers and the remainder of the day was broken into sessions with 3 streams of interest with contributed papers, panel discussions and workshops. There was a wide variety of contributed papers, allowing participants to attend papers of particular interest to them. Of particular interest were a number of papers that focussed on the ethical challenges of privacy and anonymity with social-media based research.

There was ample time available to meet other registrants and I found the networking opportunities very valuable. I would recommend any future AEN conference as both a valuable training experience and networking opportunity for all HREC members.

Monash University Intensive Bioethics Course (IBC)

December 2014

By: Dr Casey Nottage, Public Health Medicine Registrar

The Monash University Intensive Bioethics Course (IBC) was held during the 1st week of December 2014. One measure of its success is that 2014 was the 30th year the course was run, over that time several hundred Australian and international health professionals have taken part in our course. 2014 was no exception with a diverse range of participants from Australia, Malaysia and West-Papua attending and providing unique perspectives to the topics discussed.

Held at "Country Place" in the picturesque Dandenong ranges, the residential style course allowed a break from 'every-day life' and meant participants could fully immerse themselves in the course – and continue with the substantial reading material provided (both hard print, and in electronic form prior to the course). The setting was amazing and the hospitality and catering were excellent – although we were there for the teaching of course!

The course started with a viewing of the documentary "A Dangerous Mind" regarding the somewhat controversial views (and reception of those views) of Professor Peter Singer. This started the engaging and robust discussions that were to continue over the week. The formal teaching part of the course began with a full day on various ethical theories – from Utilitarianism, to Kantian theory (and the categorical imperative – which luckily doesn't form part of the National Statement!) and Virtue ethics – although a day heavy in theory it did give an excellent background into various ethical frameworks and how these have been used to shape bioethical debates.

Over the week various topics were covered including responsible reproduction, licensing IVF parents (which was topical given the recent media attention on the 'baby Gammy case'), preimplantation genetic diagnosis, organ transplantation and markets, pluralist approaches to public health policy, health resource allocation , life and death decision making and payment for egg donors. Forums and exercises were held around both clinical ethics and research ethics. Emerging topics for research ethics included stem cell research and dual-use research ethics.

Key learning points from the research ethics session included a discussion about the development of the 'National Statement' and how this framework has been useful in shaping review of research (compared to clinical ethics where there is no national framework or standard across sites and facilities etc); the need to accept a level of moderate pluralism in research ethics (ie the need to balance informed consent, autonomy and paternalism); and the need to identify what the 'ethical issue' is when making comments/questioning parts of the research proposal/PIS to ensure that we are working with the scope of the National Statement. One interesting issue raised was the issues of HREC within large institutions (universities/hospitals) and the ability of that group to maintain its independence given that many of the researchers and HREC committee members would be colleagues/team members etc – this is one area where Bellberry can claim institutional independence in its reviews.

Overall, the faculty was amazing and all considered leaders in their areas and all the sessions were well presented and well received. Thank you to Bellberry for providing me the opportunity to attend the Monash IBC – and I recommend it to anyone interested in bioethics, particularly those who have previously completed the Intensive Research Ethics course and want to further their professional development into bioethics more broadly.