Australasian Association of Bioethics and Health Law  
Melbourne - November 2016  
By: Dr Michael James, HREC Chair

The following expanded accounts are only those presentations for which I had taken enough notes. I attended many other presentations. Only the plenary sessions had invited presentations. The other presentations were from abstract submissions from investigators, including students, who were mainly from universities.

1. Joanna Manning, Faculty Of Law University Of Auckland  
Does the law on compensation for research-related injury in the UK, Australia, and New Zealand meet ethical requirements?

Payment for Research Related Injury (RRI)  
Reliance on ex gratia payment. Is this relying on the argument that the injured person accepted a position of risk and therefore payment should not be automatic.  
In the UK injured participant must prove negligence or rely on ex gratia payment up to £50,000.  
It is preferable to have a mandated / legislated No Fault compensation and not have to rely on tort action to prove fault because unforeseen risks are often the problem, Medicines Australia Guidelines state “...that the following Guidelines will be adhered to, without legal commitment,... ie without legal commitment it is an ex gratia payment.

Reform would be a legislated no fault payment for RRI. It was argued that is appropriate because:

- The aim of the trial is to benefit society  
- Society (regulators) mandates the need for trials for licensing purposes  
- The injured person has accepted a position of risk but in this framework of the societal benefit of clinical trials.

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2. Angela Ballantyne, University of Otago, Wellington, New Zealand  
Fair research and free riders: Do patients have an ethical obligation to provide health

- Medical knowledge is a public good. All can potentially benefit from medical knowledge.  
- Medical research is essential for accumulating medical knowledge.  
- Medical research requires human participants, including their data and tissue samples.

Therefore, it can be argued that we all have an obligation to be participants in human research because we all benefit. Otherwise we are ‘free riders’ on the efforts or participation of others. Therefore, our data and samples should be available for research without our consent for this secondary purpose.
Currently, the public good is assessed by HRECs to provide a waiver of consent. Use of all clinical data and samples for medical research could be superior to that from clinical trials in the respect that they are real-life data and not the restricted data that comes from the narrow base of included clinical trial participants.

The ‘free rider’ argument is one about fairness and it was argued consent is somewhat a distraction. Public good should be the larger consideration. After all, if a person has a lot of clinical data for possible research use, that means they are a large user of the health system in the first place.

Would need to bring the community along with such a move.

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3. Angela Ballantyne and Mike King, University of Otago, Wellington, NZ and Bioethics Centre, University of Otago, Dunedin, NZ

Pay to play: Participant funded clinical research for rare diseases

The business case for pharma to pursue drugs for rare diseases is poor. Thus, commerce is unlikely to pursue treatments for rare diseases.

Alternative proposition is ‘pay to play’ and ‘pay to try’.

In ‘pay to try’, the researchers find a wealthy individual with the disease. That person funds the whole trial in exchange for access to the drug alongside the trial, ie not within the trial. This ensures they get the drug and not a placebo. In ‘pay to play’, crowd funding or individuals might pay to take part in a trial, but wouldn’t be assured of getting the drug.

The trial should be well designed and the investigators credible and the drug have biological plausibility. The only missing component is money.

Pay to try has already been done, funded by a wealthy Arizona oilman with a neuroendocrine tumour. The drug was a virus and it had shown great promise in mice in Univ of Uppsala.

While this seems extreme it is argued that it puts a value on freedom to choose. There is a very good account of the models and the experience by Alexander Masters on https://mosaicscience.com/story/plutocratic-proposal

The presentation outlined some objections such as:

- Exploitation of desperate patients
- Commodification of research
- Skewing the research agenda
- Undermining scientific validity

However, they argue these considerations are made in comparison to an ideal RCT environment and that doesn’t exist in any case and the current standard already includes many or most of the points above.
4. Lisa Eckstein, Faculty of Law, University of Tasmania

*Research ethics consultation services as a strategy for dealing with return of secondary findings of genetic research*

Research Ethics Consultation (REC) Service. These exist in several US institutions but not (yet) in Aust (or at least are not common here). They are not HRECs but serve to provide advice during or after a trial about ethical issues. A good example of their use would be to provide advice on the return of secondary genetic findings from a trial.

Lisa discussed an incidental finding of Klinefelter’s syndrome and said some US IRB’s felt such a finding should be returned but other IRBs disagreed in consideration of the potential harm if it generated a paternity suit (Klinefelter’s only affects males and individuals are sterile).

The American College of Medical Genetics and Genomics (ACMG) decided to take the ethicists out of play and published a list of 56 gene variants associated with 24 disorders with high penetrance and said incidental findings that included any of the variants on the list must be returned. However, they have changed this stance in the wake of criticism. Also, it was pointed out that adhering to regulations is not the same as ethical reflection and analysis.

According to the National Statement researchers should have an ‘ethically defensible’ plan for returning research findings to participants.

Arguments for: respecting participant autonomy, beneficence, respect of right to know. Arguments against: possibility of doing harm, might be misconception about disease possibility, emotional harm from an unnecessary burden.

A REC could help with this and importantly, help with decision making in the event of a secondary genetic variant finding of clinical significance.

5. Narcyz Ghinea, Jessica Pace, Claudia Harper, Wendy Lipworth. Centre for Values, Ethics and the Law in Medicine, the University of Sydney

*Finding the ‘mean’ in debates about access to high cost cancer medicines*

I took part in this interactive workshop. There were presentations on the cost of cancer medicines, the Pharmaceutical Benefits Advisory Committee (PBAC), and the pressure brought to bear by patient advocacy groups and consumer websites that probably are funded/assisted by Pharma.

The PBAC seems to have an impossible job to balance moral demand and compassion with economic models.

An interesting fact was that 31 US states have laws giving patients the right to request a drug from a company, provided it has completed a Phase 1 trial. Other than the Phase 1 there is no FDA involvement.
We then split into groups to consider if we (PBAC) would recommend listing some cancer medicines presented to us in different scenarios. We either had to recommend approval or non-approval according to which group we were in.

An example was:
Young girl has advanced melanoma.
Her currently available treatment would be a drug costing $100,000pa and the trial results have shown a mean increase in survival of 3 months, although 10% of participants did much better.
There is a new drug before the PBAC which would cost $150,000pa and the trial results have shown a mean increase in survival of 6 months, although 10% of participants did much better.

Would we recommend funding?

There were a couple of scenarios and we had to swap between yes and no recommendations.

At the end we all agreed it was an impossible task to provide a rationale argument, especially for the no case.

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Some others:

6. Wendy Rogers’ plenary “Bioethics, advocacy and activism” was excellent.

7. Jon Jureidini (Paediatric Psychiatrist, WCH and a spokesperson for Healthy Skepticism Inc) “Does publication policy and practice compromise academic freedom?” Jon spoke on GSK’s pivotal trial of paroxetine for adolescent depression. He demonstrated that the publication of the results of this trial were ghostwritten and misleading and he and others from Critical and Ethical Mental Health research group within the Robinson Inst at Univ of Adelaide have published a critique to that effect. He discussed the long battle to get such a critique into the public domain, given the back pressure from Pharma.

8. Peter Harris (Lawyer and PhD student from NZ) “Mistaken for Medicine” spoke about the regulatory framework for health claims on Complementary and Alternative Medicines (CAMs). As part of this they surveyed students using four examples. One was a medicine (brufen) and the others were CAMs (olive leaf, etc). The students were asked to identify which were CAMs and which were medicines, having read the labels and claims. As he said, empirical research doesn’t always give the results one is expecting.
The labels made no difference at all. The overwhelming influence was whether they were packed in a cardboard box or a bottle with no other packaging. The one CAM in a cardboard box was considered a medicine whereas the other two CAMs in bottles were not. The results were overwhelming in that one direction.

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9. Discussion Group  
I took part in a discussion group on the extent to which consent to research is voluntary.

- There were several who used the example of patients in a ward approached by a clinician researcher – they are in a vulnerable position and the consent may not be voluntary. I agreed but said it isn’t necessarily not voluntary.

- I argued that for a cancer trial where the patient has failed 1st line and then 2nd line Tx, the person best placed to explain a clinical trial and act in the patient’s best interest is probably their oncologist. They have been already on a long journey with their oncologist and in the end we have to trust the clinician researcher to act in the best interests of their patient. The patient is still in a dependent/vulnerable position but their consent can still be voluntary and in their best interest. Most agreed with me.

- Consent may not always be what the patient wants and we discussed the example of pressure brought to bear by the family of a patient who doesn’t want to go into a trial, but the family wants them to try everything.

- The position of dependency in a lecturer recruiting their own students was an easy one and we all agreed it needed 3rd party consent.

10. Research Ethics Stream of AABHL  
I attended a meeting of the Research Ethics Stream of AABHL. Andrew Crowden from UQ is the theme leader.

Issues discussed:

- It was considered unfortunate that AABHL and AEN overlapped this year. However, some said they are different kinds of meetings with different audiences. AEN attracts those who run and/or serve on HRECs and AEN is concerned with HREC function. It was said to be dominated by the health groups whereas AABHL attracts the academic ethicists. It was said the two groups represent the longstanding hospital/university divide. However, I pointed out that universities have both social science and medical research HRECs within the same institution.

- There will be no AABHL meeting next year and the planning is for a combined AEN/AABHL in 2018, possibly in Townsville. The meetings might be concurrent or sequential. It is still a loose plan.

- AABHL has five streams and several are planning one day meetings together next year. It was agreed it would be good to explore a concurrent one day Research Ethics Stream meeting in conjunction with the other streams. Also discussed is extending to 2 days.
Monash University Intensive Bioethics Course  
Dandenong Ranges - December 2016  
By: Emeritus Fellow Ian Leader-Elliott, Lawyer

I am very grateful to Bellberry for the opportunity to attend the Monash Intensive. It was a lively and intellectually engaging weekend. The course material and presentations were excellent and the conversation and company of fellow participants stimulating and enjoyable.

The intensive course, presented annually by the Monash University Centre for Human Bioethics, is taken over three days in a location sufficiently remote to ensure that participants are in residence for the duration. In earlier years, when Peter Singer directed the Centre, it was held at Mt Buffalo Chalet. More recently the venue has been Country Place Retreat, in the Dandenong Ranges. The Retreat is secluded and pretty with tall trees, scenic walking trails. Mobile phone reception is, however, variable. Food and wines at the Retreat were good to superior and the accommodation comfortable.

The course programme commenced with registration and dinner on Friday December 2, which was followed by 9am – 5.30pm presentations on Saturday and Sunday and a morning session and final luncheon on the following Monday. Participants, about 30 in number, were predominantly researchers and practitioners with medical and nursing qualifications. Though few among the participants had legal qualifications, ethics and law were inseparable in many of the subjects for discussion. Among presenters Professor Loane Skene, who has had a long association with the Centre, is the author of a leading Australian text on law and medical practice.

The course follows much the same pattern each year. The first morning provides an outline of alternative ethical systems, utilitarian, virtue ethics, and Kantian, before the course moves on to particular problems in contemporary bioethics. The problems, for the most part, reflect the research interests of the Monash Centre Members and the invited guest presenters. Presentations in 2016 ran with clockwork precision under the guidance of the course coordinator, Dr Ryan Tonkens, who allowed ample time for questions and responses by presenters.

In this short report I will restrict my remarks to four of the presenters who were of particular interest to me and likely to interest members of the Bellberry community: Professor Julian Savulescu, Professor Angus Dawson, Professor Lynn Gillam, and Professor Michael Selgelid, who is the Director of the Monash Centre.
Julian Savulescu, Uehiro Chair in Practical Ethics, University of Oxford: the intellectual range and volume of his work, which is very accessible on Researchgate, is astonishing. At the intensive he spoke on the ‘Ethics of Assisted Dying’. The title of his paper, ‘A simple solution to the puzzles of end of life? Voluntary palliated starvation’,1 provides a succinct account of Savulescu’s argument for the permissibility of euthanasia without enabling legislation. Among his recent publications, ‘Science wars--How much risk should soldiers be exposed to in military experimentation?’2 is challenging and his editorial comment on ‘Risk and Regulation in Research’3 is particularly pertinent in his expression of concern that a ‘pernicious tendency for a legalistic approach to ethical concepts such as informed consent has replaced a genuine consideration of the balance between individual risks and benefits, and that the primary duty of ethics committees is to ensure that risk is reasonable’.

Angus Dawson, University of Sydney: spoke on ‘Public Health Ethics’,4 arguing that distinctive ethical principles governing the practice of public health await articulation and development. In contrast to the respect for autonomy that we take to be intrinsic to medical ethics when dealing with individuals, an ethics of public health will often require collective action in which individual autonomy must be sacrificed in recognition of the necessity for biological and social constraints on that autonomy, if we are to flourish as a community. Conflicts over rights of conscientious objection to vaccination and arguments about euthanasia and assisted suicide are illustrative. Dawson has also written challenging papers on circumstances in which informed consent is unnecessary in medical research.5

Lynn Gillam, University of Melbourne: presented two sessions on Clinical Ethics and HREC decisionmaking. First was a forum on the work of Human Research Ethics Committees, based in part on research by Professor Gillam and her associates on attitudes and practices of health researchers and HREC members in Victoria on the ways in which they conceptualise ethical issues, how they use the National Statement, and what deliberative strategies they use to assess the acceptability of research proposals.6 As one might expect, the perceptions of researchers and HREC members were often at variance. Prof Gillam’s exploration of the complex relationship between risk and informed consent, in which risk plays the central role,

1 Savulescu, Editorial, (2014) 40 Journal of Medical Ethics, 110.
3 Savulescu, Editorial. (2015) 41 Journal of Medical Ethics, 503, commenting on an article in the July issue of the JME.
is of particular interest. The second of her presentations was one of the few that required active involvement by participants. We were separated into small groups and required to take the role of HREC or CEC members in a mock consideration of problems and report on some difficult HREC or CE applications. Gillam was challenging, confrontative and illuminating. This was an exceptional and engaging presentation. See Appendix 2, Lynn Gillam, Power Point Slides and IBC discussion problems.

**Michael Selgelid, Director, Monash Centre for Human Bioethics**: spoke on the ‘dual use dilemma’ that arises when research of potential value in scientific or medical innovation may facilitate the development of biological weapons and bioterrorism. (Selgelid is an international authority on the ethical issues involved in dual use research.) He used as an illustration a CSIRO research project in 2001, in which a gene for mouse pox virus was modified with a gene for infertility in the expectation that it would provide an infectious contraceptive for mice. The potential for the control of rodent damage to food stores seemed promising. The effects were unexpected. The modified virus was far more virulent than anticipated and killed the mice. It also killed the mice in the control group that had been vaccinated against the virus. The possibility that the research findings might permit the malign development of a form of smallpox, which is related to mouse pox, against which vaccination would be ineffective, gave rise to immediate alarm. The bioethics dilemma that arises in such cases is the possible necessity to suppress publication and dissemination of research that has the potential for catastrophic harm in the hands of bioterrorists. Dual use research involves another face of public health ethics, in which the relative autonomy of the research community must be constrained in some circumstances, by considerations of the common good.

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8 Rachel Nowak, 10 January 2001, New Scientist Online News: ‘Killer virus: an engineered mouse virus leaves us one step from the ultimate bioweapon’. Fortunately, the danger seems to have been overstated. [http://online.sfsu.edu/rone/GEEssays/killervirus.html](http://online.sfsu.edu/rone/GEEssays/killervirus.html)