SOUTH EAST QUEENSLAND COMBINED

HUMAN RESEARCH ETHICS COMMITTEE TRAINING

22 October 2015

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WELCOME

Bond University is proud, once again, to host the South East Queensland Combined Human Research Ethics Committee training seminar. Events such as this encourage respectful, reflective debate and discussion on significant topics that impact on the lives of participants in human research. It is through open dialogue that committees develop the capacity for better engagement with the research community. It is through reasoned debate that committee members improve their capacity to make evidence-based decisions.

We are very pleased to have such high calibre speakers this year. Please take the time to engage with the discussion, ask questions, and enter into debate. Take this opportunity to talk to your fellow attendees and with the presenters about issues that you are having within your committee or potential problems you can foresee. Learn from each other and contribute positively to the learning that others take from here.

The day will consist of a mix of formal presentations and case studies with plenty of opportunity for unstructured discussions built in. Please feel welcome to stay and talk after the event.

It is in this collegiate spirit that I take great pleasure in welcoming you to the South East Queensland combined human research ethics training day.

Dr. Mark Bahr

Chair, Bond University Human Research Ethics Committee

South East Queensland Combined Human Research Ethics Committee Training Day

Bond University,
Varsity Lakes Campus
22nd October 2015

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Time	Topic	Presenter
09:15	Registration	
09:45	Welcome	Bond University
10:00 – 10:45	The Principles of the National Statement	Professor Colin Thomson
10:45 – 11:30	Considerations within Aboriginal and Torres Strait Islander Research Ethics	Assoc Prof Karen Martin
11:30 – 12:00	Morning Tea	
12:00 – 12:45	Tissue Sharing and Informed Consent	Dr Gary Allen
12:45 – 13:30	Case Study – travelling consent and the re-use of tissue	Mr Ian Pieper
13:30 – 14:15	Lunch	
	Ethics within Genomics Research	Dr Ainsley Newson
	Case Study - Unintentional Disclosure and Incidental Findings	Dr Mark Bahr
15:45	Close	
	Informal Discussions	

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SOUTH EAST QUEENSLAND COMBINED HUMAN RESEARCH ETHICS COMMITTEE TRAINING DAY
17 October 2014
BOND UNIVERSITY

PROFESSOR COLIN THOMSON

Colin Thomson BA, LLB, LLM (Hons) has a fractional appointment as Professor of Law at the University of Wollongong where he is the Academic Leader for Health Law and Ethics in the Graduate School of Medicine and Health. He was Chair of the Australian Health Ethics Committee of the National Health and Medical Research Council (NHMRC) from 2006-2009 and a member of that committee from 1998-2002 and is currently the Chair of the University of Wollongong and Illawarra Shoalhaven LHD Health and Medical HREC.

Colin has published and spoken widely, both nationally and internationally, on issues in health law and ethics for over 30 years.

Using the National Statement to promote ethically sound human research.

The purpose of the National statement is to promote ethically good research, that is, research in which participants are accorded the respect and protection due to them and research that is of benefit to the community.

Institutions, researchers and ethics review body members all share a responsibility to fulfil this purpose and each has distinct functions that the National Statement clarifies.

Institutions are responsible to establish, resource and regularly review ethics review processes, whether HRECs or low risk review panels; researchers are responsible for designing and conducting research and for fully disclosing to HRECs the aims, benefits and methods of the project and demands and risks it has for participants. Ethics review body members are responsible for establishing, disclosing and applying clear review criteria to researchers' proposals and in communicating and justifying their reviews.

Effective communication is central to fulfilling these responsibilities.

ASSOCIATE PROFESSOR KAREN MARTIN

Associate Professor Karen Martin is a Noonuccal woman from Minjerripah (North Stradbroke Island - south east Queensland) and also has Bidjara ancestry (central Queensland). She is a qualified early childhood educator who has taught for more than 20 years in Aboriginal Community education services from early childhood, compulsory schooling to adult training in remote, regional and urban areas of Queensland. She is a James Cook University Medallist (2007); joint winner AARE Dissertation Award (2008) and NAIDOC Scholar of the Year (2008) with some 18 years' experience in higher education lecturing in Aboriginal Australian Studies, Aboriginal education and early childhood education. Dr Martin has national and international recognition for her scholarship in Aboriginal research paradigms, ethics and methodology and is author of the best-selling book 'Please knock before you enter: Aboriginal regulation of Outsiders and the implications for research and researchers' (2008). She is a member of the National Indigenous Knowledge Network (NIRAKN); the Indigenous Research Unit: Griffith University and leader of the Aboriginal Education – Research SIG (GIER) and an academic advisor of the former Indigenous Clearinghouse Board (AIHW). Currently employed as Associate Professor in the School of Education and Professional Studies (Griffith University), Karen is also the Deputy Chair of Griffith University Human Research Ethics Committee; Deputy Chair of the Longitudinal Study of Indigenous Children (DSS) and recently completed an Office of Learning & Teaching Fellowship titled, 'The role of Aboriginal Knowledges in higher education in the 21st Century'.

Aboriginal research and ethics: What's the difference – What does that mean?

In this presentation, questions on what makes Aboriginal research and ethics distinct and therein, different are outlined. This includes identifying some common approaches to research involving Aboriginal peoples and the strengths and limitations. There will be further consideration of key ethics requirements and what this means for researcher roles, responsibilities and relationships.

DR GARY ALLEN

During the past 16 years Gary has worked with a number of research ethics committees in Australia, Canada, the United Kingdom and Vietnam. He has a degree in education and a professional doctorate in social sciences.

His knowledge and expertise in regards to the national and international governance of ethical conduct in research has resulted in him serving as a training facilitator for the NHMRC and advising the committee reviewing the National Statement on proportional review. He has completed consultancy work for the CMC, CSIRO, NHMRC, FaHCSIA, various universities and health commissions, and for the Tasmanian Human Research Ethics Committees.

Gary is a frequent presenter at conferences and has been invited by a number of Australian universities to conduct workshops on the National Statement and the Australian Code. In 2007, his work in human research ethics was recognised by the ALTC with a national Citation for Outstanding Contributions to Student Learning.

He is a member of the sub-committee responsible for research ethics of the Australian and New Zealand Society of Criminology

Tissue Sharing and Consent

Work with human biospecimens, including banked specimens, re-use of existing and importing/exporting samples can raise significant consent, privacy and other respect questions for researchers and research ethics reviewers. This short talk suggests an approach to these practical questions and proposes a good practice approach for prospective collection and banking.

IAN PIEPER

Human Research Ethics Consultant

Ethical Futures

Ian has recently begun running Ethical Futures, a human research ethics and governance consultancy service. By doing so, Ian is following a long held interest in normative philosophies and practical ethics. This venture follows on from his practical experience as the Research Governance Officer for the Gold Coast Health and Hospital Service and the Research Grants Officer (Health and Medical) for Griffith University.

Ian has organised combined HREC and researcher training for the GCHHS and the Universities based in SE Qld and Northern NSW. As part of these combined training days provided training in the application of the National Statement in consenting processes. For four years, Ian conducted the induction training for all new members of the GCHHS HREC and acted as a mentor for the Committee, particularly in ensuring compliance with research governance frameworks.

Ian also has extensive experience in providing technical training to technology users, including the use of business computing applications, databases and computer programming.

Ian has formal qualifications from a number of Australian universities - Bachelor of IT, Grad. Cert. HRM, Grad. Cert. Research Ethics and a Masters of Ethics and Legal Studies.

Ian has several peer-reviewed publications on research ethics co-authored with Professor Colin Thomson and has presented on research ethics at national and inter-national conferences.

Publications

Pieper, Ian; Thomson, Colin. 2011. 'Contextualising merit and integrity within human research'. *Monash Bioethics Review* 29 (4): pp. 15.1 to 15.10.

Pieper, Ian; Thomson, Colin. 2013. 'Justice in Human Research Ethics: A Conceptual and Practical Guide'. *Monash Bioethics Review* 31 (1): pp 99 - 116.

Pieper, Ian; Thomson, Colin. 2014. 'The Value of Respect in Human Research Ethics: A conceptual analysis and a practical guide'. *Monash Bioethics Review*, 2014, 32, (3-4): 232-53

Human Bio-specimen Case Study

What advice would you give the researchers proposing this project?

Part of the function of an HREC ought to be to promote the conduct of ethical human research. In order to do that, there should be an engagement with the research community about what constitutes ethical human research. The common vocabulary available to both the committee and the researcher is the National Statement.

The purpose of this case study is to think about the research in terms of the principles of the National Statement and to practice using that guide as the point of commonality between researchers and the Committee. Ask yourself and your group:

1. Is this research?
2. What are the risks?
3. What are the potential benefits?
4. Does this project reflect the values of the National Statement?

    Research Merit and Integrity

    Respect

    Justice

    Beneficence

5. What questions would you ask around these principles?
6. What feedback would your group provide to the research team?

Reuse of Human Bio-specimens for Research

Experienced paediatric oncologist, Dr Patty approaches your committee for advice on extending research that she conducted from 2005 - 2010. The original research collected blood and bone marrow samples from teenagers who had been diagnosed as having Hodgkin's lymphoma along with their clinical history, treatment details and interviews over a 5 year period.

There has been significant work done in improving the testing of the bone marrow samples. Dr Patty would like to share the stored samples with a colleague, Dr Selma, to develop an improved test and then run a comparative study between the original method and the new one. They propose to re-run the tests that they originally conducted during the study and compare those results with the testing conducted with the new method. Dr Patty believes that the new test should be up to 10 times more sensitive as well as being quicker.

Is this human research?

Consent: Consent was originally obtained from the parents with the patients providing their assent. The documentation included a statement requesting permission to store the samples to conduct unspecified, but related, future research.

Consent issues to consider:

- Would this constitute "unspecified, but related, research"?
- Is there a need to seek further consent?
- Does it matter that those patients that survive would now be adults?
- Are there any risks that might be associated with re-consenting a group of cancer patients 5 – 10 years after the initial research project?
- Are there any additional privacy considerations involved in sharing the bio-specimens with researchers not on the original project?

Risks: What risks might there be in re-using this material?

Benefits: What benefits might come from this research?

Does this project reflect the values of the National Statement?

DR AINSLEY NEWSON

Dr Ainsley Newson is Senior Lecturer in Bioethics at the University of Sydney, where she has worked since January 2013. She previously worked for a decade in the United Kingdom; holding posts at the University of Bristol and Imperial College London. She has a PhD in Bioethics from the University of Melbourne. Ainsley also holds Bachelor degrees with honours in Science (majoring in human genetics) and Law (majoring in medical law and intellectual property). Ainsley works on the ethical aspects of genetics and genomics, as well as other emerging biotechnologies. She has also taught medical ethics and bioethics at undergraduate and postgraduate level for 18 years, and currently directs the Sydney Bioethics Program (http://www.sydney.edu.au/bioethics). Regarding research ethics, Ainsley has designed professional development online training materials and has a decade of experience in training HREC members. Ainsley has also been a member of two human research ethics committees, including four years as Deputy Chair of the Faculty of Medicine and Dentistry Research Ethics Committee at the University of Bristol, UK.

Session Learning Objectives: "Ethics within genomic research"

In this session, Dr Ainsley Newson will lead a discussion on the ethical aspects of genomics research. By the end of the session, participants will be able to:

1. Describe some key features of genomic science;
2. Articulate how aspects of genomics may be distinguished from genetics;
3. Critically reflect on aspects of consent in a genomics context; and
4. Consider some of the issues arising in considering the return of results from genomic research, including:
    a. Balancing interests;
    b. Disclosing results to third parties;
    c. Considering autonomy and paternalism; and
    d. Managing incidental findings.

Ethics within genomics research: Further reading

Dr Ainsley Newson, University of Sydney: ainsley.newson@sydney.edu.au

If you would like to undertake some further post-session reading, the following papers may be of interest.

Further reading freely accessible online (in alphabetical order):

Beskow LM, Burke W. Offering individual genetic research results: context matters. *Sci Transl Med. 2010*; 2(38). http://www.ncbi.nlm.nih.gov/pubmed/20592417

Caulfield T, McGuire AL, Cho M, et al. Research ethics recommendations for whole-genome research: consensus statement. *PLoS Biol.* 2008; 6(3):e73. http://www.ncbi.nlm.nih.gov/pubmed/18366258

Christenhusz GM, et al. To tell or not to tell? A systematic review of ethical reflections on incidental findings arising in genetics contexts. *Eur J Hum Genet*, 2013; 21(3):248-55. http://www.ncbi.nlm.nih.gov/pubmed/22739341

Gliwa C, Berkman BE. Do Researchers Have an Obligation to Actively Look for Genetic Incidental Findings? *The American Journal of Bioethics*, 2013; 13(2): 32-42. http://www.ncbi.nlm.nih.gov/pubmed/23391059

Kaye J, et al. Ethical implications of the use of whole genome methods in medical research. *Eur J Hum Genet*, 2010; 18: 398–403. http://www.ncbi.nlm.nih.gov/pubmed/19888293

Solum Steinsbekk K, Kare Myskja B, Solberg B. Broad consent versus dynamic consent in biobank research: Is passive participation an ethical problem? *European Journal of Human Genetics* 2013; 21: 897–902. http://www.nature.com/ejhg/journal/v21/n9/pdf/ejhg2012282a.pdf

de Vries J, Bull SJ, Doumbo O. Ethical issues in human genomics research in developing countries. *BMC Med Ethics*. 2011; 12(5). http://www.ncbi.nlm.nih.gov/pubmed/21418562

Additional readings available via subscription access:*

Knoppers BM, Chadwick R. Human genetic research: emerging trends in ethics. *Nat Rev Genet*. 2005; 6(1):75-9. http://www.nature.com/nrg/journal/v6/n1/full/nrg1505.html

Lázaro-Muñoz G, et al. (2015) Looking for trouble: Preventive Genomic Sequencing in the General Population and the Role of Patient Choice. *Am J Bioethics*, 2015; 15:7, 3-14.

Lunshof JE, Chadwick R. Vorhaus DB, Church GM. From genetic privacy to open consent. *Nat Rev Genet* 2008; 9: 406-411. http://www.nature.com/nrg/journal/v9/n5/full/nrg2360.html

Rodriguez LL, Brooks LD, Greenberg JH, Green ED. The complexities of genomic identifiability. *Science* 2013; 339(6117), 275-276. http://www.sciencemag.org/content/339/6117/275

* Googling the titles of these papers may find versions housed on other websites.

DR MARK BAHR

Chair Bond University Human Research Ethics Committee

BA, Pg. Dip App. Psych, Ph.D

Mark has served as the Chair of the Bond University Human Research ethics committee since 2005. As a research methodologist he is interested in the opportunity serving on ethics committees provides to engage with many different methodologies and to keep informed as to research developments across disciplines.

Dr. Bahr is a cognitive developmental psychologist with research interests in the acquisition of cognitive skills and the detection of loss of cognitive function, as well as general educational Psychology. He was part of a multidisciplinary team involved in the evaluation of the implementation of the New Basics in Queensland schools. This evaluation represented a radical shift in the nature of evaluation in Queensland education. The evaluation is strongly evidence based consisting of a total of 27 studies arising from 7 fundamental research questions. The studies utilised both quantitative and qualitative methods and were designed to identify evidence of substantive change in the system triangulated against multiple sources of evidence. He has taught multivariate research methods and Human experimental research design classes since the 1990s. Dr. Bahr has served as the Chair of the Bond University Human Research Ethics Committee since 2007. His experience with as a researcher and a methodologist informs his approach to his work with the ethics committee.

Case Study 2:

Building a Radiographic Database: What do typical bones look like?

An eminent radiologist was employed at a hospital and general healthcare service located at a small island nation early in his career. In that role he had responsibility for radiology data taken as part of a general population health initiative screening for diet related bone density disorders as well as radiology data from routine operations. Over several years the hospital amassed several thousand records from a broad cross-section of the community including images associated with known pathology, and with no evidence of pathology. After the usual archiving period had elapsed the hospital would discard the records in the normal course of events. However, Dr. X believed the data had value for research (although he didn't have time to do it at that point in time). He sought approval from the hospital administration to take custody of records intended to be discarded for later analysis. The records include radiographic data and partial case notes from the patients the images relate to. The data covers patients over the complete lifespan from neonates to advanced old age.

Some twenty years later he has decided to retire and he has formed the opinion that he will never conduct the intended analysis. However, he has offered the data to a young researcher who is interested in using the radiographic image to construct a bone physiology database, complete with digitisation of the original film media. The young researcher has approached the ethics committee for low risk approval to use the data archive.

Identified risks: None. The researchers claim that the data required forms part of an existing archival data source. No new data is being collected.

Identified Benefits:

- Establishment of the data base will provide an empirical basis for evaluation of population variation in bone structure in this population improving assessment of typical development and improving diagnosis.
- Population data does not currently exist for this population.
- Recent work indicates a particular bony lesion may indicate a familial propensity to develop a slow growing bone cancer, which is manageable if detected early. The researcher hopes to identify prevalence of this type of lesion in the population sampled.

Participants:

Data were collected from the single hospital. However, the hospital has a large catchment as the single relatively well resourced hospital for a small island nation. Historic conditions of data collection not known with precision. The new researcher believes as least some of the data was gathered as part of a project for other research purposes and this was reviewed and approved at the time but there is no existing documentation.

The island population is somewhat diverse and multi-ethnic but the majority of the data will have come from indigenous peoples of the nation who have strong belief in the power of images and strong clan/family beliefs. The community is strongly matriarchal and major decisions that relate to the community are usually done with the assent of the community matriarch.

Consent:

No data is available to indicate that consent was obtained for research use.

The data is extensive and contains identifying information as well as incidentally collected information describing participant health status.

Identifying data is available to identify patients and to allow cross-matching of image to diagnostic and demographic records. The researcher plans to match records to identifiers and then de-identify data prior to release of the data base.

It claimed that it is not possible to obtain retrospective consent as with the passage of time contact details will not be available (they were not good at the time of collection) and indeed there will be attrition of patients due to the passage of time.

Participant Groups:

Research Team: No declared conflicts of interest. The research team is well qualified and includes a local researcher as well as members with expertise in orthopaedics, knowledge of radiology and tropical disease and Bio-informatics. The data will be stored on a cloud repository once constructed and made a public resource for researchers and practitioners.

Principal Investigator: B.Sc.; B. Med.; completed orthopaedics residency 2012.

Role: Research design and methodology; diagnostic coding of samples and enhancing image quality of scanned images development of coding criteria combining case notes and radiology data; literature review.

Investigator 2: B.Sc. Microbiology; Ph.D. Tropical Medicine. The applicant was trained in Tropical medicine and epidemiology. Has volunteered with *Medecins Sans Frontiers* and has considerable experience with the treatment of tropical disease.

Role: Research design and methodology; diagnostic coding of samples and development of coding criteria combining case notes and radiology data; literature review.

Investigator 3 B.Sc. Physics; B. Med.; Accredited Medical Radiation Practitioner. Trained in Medical Radiation Sciences at the University of Melbourne before pursuing post-graduate studies in Clinical Magnetic Resonance Imaging (MRI) at Baltimore University Hospital, USA. Post-professional work led to commencement of a gaining his PhD in Medical Imaging with porous bone samples.

Role: Research design and methodology; diagnostic coding of samples and enhancing image quality of scanned images development of coding criteria combining case notes and radiology data. Will supervise digitisation of images and development of database file system.

Data: Data will initially be identified by case note identifiers matched to radiographic data (x-rays and contrast images) of patients scanned at the hospital during a 5 year period during the 1980's. After collation of data in the database, personally identifying data (patient names) will be stripped and the resultant data file will not be re-identifiable.