



BARWON HEALTH RESEARCH WEEK

## Welcome to the first Barwon Health Research Directorate newsletter.

In this inaugural issue meet REGI and the research Directorate team

### “Why is research important?”

It leads to a different level of discussion in hospitals, attracts staff, changes the culture of the organisation... but research leads to quality of care. That’s why we do it.”

Ministry of Health Senior Executive Roundtable  
NSW Health and Medical Research Strategic Review, 2012

## REGI . . Who we are and what we do

The Office for Research is changing its name. Meet the new look Research Ethics Governance and Integrity Unit (REGI Unit) and our new staff, Lisa Fry and Melissa Cadwell.

Barwon Health has a vibrant research culture and enviable track record in research achievements. This research activity is supported by the REGI Unit, located in Kitchener house. REGI, as an organisational unit of the Research Directorate, manages the many aspects of research compliance, research ethics applications and review processes. Our new team has a strong background in research ethics and management and can provide support and advice on research design, data management and analysis and ethics applications. We also offer training in all aspects of research conduct for less experienced researchers. All BH staff and associates interested in research are encouraged to drop in to meet the REGI team and get some tips for successful negotiation of research ethics and governance processes.

# Barwon Research Bulletin

Inaugural issue

## November

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### DID YOU KNOW?

REGI offers expedited review for projects with prior HREC approval from other NHMRC accredited HREC’s and for negligible risk projects (including audits) see our website

<http://www.barwonhealth.org.au/research/column-1/office-for-research>

# Meet the Research Directorate Team

## Director of Research

**Professor Frances Quirk**, is a



Chartered Health Psychologist (Health Professions Council, UK), behavioural scientist and sexologist. Prof Quirk has worked in both

the public and private sectors and her research interests and experience fall under the broad umbrella of behavioural and clinical science, but are defined by specific disorders (respiratory disease, sexual dysfunction, eating disorders, mental health) and the concept of performance enhancement (in sport and more generally in the development of clinical reasoning in medical trainees). Underlying each of these research areas is a commitment to quality of life and wellbeing for individuals and populations. Prof Quirk is associated with successful funding applications of approximately \$6.5million. Prof Quirk has a notable citation record (most cited publication >900) and is a cross-disciplinary and collaborative researcher with over 70 co-authors. Prof Quirk has a Conjoint Honorary Clinical Professorship in the School of Medicine, Deakin University, is an Adjunct Professor in the School of Medicine and Dentistry, James Cook University and a Research Fellow at the Cairns Institute, James Cook University. Prof Quirk has held several Board positions (Academic Board (Deputy Chair), James Cook University; Central and Northern Queensland Region Parole Board) and is an Editorial Board Member of the Elsevier journal, Performance Enhancement and Health, previously Co-Editor-in Chief. Outside of work, Frances and her new husband, Floris, enjoy a rural lifestyle and the company of a 'family' of Hungarian Vizlas. Frances' claim to fame is being able to do a back flip off the Flying Trapeze!

## Manager, REGI Office

**Dr. Giuliana Fuscaldo** Prior to joining Barwon Health Giuliana held academic positions at the University of Melbourne, Victoria and Monash Universities. Giuliana has been involved in health ethics research and teaching for many years. Giuliana's background is in reproductive technology. She



worked for ten years as a clinical scientist and Researcher in a Melbourne IVF Clinic. During this time she completed a Masters of Bioethics at Monash University and later a PhD at Melbourne University, on ethical issues arising from advances in reproductive technology. Giuliana is a longstanding member of several ethics committees and has designed and delivered education and training programs on research ethics and research methods for health professionals, researchers and HREC members. Outside of work Giuliana is learning to sail and plans to be the oldest woman to circumnavigate the earth. Giuliana lives with her two daughters who are keen researchers of hair and fashion.

## Senior Biostatistics Officer

**Dr. Stephen Lane** is a Senior Biostatistics Officer within the Biostatistics Unit/Research Directorate.



With a first-class Honours degree in mathematics and a PhD in statistics (both from The University of Melbourne), Steve has been at Barwon Health since mid-2012. Prior to his current role, Steve was a tutor in the Mathematics and Statistics department at The University of Melbourne, and was also a Senior Research Officer with the Australian Bureau of Statistics, where he was part of a team that developed methodology for the

Australian House Price Indices. Steve collaborates with both Barwon Health staff and external researchers on many different projects, from secondary data (e.g. electronic medical record) studies to randomised clinical trials. In addition to biostatistical and research-related work, Steve is a fully-qualified chef and keen BBQ-er, who these days, cooks at home with his wife and four kids.

## Health Services Research Coordinator

**Dr. Stephen Gill** is a researcher and clinician. He completed his PhD in 2009 by running a clinical trial comparing exercise-based



interventions for people awaiting joint replacement surgery of the hip or knee. Recently he commenced a new role with the

Research Directorate as Health Services Research Coordinator, prior to which he had a research portfolio with the Safety, Quality, and Innovation Unit. Stephen's research interests include health services research including both quantitative and qualitative methods. Stephen continues to practice as a physiotherapist in Barwon Health's Emergency Department and Fracture Clinic. Beyond work life, Stephen has two young children and a beautiful wife. His spare time is spent enjoying the outdoors and being physically active: jogging, cycling, surfing, tennis, golf, gardening and travelling.

## Research Governance Officer

**Ms Lisa Fry** completed a BSc majoring in Medical Science and Genetics at Latrobe University. She then gained over 8 years' experience working in hospital pathology department diagnostic laboratories, with a focus on histology. Lisa went on to secure a medical research role as Biobank Coordinator with the Victorian Cancer



Biobank in 2009. Here, she established two new VCB Biobanking sites, at Cabrini Health and Alfred Health. This work sparked Lisa's interest in medical ethics, and saw her complete a Master of Public Health (Social Health and Ethics) at Melbourne University, alongside her full-time work. Lisa left her lab coat behind to enthusiastically join the REGI team at Barwon Health as Research Governance Officer in June this year. This role excellently combines her medical research experience with her knowledge of medical ethics (and love of the ocean!). Outside of work, Lisa hones her reflexes catching her 18month old son falling from various home and playground apparatus, and spends weekends with her husband scouring the coast for the elusive 'perfect block' or 'dream house'.

### Don't forget

REGI is here to provide advice and assistance on research design and ethics applications- see our website for **new improved guidelines** for audits and negligible risk projects

### Research Ethics Officer

**Ms Melissa Cadwell** joined the unit in June 2014 pursuing a career in public health research, following on from two years as the Project Coordinator, Barwon Infant Study. Her background is in social research, evaluation and project coordination within the humanitarian aid and development sector. Melissa worked for 9 years with World Vision Australia (WVA). She has a Bachelor of Arts in



Anthropology and Sociology from Monash University. Her studies in research methodology &

applied ethics, Peter Singer's 'Practical Ethics', and the opportunities to participate in evaluation research whilst at WVA spurred her interest in research and ethics culminating in her dream job as the Research Ethics Officer with the REGI Unit. Melissa

enjoys connecting people to information and providing researchers with support and advice on ethics submissions. When she is not working Melissa enjoys seeking out local coffee haunts, finding a renewed love for her home town and family time, reading, eating cheese, running, yoga, inspecting properties and forever dreaming about home renovations. She currently spends many of her Saturday's invigilating to fund travel and property dreams.

### Research Administration Officer

**Ms Kristin Wallis** has brought energy and order to REGI since her commencement at Barwon Health in July 2012. One of her most significant achievements is the coordination of the



annual Barwon Health Research Week culminating in the Poster Competition and Audience Choice Awards.

Kristin has completed a course in Business and now hopes to further her interests by completing a degree in Health Sciences, commencing in 2015. When she is not at her desk, Kristin spoils her three crazy, googly-eyed pugs and enjoys her yearly getaways to Noosaville and Surfers Paradise.

### Temporary Administration Assistant

**Ms Gail Benson** has been working with REGI since May. Prior to this Gail worked in BHs Safety & Quality Unit. Since joining REGI Gail has revolutionised the filing system and updated all of REGI's forms. Gail has brought significant experience in



problem solving and complaint management to the office, as well as much laughter and coffee. Outside of work Gail enjoys

photography and taking her dog 'Bob' caravanning on the Great Ocean Road, where she hopes to get that National Geographic shot that will make her rich.

# A DATE WITH DATA

## Biostatisticus sapiens (common: Biostatistician)

by Stephen Lane

*B. sapiens* is a species of mathematician, closely related to the similarly named *Statisticus sapiens*. *B. sapiens* is often found frequenting the offices of health services and academic health departments of universities, as well as some pharmaceutical outposts.

A generally docile beast, *B. sapiens* is renowned for its almost obsessive attention to data, algorithms and explaining the variation in biological systems through careful experimental design.

Whilst *B. sapiens* can often be found possessing various computational tools, and is generally not afraid to use them, *B. sapiens* may not take kindly to pure computational requests. However, *B. sapiens* can be easily pacified through early collaboration, communication, and a willingness to sometimes think outside the box.

*B. sapiens* is a sought after species for research farming, often for its production of power and sample size calculations. Many studies have however investigated the use of *B. sapiens* in the production of research protocols, specifically in their early development, with overwhelmingly positive results. Investigations into the production of data management have likewise been highly successful.

*B. sapiens* standard diet consists of regression (logistic being the most common), stratification, propensity scores and multiple imputation. *B. sapiens* may also be seen grazing on Markov chains and Monte Carlo simulations.

Contrary to popular belief, many *B. sapiens* do not consume t-tests, Chi-squared tests or rank-sum tests with any regularity.

Most *B. sapiens* speak many software environment dialects.

Amongst the most popular are R, SAS and Stata. *B. sapiens* are also commonly versed in SQL, with some individuals also speaking python, Julia and C/C++.

All *B. sapiens* are approachable, and welcome contact. If you see one, say hello!



## Research Highlight

### BH-Deakin Researcher in Lancet

Diabetes Mellitus in Older People—New Insights and Residual Challenges

A Sinclair, T Dunning, L Rodriguez Manas, Lancet (in press)



Prof Trisha Dunning

Until recently, most diabetes-related clinical practice guidelines included very

limited information

about optimal diabetes management that almost exclusively focused on glycemic, lipid and blood pressure targets. Two exceptions are the IDF Global Guideline for Managing Older People with Type 2 Diabetes (IDF 2013) and The McKellar Guidelines for Managing Older People with Diabetes in Residential and Other Care Settings (Dunning et al 2014). The latter is now policy in the McKellar Centre.

As a result of collaborative work concerning diabetes and older people Professors Sinclair, (from the UK), Trisha Dunning (from Barwon Health and Deakin University and Rodriguez Manas (from Spain) were invited to write a review article for the Lancet which is now in press. The article was reviewed by 17 international geriatricians and endocrinologists; a very rigorous peer review process.

## Research in the News

### Australia puts science in 'competitiveness' drive

<http://blogs.nature.com/news/> 14 Oct 2014 by Daniel Cressey

The Australian government has unveiled plans to increase the commercial return on its billions in research funding and to pump more resources into boosting industry-science links.

The government appointed ten experts — five business leaders and five leading researchers — to a 'Commonwealth Science Council' to advise on science priorities and to become the "pre-eminent body for advice on science and technology" in Australia. The council will be chaired by Prime Minister Abbott, with Industry Minister Ian Macfarlane as deputy chair.

The statement also says that there will be a "sharpening" of incentives for collaboration between research and industry. Five new centres to improve collaboration, and increase the competitiveness of industries including mining, oil and medical technologies, will be set up at a cost of Aus\$188.5 million (US\$164 million).

## European regulator confirms milestone medical-data transparency rules

<http://blogs.nature.com/news/> 03 Oct 2014 by Daniel Cressey

Clinical trial data previously kept behind closed doors is to be released to the public by Europe's medical regulator, after a new transparency policy was finally agreed at the European Medicines Agency (EMA). The EMA, which is responsible for licensing drugs to be sold in European Union states, has been embroiled in a long-running debate about how it could or should release information submitted by drug companies seeking permission to market their medicines. A key change is that researchers, and other members of the public, will now be able to download data down to the level of individual patients. However, companies will be able to request that parts of their data do not go into the public domain if they consider them to be 'commercially confidential'.

## WHO plans for millions of doses of Ebola vaccine by 2015

<http://blogs.nature.com/news/> 24 Oct 2014 by Lauren Morello

The World Health Organization (WHO) announced plans on 24 October to produce millions of doses of two experimental Ebola vaccines by the end of 2015. Phase I trials of two vaccine candidates have started, and as many as five other vaccines could begin testing by 2015.

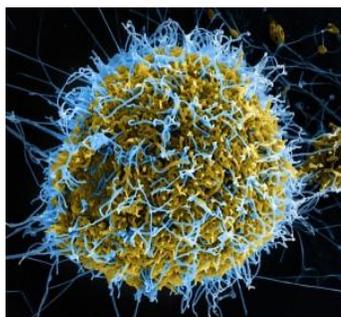
## Is it Ethical to give Ebola-Sufferers a Placebo?

The Lancet, 384:9952, 1423 - 1424, 18 October 2014

Recently prominent bioethicists have voiced disagreement over whether it could be ethical to test experimental

Ebola vaccines in placebo-controlled randomized trials. The main worry with these trials is that it is unethical to give Ebola-sufferers a placebo when an experimental vaccine is available that holds the prospect of benefit. (The prospect of benefit is typically inferred from success in trials with animals; at least one experimental vaccine, ZMapp, has showed notable efficacy at preventing deadly disease in macaque monkeys inoculated with a virulent strain of Ebola.) As a prominent group of bioethicists recently pointed out, conventional care for Ebola “does not much affect clinical outcomes,” resulting in a mortality rate as high as 70%. “When conventional care means such a high probability of death,” they continue, “it is problematic to insist on randomizing patients to [a placebo arm]

when the intervention arm holds out at least the possibility of benefit.”



## Researchers cleared of misconduct in row over sugar link to obesity

<http://www.theguardian.com/world/2014/jul/21/sugar-row-nutritionists-cleared-misconduct>

Michael Safi theguardian.com, Monday 21 July 2014

A controversial study by high-profile Sydney scientists challenged the role of sugar in Australia's obesity epidemic. Two high-profile Sydney University scientists have been cleared of misconduct over a controversial research paper challenging the idea that sugar is a unique contributor to Australia's obesity epidemic.

But an independent investigator did find some problems with the key argument of Jennie Brand-Miller and

Alan Barclay that Australian sugar consumption has declined over the past three decades.

After a six-month investigation Robert Clark, chair of energy strategy and policy

at the University of New South Wales, found that the allegations of sugar's decline in consumption were unsubstantiated, but said the saga highlighted a number of "lessons learned".

The study has formed part of the food industry's argument against public health initiatives aimed at curbing sugar intake, such as a sugar tax or ban on extra-large soft drinks.

## National Institute for Dementia Research

[Establishing the NHMRC National Institute for Dementia Research](#)

The National Health and Medical Research Council (NHMRC) has opened an Expression-of-Interest process for organisations interested in providing services to establish the institute. Health Minister Peter Dutton said the NHMRC National Institute for Dementia Research was a cornerstone of the Australian Government's \$200 million commitment to boosting research into dementia.

It is anticipated that five teams will be funded for up to \$6.5 million each over five years, to pursue collaborative research, promote effective translation of research, and develop capacity under a dementia research priority framework. Outcomes will be announced in 2015.

## Upcoming Events

### Securing University Research Funding Masterclass 2014

Practical Strategies and Insights for attracting funding and driving research outcomes in a dynamic and competitive environment. 11-12th Nov 2014 Melbourne.

### Deakin University Human Research Ethics Seminar

20 Nov 2014 10:00am to 12:00pm at ad5.005, Geelong Waterfront Campus  
This seminar will briefly introduce the National Statement on Ethical Conduct in Human Research (2007) and its 4 guiding principles. The ethics process at Deakin will then be outlined including the eligibility criteria and submission requirements for negligible, low and higher risk research. The outcomes of the various review processes will be discussed and advice will be provided on how to avoid some common pitfalls. Register Online via <http://www.deakin.edu.au/research/integrity/human/>

**Next BH HREC meeting (last one for the year ) 10th Dec. Submit documents by 26th November 2014**

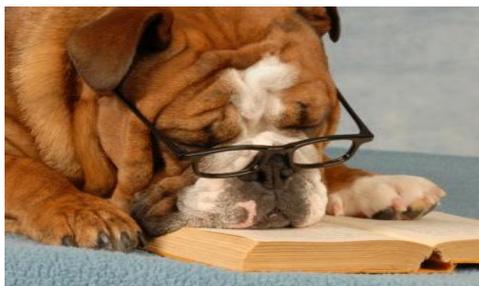
**Next REGI Drop in Session Monday 17<sup>th</sup> Nov, 2 – 4pm**

This Weeks MJA Poll

**Should doctors give potential kidney donors an “alibi” if they change their mind?**

<https://www.mja.com.au/insight/category/week>

## Selected Recent Publications



Coulson CE, Williams LJ, Berk M, Lubman DI, Quirk SE, Pasco JA. **Association between alcohol consumption and self-reported depression among elderly Australian men.** *Geriatric Mental Health Care* 2014; 2(1-2):3-8.

Pasco JA, Holloway KL, Dobbins AG, Kotowicz MA, Williams LJ, Brennan SL. **Body mass index and measures of body fat for defining obesity and underweight: a cross-sectional, population-based study.** *BMC Obesity* 2014; 1: 9.

Stuart AL, Williams LJ, Brennan SL, Kotowicz MA, Pasco JA. **Poor agreement between self-reported diagnosis and bone mineral density results in the identification of osteoporosis.** *Journal of Clinical Densitometry* 2014 Jun 7

Florencia María Aguirre Seret, Trisha Dunning, Anne Belton & Susan McLaughlin. **Preparing health professionals to work in diabetes education and care: a situation analysis.** *International Journal of Health Promotion and Education* 2014 Aug 4

Holloway KL, Brennan SL, Kotowicz MA, Bucki-Smith G, Timney EN, Dobbins AG, Williams LJ, Pasco JA. **Prior fracture as a risk factor for future fracture in an Australian cohort.** *Osteoporosis International* 2014 Sep 18

Williams LJ, Berk M, Henry MJ, Stuart AL, Brennan SL, Jacka FN, Pasco JA. **Depression following fracture in women: a study of age-matched cohorts.** *BMJ Open* 2014; 4: e004226.

Dipnall JF, Berk M, Jacka FN, Williams LJ, Dodd S, Pasco JA. **Data Integration protocol in ten-steps (DIPIT): a new standard for health researchers.** *Methods* 2014; 69(3): 237-246.

### HELP AND ADVICE

REGI hold regular drop in sessions to provide advice and assist researchers in preparing applications for ethics review the first and third Wednesday of the month 2-4pm

<http://www.barwonhealth.org.au/research/column-1/office-for-research>

## RESEARCH TIPS

REGI has three types of review based on level of risk

- Negligible risk projects (and Audits) are eligible for an Exemption
- Low risk review by the Research Review Committee (RRC)
- Greater than low risk projects have a two-step review firstly by the RRC and then proceed to a full HREC review

Many QA and negligible risk projects can be exempt from full HREC review, however these will be reviewed by REGI with advice from the Barwon Heath HREC where appropriate.

See guidelines on the REGI website <http://www.barwonhealth.org.au/research/column-1/office-for-research>