



RESEARCH ETHICS MONTHLY

JANUARY/FEBRUARY 2020

Dear <<First Name>>,

Can you believe it is already February 2020? We can't, in fact Gary's in denial it's the 21st Century. If you are interested in disability research ethics shoot him an email at gary.allen@ahrecs.com to find out what he's up to at the moment.

Not a subscriber yet? Please consider subscribing [at this link](#), because it is incredibly affirming and would be greatly appreciated. Subscribing is free, easy and keeps our in-house internet elf happy ("Gary stop zooming around the office in your wheelchair and stop bringing to work your digital countdown to The Mandalorian s2"). More about Gary's obsession with sci-fi if you stand beside him for 5mins (or even less!).

More information about the Research Ethics Monthly can be found on the [blog pages](#).





Conversations with an HREC: A Researcher's perspective

Dr Ann-Maree Vallence and Dr Hakuei Fujiyama

College of Science, Health, Engineering and Education, Murdoch University, Perth, Australia

<http://profiles.murdoch.edu.au/myprofile/ann-maree-vallence/>

<http://profiles.murdoch.edu.au/myprofile/hakuei-fujiyama/>

In our careers to date, we have had many formal conversations with members of HRECs across different institutions regarding human research ethics applications and amendments. We have also had many informal conversations with members of HRECs regarding standard operating procedures in the labs we have worked in. In this article, we share our experience engaging with our HREC in a different context, specifically, formal negotiations with our HREC following an adverse incident that occurred during our data collection for one of our projects.

To provide some context, our research often uses non-invasive brain stimulation techniques including transcranial magnetic stimulation (TMS). TMS has been commonly used in research since the mid-1980s, and is considered safe, non-invasive, and painless. TMS involves a brief, high-current electrical pulse delivered through a handheld coil placed over the scalp, which induces a magnetic field that passes through the scalp and skull with little attenuation. The magnetic field induces current flow in the underlying brain tissue, and if the stimulation is sufficiently intense, it will activate the underlying brain cells providing a measure of brain excitability [1, 2]. There are published international guidelines for the safe use of TMS [3, 4] that are used to design the experiments and screen for contraindications to TMS (for example it is routine

to exclude any persons who have a history of epilepsy, metal implants in the skull, or cardiac pacemakers). Nonetheless, research using TMS involves a small but finite risk. Occasionally, research participants experience a mild and temporary headache, nausea, muscular problems, dizziness, or fainting during or after TMS.

In a 12-month period in 2017, we experienced three adverse incidents: three participants in our research projects using TMS fainted. As mentioned above, TMS studies involve a small but known risk of fainting. There have been some reports of syncope in the literature [5-7]. It is proposed that anxiety and exposure to a novel stimulus are likely responsible for fainting in the context of TMS [3, 5-7], however, it is not possible to determine whether fainting or syncope is a secondary effect of an emotional response or a direct effect of the TMS on the nervous system.

It was following the reporting of these adverse events that we found ourselves in formal conversations with our HREC as well as informal interactions with several members of the HREC. There were two key steps involved in these conversations worth outlining. First, we invited the members of the HREC to visit the lab and attend a lab meeting in which we were discussing the adverse events. This engagement with the members of the HREC in our lab environment was a mutually beneficial exercise: it helped researchers to fully understand the concerns of the HREC and helped the members of the HREC to better understand our research procedures and aims, and observe our commitment to minimizing the risks associated with our research.

[Read more](#)

How do you compare?

Interested in how your planned policy compares to good practice across the sector?

Want to check if an alleged breach should be considered research misconduct?

Faced with a human research project that's proving difficult to review? These are some of the ways clients are using the AHRECS on-call advisory service. Pre-purchase a block of 10 hours at \$230/hr. There is no expiry date on your hours. It's like adding a world class expert to your team at a fraction of the cost. Send an email to enquiry@ahrecs.com to find out more.

Competition reminder

Don't forget to send us your entry to win for your institution a 12 month subscription to <https://www.ahrecs.vip>. This prize is worth \$350. See the story from the December 2019 edition that has the competition details and closing date. [See details here](#) Don't miss out on this chance to secure a growing library of Creative Commons resources for your institution. Send an [email to enquiry@ahrecs.com](mailto:email_to_enquiry@ahrecs.com) to find out more.



A users perspective on the ethics application process in Australia-room for improvement

1. Suat Chin Ng. MBBS, BMedSc, FRACS. Department of Surgery, Eastern Health, Melbourne, Australia.
2. Wei Ming Ong MBBS Department of Surgery, Eastern Health, Melbourne, Australia.
3. Shane Belvedere MBBS Department of Surgery, Melbourne Health, Melbourne, Australia
4. Creski Gilong. MBBS Department of Surgery, Austin Health, Melbourne, Australia.
5. Dr Nikolajs Zeps. BSc, PhD Research and Development, Epworth HealthCare, Melbourne, Australia. Eastern Clinical School, Monash University, Melbourne, Australia
6. Philip Smart MBBS, D.Med.Sci, FRACS. Gastrointestinal Clinical Institute, Epworth HealthCare, Australia Department of Surgery, Austin Health, Melbourne, Australia.

Compliance with ethical standards is fundamental to conducting human research. While there is a need for a thorough review process to prevent unethical research, the administrative workload required can often be significant. Indeed, researchers largely regard the ethics process as an obstacle that needs to be overcome, rather than a key part of the research process itself. In a recent blog on the AHRECS website entitled “[Research Ethics Review as a Box-Ticking Exercise](#)”, A/prof Angela Romano identified a significant problem with our current approach to ethical review as being one that promotes a compliance mentality rather than one that actively encourages appropriate and useful ethical reflection throughout the lifecycle of a research project.

Health and Medical Research is aimed at providing new knowledge to improve the health and wellbeing of the community and the fruits of this work will hopefully translate into tangible benefits for everyone. Significant concerns have been expressed by others that the current processes employed to regulate this work in fulfilment of ethical and legal requirements can itself be unethical. For instance, in a recent [Blog](#) by Prof Julian Savulescu he comments that whilst no-one is suggesting that research should not be subject to appropriate regulation and ethical review, given the potential to unnecessarily delay important research, all review processes should be as efficient and proportionate to the risk as is possible. Whilst we cannot immediately fix the lamentable lack of investment in undergraduate and post-graduate training in and practical application of ethics, the processes for review of projects could, in our view, be vastly improved with some fairly low-cost interventions.

What are researchers supposed to do to obtain ethical approval?

We reviewed the webpages of 78 Human Research Ethics Committees (HREC) associated with both public and private health services that we identified from the [NHMRC list](#) of registered HRECs. This list is only current to 1st March 2018 and we noted that several of the listed HRECs have in fact closed leaving just 71 that could be assessed. We also excluded from our review websites of small clinics which appear to serve only their own needs, eg IVF clinics.

[Read more](#)



The Ethics and Politics of Qualitative Data Sharing

Mark Israel (AHRECS and Murdoch University) and Farida Fozdar (The University of Western Australia)

There is considerable momentum behind the argument that public data is a national asset and should be made more easily available for research purposes. In introducing the [Data Sharing and Release Legislative Reforms Discussion Paper](#) in September 2019, the Australian Commonwealth Minister for Government Services argued that proposed changes to data use in the public sector would mean that

Australia's research sector will be able to use public data to improve the development of solutions to public problems and to test which programs are delivering as intended—and which ones are not.

Data reuse is seen as a cost-efficient use of public funds, reducing the burden on participants and communities. And, the argument is not restricted to government. Journals, universities and funding agencies are increasingly requiring social scientists to make their data available to other researchers, and even to the public, in the interests of scientific inquiry, accountability, innovation and progress. For example, the [Research Councils United Kingdom](#) (RCUK) takes the benefits associated with data sharing for granted

[Read more](#)

While you are here...

Did you enjoy this edition? Would you like to support the work we do? If so, please consider helping us cover the cost of matters such as hosting the Research Ethics Monthly and other web development by becoming an AHRECS Patron.

In addition to the warm glow from supporting our work, you will be subscribed for monthly updates of useful material (such as resources for use in your local workshops).

An institutional subscription is \$350.

Individual subscriptions start at USD1/month and USD15/month gives you access to all materials.

A few profiled items from the subscribers' area:

1. New member of a research ethics committee resource sheets

- [The Meaning of Membership - NMRECRS#01](#)
- [The categories of membership and their responsibilities - NMRECRS#02](#)
- [Preparing for your first meeting – NMRECRS#03](#)
- [Human research ethics - NMRECRS#04](#)
- [At the first meeting – NMRECRS#05](#)
- [The National Statement – NMRECRS#06](#)

2. [What constitutes “quality” in preclinical biological studies? - A human research ethics commentary](#) - A research integrity commentary0

3. [Quality in research ethics review](#) - A Human Research Ethics talk by Prof. Colin Thomson AM

4. [Human bycatch](#) - A Human Research Ethics commentary

5. [Group recruitment/consent](#) - A Human Research Ethics discussion activity

6. [Flow to determine whether research on material published to the web/social media posts require research ethics review/consent?](#) - A Human Research Ethics resource

7. [Dracula attacks: Consent for wider use of blood](#) - A Human Research Ethics discussion activity

8. [Brainstorming - A Human Research Ethics discussion activity](#) - A discussion activity about the ethical conduct of research with brain organoids.

9. [Questionable publishers - Shell ppt with speaking notes for your modification | AHRECS version with an embedded audio by Mark Israel. Material includes a further reading sheet](#) - A research integrity professional development resource

Please join us in saying a big thank you to our new Gold Patrons:

- Bendigo Health
- CanTeen
- Central Queensland University
- James Cook University
- The internal Ethics Review Panel of the Department of Employment, Skills,

- Torrens University
- University of Melbourne
- University of Southern Queensland
- The University of Sydney Ethics Office
- University of Wollongong Ethics Unit

Things You May Have Missed...

Our Resource Library

01. [Google health-data scandal spooks researchers](#) - Science
02. [Guest Post: Interesting Versus True? Measuring Transparency and Reproducibility of Biomedical Articles](#) – Scholarly Kitchen
03. [Misrepresenting “Usual Care” in Research: An Ethical and Scientific Error](#) - Paper
04. [Reasoning “Uncharted Territory”: Notions of Expertise Within Ethics Review Panels Assessing Research Use of Social Media](#) - Paper
05. (China/Gene) [Chinese scientist who produced genetically altered babies sentenced to 3 years in jail](#) - Science
06. [Research Ethics in an Unethical World: The Politics and Morality of Engaged Research](#) - Paper
07. (China) [Academic misconduct standards to be tightened](#) - China Daily Global
08. [How about personally optimized treatment?](#) - The Ethics Blog
09. Holiday funny - [New Years resolutions for your research ethics committee](#)
10. [Don't let researchers recommend who reviews their work](#) - Nature Index
11. [This Researcher Exploited Prisoners, Children, and the Elderly. Why Does Penn Honor Him?](#) - The Chronicle of Higher Education
12. [Guidelines to Counter Foreign Interference in the Australian University Sector](#) (University Foreign Interference Taskforce November 2019)
13. [Eleven tips for working with large data sets](#) - Nature
14. [Gazing into the Abyss of P-Hacking: HARKing vs. Optional Stopping](#) - R-Bloggers
15. [Rude paper reviews are pervasive and sometimes harmful, study find](#) - Science

There were more than 22 more great items in the last 30 days. Follow us on social

Our Blog

1. [Question for Research Ethics Monthly readers: Win for your institution a new 12-month subscription to <https://www.ahrecs.vip>](#)
2. [Advances in Medicine often require innovation in ethical thinking too](#)
3. [It's the hand you're dealt: Copyright card games and publishing board games are in!](#)
4. [A preliminary genealogy of research ethics review and Māori](#)
5. [Inclusion of Culturally and Linguistically Diverse populations in Clinical Trials:](#)
6. [The research use of online data/web 2.0 comments](#)
7. [Inclusion of Culturally and Linguistically Diverse populations in Clinical Trials:](#)
8. [A preliminary genealogy of research ethics review and Māori](#)
9. [Clergy service to HRECs: the useful paradox within secular governance of research involving human participants](#)
10. [Fighting Fiction with Fiction: A novel approach to engaging the public in bioethics of medical research](#)



Do you know someone who hasn't subscribed yet to the Research Ethics Monthly? Please encourage them to subscribe now and help us grow this community.



Got an idea for a post or a suggestion for a guest? Send an email to gary@ahrecs.com



Do you have a view, feedback or some constructive criticism on this or other posts? Every item has comment link so you can have your say and continue the conversation.



Copyright © 2020 Australasian Human Research Ethics Consultancy Services (AHRECS), All rights reserved.

We hate spam and definitely don't want to bother you with unwanted emails.
You can [update your preferences](#) or [unsubscribe from this list](#).

This newsletter is authorized by the AHRECS team, [click here](#) for contact and other details.

We would never divulge your details to anyone else, including not disclosing you're a subscriber, without your permission.

