



SEPTEMBER/OCTOBER 2021

Dear <<First Name>>,

Welcome to the September/October 2021 edition of the Research Ethics Monthly.

We are currently busy with a couple of jobs around Australia, enjoying chatting to partners in Aotearoa New Zealand, Kazakhstan and the UK, and collaborating with Chrysalis Clinical and Endpoint IQ.

This is a free email newsletter about human research ethics and research integrity, in Australasia and beyond.

If you are a subscriber to this publication, your name should appear above. Please let us know if we made any mistakes. Know someone who you think might like the REM? Please encourage them to [subscribe](#). If you aren't named above, please consider [subscribing](#) to the *Research Ethics Monthly*. It's free and we generally only send one email every month.

More information about the *Research Ethics Monthly* can be found on the [blog pages](#). Also there are links to our previous editions all the way back to May 2015.

Would you be prepared to support this publication? Become an institutional patron at <https://www.ahrecs.vip> (for \$350/year) or an individual patron at <https://www.patreon.com/ahrecs> (for USD1-15/month).





When it comes to the approach to human research ethics, did we buy London Bridge thinking it was Tower Bridge?

Gary Allen and Kim Gifkins

A common urban myth when Robert McCulloch bought London Bridge in 1968 was that the millionaire thought he was buying the more iconic Tower Bridge. The US\$2,460,000 he spent purchasing it, plus the expensive shipping and reconstruction costs, were an example of the more money than sense approach that the Brits considered their US cousins to be plagued by.

The story was an urban myth; it was false. McCulloch knew he was buying London Bridge and bought it for a very different purpose – to attract real estate investment. Indeed, it was initially reconstructed in the US on land, with the ‘river’ beneath it only added later.

Nevertheless, it is perhaps a useful metaphor when we think about the typical national approach to the governance of ethical conduct in human research.

The atrocities perpetrated by Nazi scientists and the researchers behind Tuskegee (and the Guatemala STD research before that) were used to justify the Nuremberg Code, the Belmont Report and the Declaration of Helsinki – with all the national research ethics standards and regulations that have flown from them.

The costs of establishing and operating (as well as insuring) research ethics committees, the practicalities of operating research ethics review arrangements as well as the time and effort researchers expend obtaining ethics approval, were all justified so that we will not repeat the awful acts, crimes, the missteps, and mistakes of the past.

It is a worthy objective, where the cost, time and frustration are justified by the results.

But are we actually getting what we paid for? Are we justified in using this history in our approach to professional development for human research

Are we also guilty of using history to publicise why ethical conduct is a worthy goal?

[Read more](#)

Friday Arvo Funnies

Have you visited the LinkedIn page for AHRECS page for our Friday Arvo Funnies (<https://www.linkedin.com/showcase/53189674>) recently? Over the last few years, we have been adding a new cartoon to the page every week. Based on these cartoons, we have also been creating discussion activities and adding these to our patrons' pages (for [institutions](#) & [individuals](#)).

In most cases, in addition to providing a chuckle, these cartoons offer an opportunity to reflect upon a serious matter in Human Research Ethics or Research Integrity.

These items might interest your research community (e.g. the members of your Research Ethics Committee and your Research Integrity Advisers).

Later this year, we will publish a story about some of our favourite funny items. We will also invite some members of the AHRECS community to contribute. If you have your own favourite cartoon from the series, please drop us a line to enquiry@ahrecs.com.

Ways to use our on-call service

Institutions that have purchased our on-call service can use it to:

1. Seek our independent and expert feedback on a policy, procedure or resource item that they produced in-house. This would include benchmarking against approaches used by other institutions in the sector, the relevant national policies and guidance material. We can also help identify any institutional risk exposure.
2. Engage us to draft material for clients' use.
3. Obtain our advice on whether a research integrity breach constitutes research misconduct.
4. Gain our feedback on appropriate investigation approaches and outcomes.
5. Ask us to propose recent literature and cases to include within professional development material produced by the client.

The cost structure for the purchased hours is listed below. The hours are used in 15-minute blocks. They don't expire until they are used.

- 10 hours \$230/h
- 20 hours \$200/h
- 30 hours \$170/h

Sadly, many jobs have been lost from the university sector in Australia over the last 18 months. Many of those who departed have significant knowledge, skills and experience in human research ethics and research integrity. Some universities now find it difficult to meet any additional demands on their research office staff and AHRECS is occasionally asked to help find professional staff with experience in Australian research ethics and integrity who can act as locums. The shift towards working online now allows those staff to be based well away from the university that is seeking to hire. If you have colleagues with research ethics and/or integrity background (HEW 5 and above), they are welcome to submit a short CV to us at AHRECS so that we can help both our clients and those in the sector looking for work.

Email us at enquiry@ahrecs.com to discuss.

Second annual free online HREC conference

Following the success of last year's event, the 2nd Annual HREC Conference will take place virtually from 1-3 December 2021. Featuring 3 plenary speakers (see flyer) and being opened by the Federal Information Commissioner, Ms Angelene Falk, the conference will include many topics and talks of interest to HRECs and researchers. These topics include: Consent; Ethics of vulnerabilities; Research involving First Nations Peoples; Social science research; Privacy; and HREC processes. The conference will feature a privacy training session by Salinger Privacy, and an HREC training session provided by Praxis. The conference is sponsored by AHRECS, Praxis, Salinger Privacy, Bellberry and is facilitated by Brisbane Diamantina Health Partners.

The organising committee are still seeking interest from anyone wishing to submit an abstract. These can be sent to info@bdhp.com.au

Registration is at <https://www.eventbrite.com.au/e/163598554681>

We look forward to meeting you online.

Gordon McGurk - Chairperson, Conference Organising Committee.

AHRECS is a proud sponsor of this event.

[FLYER ABOUT THE EVENT](#)

ERROR of Judgement!

Unnatural justice: Public allegations could cause significant harm to vital clinical trial activity

Nik Zeps

Summary

A recent allegation by Public Citizen featured on the [AHRECS latest news webpage](#) has implied that a clinical trial was unethical by design and conduct. In this blog I have examined the nature of the allegation in the context of the type of trial that is being criticised. Whilst it is important that any research be open to scrutiny and where appropriate criticism, the way this is done is important. I outline why I believe that in this instance the allegation is problematic not only because it denies natural justice to the researchers but because it makes assertions about an entire methodology that is essential to avoid wasteful and potentially harmful medical practices. At a time when there is almost a war between science and some sectors of the community, these kinds of allegations have the potential to create very real harm.

Why do we need to do clinical trials?

Clinical trials are the cornerstone of how we determine whether a particular clinical intervention is safe and effective. Although the term "Clinical Trial" is often applied as a collective noun to a group of activities it is better understood as a methodology. That is, a clinical research project is defined as a clinical trial if it employs one of several key methodologies that eliminate bias, such as the use of randomisation or blinding of observers and/or participants. Most people still think of clinical trials as being mostly for novel interventions such as new drugs and devices. However, some of the most important trials are comparisons of existing treatments that are already in widespread use. These so-called Comparative Effectiveness Trials (CETs) are particularly important in addressing the lack of evidence for routine care identified earlier in this piece.

Clinical trials are incredibly powerful in ensuring that what we observe experimentally is real and not due to some confounding factor. If we relied on observation alone, we may miss important non-random factors that influence the outcomes. A good example of this is whether the use of Vitamin E

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suggested a benefit, when nearly 40,000 women were randomised between Vitamin E and Placebo in the Women's health study over a 12 year period it was not found to have any beneficial effect.¹ Similar findings were shown in a related study of men and women with existing vascular disease or diabetes, which showed a small extra risk for heart failure in the supplement group.²

[Read more](#)

Why support AHRECS?

When we set up AHRECS, we wanted to support the culture of Human Research Ethics and Research Integrity in Australasia. We strongly believe these sectors can benefit from a vibrant and mutually supportive community of practice. Consequently, we have been using a proportion of the fees we receive for jobs to pay for matters such as:

1. Producing and distributing the *Research Ethics Monthly*.
2. Curating and hosting the Resource Library.
3. Adding material to our social media pages each day.
4. Conducting free online events.
5. Adding new items to our patrons' pages (for [institutions](#) & [individuals](#)).

We plan to continue setting money aside to maintain these things but they aren't cheap. So, a little assistance would be welcome.

If you like our online and community activity, becoming a patron is a great way to show your support.

Institutions can become a patron for \$340 per year. We can issue you with a tax invoice for this payment. Individuals can become a patron for between USD1-USD20/month.

Email us at patron@ahrecs.vip to discuss. We would really appreciate your support.

Contributing an item to the Research Ethics Monthly

Do you have an idea for an item for a future edition of the REM? This might be an item that you write or an item that might be produced by a member of the AHRECS team.

Stories could relate to Human Research Ethics, Research Integrity or Animal Ethics. You might like to consider writing an item on one of the following topics:

1. A new policy, procedure or approach that you have introduced at your institution.
2. An issue you are struggling with.
3. If you have been published in the academic or grey literature, a short item discussing the content of that publication and a link to it (with the agreement of the publisher).

International Readership

In recent months, we are seeing an increasing number of opens and click-throughs from persons based outside Australia and New Zealand. Our readership is growing in the UK (where we are now working as consultants), North America, Europe and Asia. If you are based outside Australasia, we would be thrilled to hear from you... why are you reading the Research Ethics Monthly, are there extra features you would like to see, or are you prepared to submit an item for a future edition?



HREC and AEC Workshops in Perth

Members of ethics committees often find themselves as the only member in their category on a committee[i]. This can lead to a sense of isolation in a member's role on the committee and especially lay members sometimes question their abilities to contribute effectively and make informed decisions. Both the *National Statement on Ethical Conduct in Human Research* (2018) and the *Australian code for the care and use of animals for scientific purposes* (2013) express requirements for committee member support and training[ii].

In response to this, Perth based HRECs and Animal Ethics Committees (AECs) have each gathered for annual workshops over the past 12-15 years. This has been a valuable process for training input (as required by the respective codes), a resource for connecting committee members across committees, and has provided useful quality assurance mechanisms.

The HREC forums initially began both as an educational opportunity and as a mechanism to provide conversation concerning decision-making across institutions, especially given the growth in collaborative research being undertaken. Typically, some researchers had experienced differences in decision-making between institutions. However, when at one workshop HRECs

This gave many members increased confidence in their participation on their HREC. These workshops have also offered direct opportunities for researchers to provide feedback on how the ethics review process is perceived and managed from their perspective, providing for open dialogue between researchers and committee members without directly influencing any particular committee and their decision making. In addition, speakers have been invited to provide specific input in more technical areas such as data requirements, privacy, emerging research, and legislative requirements, and explain these in lay language. Time is provided at the workshops for people in similar member categories on different committees to interact both formally in sessions and informally during coffee and lunch breaks.

The AEC workshops originally began as a forum to provide input and interaction for the lay members (Category C and D) of AECs. Category C members are lay people who represent the interests of animal welfare organisations while Category D members are lay people from the wider community[iiii]. These members are often the only individuals in their category of membership on an AEC and some had expressed a sense of uncertainty in fulfilling their roles. The workshops were designed to provide relevant education and to assist these members in their committee roles. For instance, they had opportunity to review de-identified ethics applications from other institutions, received presentations from specialists including a workshop on trapping wildlife, veterinarians explaining specific animal procedures, interactions with researchers and discussions of ethical frameworks. These workshops became a way of providing strong training input, relevant to the lay members of AECs and have helped to promote good communicating and decision making based on current understanding of best animal welfare practices. Researchers who gave presentations also felt that they have been able to have an open discussion with AECs about their work outside the scope of an application being reviewed. The workshops were regarded as so valuable by all those who attended that in response to demand they were expanded to incorporate the Category A (veterinarian) and B (researcher) members of AECs.

Due to the impact of COVID-19, workshops were not run during 2020. The continuing impact of COVID-19 has provided an opportunity for AHRECS to contribute expertise and ensure these workshops continue into the future.

Wed 3 November 2021 - Animal Ethics workshop

The theme this year focuses on managing large groups of animals such as in laboratories, farms and in the wild. Researchers are adept at managing animals, but when the numbers become very large things can become ethically complex. For instance, how are the 3R principles being met[iv]? Further, when there is overlap between research and the management of a farm or when research is focused on the needs of wildlife the ethical complexities of managing animals as part of research can increase. What are the key issues an AEC needs to focus on and how is this best approached? Expert speakers will address these issues covering the ethical considerations of integrating research into large farm operations, the ethical issues of undertaking environmental research involving large numbers of animals, and a panel of

Wed 17 November - Human Ethics workshop

The theme this year focuses on “what I wish I knew before I started”. It is not uncommon for research to raise ethical questions that were not thought about during the research design or ethics application stages. Such questions may be related to participant experiences or to the conduct or outcomes of the research. Three speakers will address these issues. A former Head of discipline, HREC member and researcher will reflect on ‘lessons learned’, thinking about a holistic picture and what we should be equipping the next generation of HREC members with. A researcher will speak about their research and interactions with several HRECs over many years - What is the HREC process like for a researcher’s perspective and what eventuates when a relatively simple research project becomes contentious or generates substantial community reactions? A data specialist will consider emerging ethical issues in relation to creating, maintaining and curating data especially when researching ‘in the field’.

[Read more](#)

Digital Health CRC + Sydney University Postgraduate Research Scholarship in Practice Analytics

The Practice Analytics research program seeks to understand how hospitals can provide clinical teams and individual clinicians actionable data that relates to the quality of clinical practice. This project is a collaboration between a number of partners across Australia including the Royal Australasian College of Surgeons, Royal Australasian College of Physicians, Cabrini Healthcare (VIC), Sydney Adventist Healthcare (NSW), St John of God hospital (WA), Ramsay Hospital Research Foundation and Epworth Healthcare (VIC). The project is part of the Digital Health Centre for Cooperative Research. All project partners are interested in exploring research and development projects related to the use of electronic health data for reflective practice and enhancing professional practice. Some clinical partners have already begun exploring how data is collected within their organisations and how it can be presented to their clinical workforce.

The research program is delivered via a suite of applied research projects. There are currently scholarships available to undertake a PhD for two of these exciting projects:

Ethical and Legal Considerations of Practice Analytics: The project aims to understand the ethical and policy implications for organisations and individual clinicians when using electronic health data for reflective practice.

Clinical Career Transitions: The project aims to understand how health data can support transitions in clinical careers and support reflective practice.

FURTHER INFORMATION AND APPLICATIONS:

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).

INSTITUTION

Subscriptions for institutions cost \$350/year. A tax invoice will be provided. Payments can be made by credit card over the phone, EFT or via PayPal. To become a patron email patron@ahrecs.vip

INDIVIDUAL

Subscriptions start at USD1/month and USD15/month gives you access to all materials. See <https://www.patreon.com/ahrecs>

A few profiled items from the subscribers' area:

1. [You can't sue us mechanism](#) – A Human Research Ethics discussion activity
2. [Whats wording of research recruitment material really mean?](#) – A Human Research Ethics discussion activity
3. [Impostor syndrome and HDR candidates](#) – A Research Integrity commentary
4. [Human research ethics and risk, the role of research ethics committees](#) – A Human Research Ethics talk
5. [Making Human Research Ethics professional development fun](#) – A Human Research Ethics discussion activity
6. [Notes for a report from a human research ethics committee to an institutional governing body.](#) – A Human Research Ethics resource
7. [Responding to criticisms of precedent](#) – A Human Research Ethics commentary
8. [Artificial intelligence and your job](#) – A Human Research Ethics/Research Integrity commentary
9. [Recruitment and risk](#) – A Human Research Ethics Discussion activity
10. [Principles of Māori & Indigenous research ethics \(An annotated bibliography by Dr Lily George\).](#) – A Human Research Ethics resource

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Things You May Have Missed...

Our Newsroom

01. [\(UK\) Embedding research integrity at the core of our science](#) – Cancer Research UK
02. [\(China\) Genetic papers containing data from China's ethnic minorities draw fire](#) – Science
03. [Change at the top](#) – Chemistry World
04. [Librarians seek more support as research partners](#) – Nature
05. [\(US & China\) US COVID origins report: researchers pleased with scientific approach](#) – Nature
06. [Preprint advocates must also fight for research integrity](#) – Nature
07. [“Fabulous document”, “very helpful guidance”: Sleuths react to recommendations for handling image integrity issues](#) – Retraction Watch
08. [Don't make early career researchers 'ghost authors.' Give us the credit we deserve](#) – Science
09. [\(China and Australia\) Chinese facial recognition scholar 'ignored questions, went home'](#) – Times Higher Education
10. [Recycling your thesis text – is it self plagiarism?](#) – Patter

There were more than 70 more great items in the last 60 days. Follow us on social media to get an alert when new items are added ([LinkedIn](#) | [Twitter](#) | [Facebook](#))

Our Resource Library

01. [Strengthening the incentives for responsible research practices in Australian health and medical research funding](#) - Paper
02. [International Scientific Cooperation – Challenges and Predicaments](#) - Booklet
03. [Predatory Journals – A one stop shop for resources](#) – Centre for Journalology
04. [Ten Simple Rules for Building and Maintaining a Scientific Reputation](#) - PLoS Paper

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06. [Effective Strategies for Research Integrity Training—a Meta-analysis](#) - Paper
07. [Can research integrity prevail in the market? Lessons from commissioned research organizations](#) - Paper
08. (US) [The lab management practices of “Research Exemplars” that foster research rigor and regulatory compliance: A qualitative study of successful principal investigators](#) - Paper
09. [AI, big data, and the future of consent](#) - Paper
10. (Germany) [Philosophers in research ethics committees—what do they think they’re doing? An empirical-ethical analysis](#) - Paper



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

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