

Addressing the ethics of health eResearch with human participants

A/Prof Craig Fry

Victoria University, Melbourne, Australia, craig.fry@vu.edu.au

BOF EXTENDED ABSTRACT

Australian E-Research

Australia is a world leader in e-research: the use of information and communication technologies (ICTs) to enable existing and new forms of research sampling, recruitment, data collection and linkage, and analyses. An increasingly diverse range of e-research methods are now evident in research with human participants in Australia, including: online recruitment of participants, mobile-phone based data collection and health promotion; Internet-based surveys, interviews, analysis of online discussion, and counselling trials; photo/video methods to engage specific target groups in research; and ICT enabled data linkage of electronic health and other personal records. E-research innovation will continue, especially in the Australian health sector, with initiatives like the National Broadband Network, the national electronic health record system, and other related government, industry and research investments.

E-Research with Human Participants

The use of e-research methods in Australia is common with human participants from populations that are difficult to identify, recruit and retain in research, treatment and other interventions. The health sector takes particular advantage of e-research methods development in Australia, with a growing focus on adolescent mental health and substance use issues [1]. Young people frequently use the Internet and mobile phone technologies to socialise and exchange information, and the rates of ownership and use by Australian adolescents are among the highest globally [2]. ICTs are therefore an ideal way of accessing young people for conducting research.

The Internet, mobile phones, laptops, tablets, and personal digital assistants are now used in a diverse range of research applications across health and related fields [3]. Australian e-research methods innovation has focused on human participants because of the benefits shown in therapeutic research domains (i.e. prevention, treatment and other interventions). Advantages include efficiency in intervention delivery, improved treatment protocol monitoring and adherence, and significant intervention effects [3].

E-research approaches have also proven beneficial with human participants in non-therapeutic research settings (e.g. epidemiological, social and behavioural, humanities research). Observed benefits there include: increased participant comfort and perceived anonymity encouraging disclosure; improved consent processes [5]; reduced research costs and data errors [1, 4].

Ethical Challenges in E-Research with Human Participants

E-research differs from traditional means of human participant access, recruitment, data collection, and analysis. E-research methods are ethically relevant because they alter the nature, dynamics and potential consequences of participation [6].

One challenge here is that e-research recruitment and data collection methods are still evolving rapidly. Data collection in e-research now extends to the use of captured images and information via either phone, digital or laptop camera (or CCTV records). Mobile phone recruitment and data collection is also diversifying (e.g. SMS survey, location tracking). Another challenge is that the possible negative consequences of participation in e-research may be greater for certain participant groups – for example the fields where Australian e-research is most common (e.g. mental health, substance misuse, adolescent health) focus on already vulnerable populations that are difficult to identify, recruit and maintain in research and treatment.

International experts argue that the pace of e-research development is “*forcing researchers and research regulators to rethink and re-evaluate such fundamental research ethics issues as privacy, informed consent, ownership, recruitment, public versus private space, research and scientific integrity itself.*” [7] Unfortunately, progress in developing clear ethical guidance for international and Australian e-research has been slow.

A recent NHMRC Australian Health Ethics Committee (AHEC) consultation paper on ethical issues in alcohol and drug research acknowledged: *"The National Statement was published before the ethical issues raised by these [e-research] developments became apparent so it currently provides no specific guidance for Internet-based or other forms of online research."* [8]

Addressing E-Research Ethics Challenges

The ethics of e-research innovation has been under-theorised and under-researched in Australia. The current lack of authoritative national e-research ethics guidance represents a threat to e-research progress, and may result in elevated risks of harm to already vulnerable human participants in fields where the majority of such research is occurring in Australia (e.g. in mental health, substance misuse, and adolescent health).

The available evidence shows that important questions exist about how familiar ethical issues (e.g. privacy, consent, confidentiality, benefits versus harms) should be addressed by researchers and ethics committees in the evolving e-research domain. Further research is required to inform e-research theory, practice and policy.

BOF Format

This e-research ethics session has the following aims and objectives:

- 1) Bring together colleagues with a shared interest in e-research ethics issues
- 2) Present findings from a recent national online survey of ethical issues in Australian e-research
- 3) Engage participants in discussion of the study findings and implications for e-research practice and relevant policies (research, ethics, graduate training etc)
- 4) Hear from participants about their experiences and attitudes concerning ethical issues in e-research with human participants
- 5) Explore the feasibility of convening a National eResearch ethics Network (membership, focus, agenda, outcomes etc)

Part 1 will be a 20-minute presentation by A/Prof Fry on key findings from his recent 2013 online survey of Australian e-researchers (n=71) and human research ethics committee (HREC) members (n=57) that focused on ethical issues in e-research. 27% of researchers had experienced ethics application delays due to HREC concerns about e-research methods, and 27% of HRECs had rejected e-research applications due to ethical concerns. Most respondents (73%) believed eResearch creates unique ethical challenges for existing guidelines (i.e. around potential harms, participant anonymity, confidentiality, privacy), and for research with vulnerable populations. 39% of respondents doubted the usefulness of the current NHMRC National Statement for addressing ethical challenges in eResearch, and most (77%) believe Australia needs specific eResearch ethics guidelines informed by evidence.

This material will serve as a prompt for participant discussion in Part 2 (40 minutes), covering topics such as: the definition and scope of 'e-research'; implications for e-research practice and relevant policies (e-research design and planning, e-research ethics review and governance, research graduate training etc); and the establishment of a National eResearch ethics Network (membership, focus, agenda, outcomes etc).

REFERENCES

- 1) Miller, PG, Sponderlund AL (2010). Using the internet to research hidden populations of illicit drug users: A review. *Addiction*, 105, 1557-1567.
- 2) Ewing S, Thomas J, Schiessl J. (2008). *The Internet in Australia*. Melbourne: ARC Centre of Excellence for Creative Industries and Innovation, Swinburne University of Technology.
- 3) Kypri K, Lee N. (2009). New technologies in the prevention and treatment of substance use problems. *Drug Alc Rev*, 28(1), 1-2.
- 4) Whitehead LC (2007). Methodological and ethical issues in Internet-mediated research in the field of health: an integrated review of the literature. *Soc Sci Med*, 65(4), 782-791.
- 5) Joinson, A. N. (2001). Self-disclosure in computer-mediated communication: The role of self-awareness and visual anonymity. *European Journal of Social Psychology*, 31(2), 177-192.
- 6) Jankowski NW, Van Selm M. (2007). Research ethics in a virtual world: Guidelines and illustrations. In N Carpentier, et al (Eds.), *Media technologies and democracy in an enlarged Europe* (pp274-284). Tartu U Press.
- 7) Buchanan EA, Hvizdak EE. (2009). Online survey tools: Ethical and methodological concerns of human research ethics committees. *J Empir Res Hum Res Ethics*, 4(2), 37-48.
- 8) National Health & Medical Research Council (2011). *Public Consultation on the Ethical Issues in Research into Alcohol and other drugs: An issues paper exploring the need for a guidance framework*.

ABOUT THE SPEAKER

A/Prof Craig Fry is a leading Australian health social sciences researcher with training in psychology, public health and health ethics. He is a NHMRC Career Development Fellow in e-health ethics, and Associate Professor at the Centre for Cultural Diversity and Wellbeing. Craig has worked in a variety of settings including community, health services, university, prison, policy and research institutes. Since 1999 he has received over \$4m of research funding, and authored >90 refereed journal articles, book chapters and research monographs. Craig currently leads the Culture and Values in Health research program within CCDW. <http://www.vu.edu.au/centre-for-cultural-diversity-and-wellbeing>

Relevant recent publications:

1. Coory M, Fry CL. (2012). Towards sharing health services data. *Medical Journal of Australia*, 196(7), 438-39.
2. Spriggs M, Arnold M, Pearce C, Fry CL. (2012). Ethical questions must be considered for electronic health records. *Journal of Medical Ethics*, 38(9), 535-9.
3. Fry CL, Spriggs M, Arnold M, Pearce C. (In Press – Accepted 20/4/14). Unresolved ethical challenges for the Australian personally controlled electronic health record system: Key informant interview findings. *American Journal of Bioethics – Empirical Bioethics*.