Plain Language Statement

Melbourne Law School

Project: Recording Our Genes: Electronic Medical Records, Genomics and the Law

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Introduction

Thank you for your interest in participating in this research project. The following few pages will provide you with information about the project, so that you can decide if you would like to take part in this research.

Please take the time to read this information carefully. You may ask questions about anything you don't understand or want to know more about.

Your participation is entirely voluntary. If you don't wish to take part, you don't have to, and this will have no consequences at all for you. If you start participating, you can also stop at any time.

What is this research about?

In this research project we want to find out what patients, their families, patient advocates and healthcare professionals think about the inclusion of genetic and genomic test results in networked electronic medical records. Networked electronic medical records are medical records that can be shared across different medical settings. Examples include *My Health Record* and records shared between different hospitals (eg. Parkville's *Connecting Care* system). In this study we would like to interview people who have experience of: clinical genetic or genomic testing; advocating for patients likely to use this kind of testing; or using the information generated from such tests (ie. as a healthcare professional). We would like the people we interview to tell us about their needs, preferences and any concerns about including genomic test results in networked electronic medical records.

After the interviews, we will go on to consider how the law responds to these issues, and to identify potential legal and governance approaches that could address people's concerns.

This research is not about people's genetic health conditions. Instead, it focuses on their views about how genetic test results are communicated, stored, shared and so on.

What will I be asked to do?

If you agree, you will be asked to take part in an interview of up to 60 minutes long, at a time to suit you. We will interview you via the internet (e.g., Zoom) or by phone.

We will take detailed notes during the interview. We will also audio-record the interview so that it can be professionally transcribed. The interview will be conducted by one researcher, possibly with a second researcher participating to take notes.
You may ask that the audio-recording device be paused or turned off at any point during the interview. Only named researchers will have access to the audio files and interview notes. You may access the interview recording and transcript by asking the researcher/s.

In the interview, we will ask for your views about the inclusion of genetic and genomic test results in networked electronic medical records. We are interested in understanding your experiences, needs, preferences and any concerns you may have in this area. We will not ask you to disclose any personal information about your health or the health of any family members.

What are the possible benefits?

We expect that this project will improve our understanding of the issues experienced and concerns held by different stakeholders about the inclusion of genetic and genomic test results in networked electronic medical records. It will allow us to go on to evaluate whether the laws and governance arrangements in this area are fit for purpose. It is hoped that this research will eventually help us to identify whether, and which, safeguards are needed to improve the way genetic test results are stored and disclosed through networked electronic medical records.

As thanks for your participation you will receive a $20 gift card after the interview has been completed.

What are the possible risks?

You will not be identified by name in the research outputs. Your role will be identified in general terms (eg. patient, parent of child patient, family member, patient advocacy group representative, clinician). However, given the small number of participants involved in the study, it may not be possible to guarantee your anonymity.

The interview will focus on your views about how information held in electronic medical records is protected and shared. It is possible that some people may find participating in the interview a little distressing, because although we will not ask about personal health information, it might be difficult to think about you or someone you know having undergone genetic testing or receiving a diagnosis of a genetic condition. If this occurs, you may pause or stop the interview or withdraw from the research project at any time (or for any other reason). There are a number of services that are available for you to contact if you need support, including your healthcare provider, Lifeline (ph 131114, www.lifeline.org.au), Beyond Blue (ph 1300 22 4636, https://www.beyondblue.org.au) and Genetic Support Network Victoria (ph (03) 8341

6315, https://www.gsnv.org.au/).

Do I have to take part?

No. Participation is completely voluntary. There are no consequences for you whatsoever if you do not want to take part or if you change your mind. You can withdraw at any time and for any reason.

If you withdraw from the study, then you will be given the option of deleting any identifiable information you have already provided. It will not be possible to withdraw information that has been processed in a way that makes such withdrawal impossible (e.g. if the information has already been anonymised and reported).

Will I hear about the results of this project?

We plan to present the results of this research in academic journals, and at academic seminars and conferences. We also intend to share the results via public-facing news sites such as *The Conversation*, and on the project website. If you would like a copy of any publications arising from this project, you can tick the box to indicate this on the attached consent form.

What will happen to information about me?

The data you provide in the form of researcher notes, audio recordings and their transcriptions will be kept securely as electronic data in a password-protected folder on the server of the University of Melbourne. The information you provide will inform the project outputs. Data and materials collected in this research project may be used in closely related future projects, or projects in the general area of ethical, legal and social issues relevant to the collection and use of health-related genomic information.

The identifiable data collected by this project will be kept for five years from the date of the last publication arising from the project or a related future research project. It will not be disclosed to any other person or organisation. After this time, all personally identifiable data will be destroyed. Non-identifiable research data may be retained indefinitely for use in future related research projects.

Who is funding this project?

This project is funded by the University of Melbourne through its Early Career Researcher Grants scheme (2021).

Where can I get further information?

If you would like more information about the project, please contact the responsible researcher; Dr Megan Prictor (megan.prictor@unimelb.edu.au; Ph. 03 9035 9644 or 0407 885580).

Who can I contact if I have any concerns about the project?

This project has human research ethics approval from The University of Melbourne [ID 21025]. If you have any concerns or complaints about the conduct of this research project which you do not wish to discuss with the research team, you should contact the Research Integrity Administrator, Office of Research Ethics and Integrity, University of Melbourne, VIC 3010. Tel: +61 8344 1376 or Email: research-integrity@unimelb.edu.au. All complaints will be treated confidentially. In any correspondence please provide the name of the research team and/or the name or ethics ID number of the research project.