Evidence Summary

Australian Genomics Health Alliance

Dynamic Consent

Australian Genomics responded to a need to improve the consent process for genomic research studies by coordinating a multi-disciplinary effort to deliver a product inspired by the principles of dynamic consent.

Background

Australian Genomics is committed to improving the experience of participants enrolled in genomic research programs and undergoing genomic testing.

We recognise that traditional, paper-based models of consent are not optimal and in many respects don't convey the complexities of medical genomics to research participants.

This is why we have developed a new online research consent and engagement platform for our participants called CTRL (control).

The platform is based on **dynamic consent** - an emerging mechanism which enables study participants to choose from more granular consent options, and to give and revoke consent in real time. They can also use the platforms to interact more fully in the research if they choose.

Project aims

We developed this new approach to consent over the course of 12 months by bringing together a multi-disciplinary working group, which includes the University of Oxford team who first introduced dynamic consent, consumer representatives and experts in the fields of genetic counselling, clinical genetics and bioethics, in partnership with the digital health technology company Curve Tomorrow.

Curve Tomorrow employ a product development protocol where user experience is the core principle of the design.

Key findings

The core features of the **CTRL website** have been developed and are available for use, allowing participants to:

- update their profile and contact details
- make and change consent choices
- access patient experience surveys
- contact the researchers through a messaging system
- keep up-to-date with news and information, and follow their progress through the study.

The use of CTRL to support consent and recruitment into the Australian Genomics study has been approved by our Human Research Ethics Committee and patients are signing up.

We encourage everyone to access a demo version of the site at demo-ctrl.australiangenomics.org.au

CTRL gives participants more say in their involvement in research and how their health information might be used.

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The first adaptation of the platform has been for the **Australian Reproductive Genetic Carrier Screening Study (Mackenzie's Mission).**

Further development of CTRL is planned, including representing genomic reports in a format accessible to participants, providing opportunities for self-reporting health information, as well as linking participants with other approved research projects.

Impact

Our key mission is for participants enrolling in genomic studies to better understand the research they are signing up to, and as part of that, for research participants to start to become familiar with the dynamic consent approach in all research programs they may become involved in.

This gives participants more say in their involvement in research and how their health information might be used.

To fulfil this, we are endeavouring to make the CTRL platform broadly available for other research programs to use. Therefore, it is designed and built with flexibility in mind. CTRL has been adapted to support the enrolment and ongoing participation of 10,000 couples in the Mackenzie's Mission study.

We also want patients involved in our program to provide input and help us to keep improving it.

Conclusion

Australian Genomics responded to a need to improve the consent process for genomic research studies, coordinating a multi-disciplinary effort to deliver a product inspired by the principles of dynamic consent.

The consent and engagement platform is being used by research participants enrolled in Australian Genomics Flagships clinical projects.

Future work will focus on improvements to make the website better, primarily with participant experience in mind, but also so that dynamic consent approaches can be readily adopted by research organisations.

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DYNAMIC CONSENT – A SNAPSHOT

For **patients**, dynamic consent platforms aim to provide:

- more appropriate, granular and flexible consent options
- access to better study information
- opportunity to increase scientific and medical literacy
- two-way communication between participants and researchers
- building trust in the process.

For **research organisations**, dynamic consent facilitates:

- better electronic consent records
- retention of participants in longitudinal studies
- clearer data sharing frameworks for health information
- working toward addressing ethical, legal and social issues relevant to genomic studies.