Australian Genomics

Research Snapshot
June 2021

National Clinical Genomic Consent Materials

Australian Genomics has developed clinical genomics consent materials that can be adapted and adopted nationally for use across all genetic conditions.

Background

In Australia there is no single, national approach to obtaining patient consent to undertake genetic or genomic testing. Standards and practices are fragmented, and consent forms differ between states and between genetic service providers.

This creates inconsistency in the patient experience, in the outcomes and management of patients, and is a barrier to the flow of health information between jurisdictions.

In response to this need, in 2017 Australian Genomics embarked on a project to develop clinical genomics consent materials that can be adapted and adopted nationally for use across all genetic conditions.

Project aims

The National Consent Working Group was tasked with developing national clinical genomics consent materials comprising a consent form and a supporting factsheet (a 'consent package') to meet the needs of clinicians, laboratories and patients.

The consent package would explain the complexities around genomic testing, including:

- The testing process and types of genomic tests
- Potential outcomes from the result of testing
- The impact of results for the patient and their family
- The storage of genomic data
- Options for sharing genomic data for research

We undertook a multi-stage approach to the development of the consent materials (detailed in the figure below) in three major stages:

1) The evaluation of current genomics consent forms in use in clinical and research settings.
2) Development and review of a consent package including a broad professional and public consultation.
3) Consent form clinical pilot and evaluation.

Key outcomes

Adult and paediatric consent forms and supporting documentation were finalised and piloted at two clinical sites in Australia between January and June 2019.

Significant consultation with feedback from more than 40 individuals and organisations enabled the piloting of product that was already highly developed.

The national consent materials were harmonised where appropriate with jurisdictional forms to ensure as much similarity as possible at a national level.

Feedback from the pilot suggested that in practice the consent materials were mostly fit for purpose, however some elements did require review, such as:

- Removal of statements that were not currently possible to implement by either the clinical or laboratory services
- Clarification of language in research statements
- Clarification of statement regarding withdrawal from testing

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The finalised consent materials were released in October 2019 for adaption and adoption by clinical genetic services and health professionals responsible for guiding patients through the consent process for whole exome, whole genome or panel testing.

We recommend clinical genetics services and health professionals ensure they have appropriate approval at a local level to apply these forms in their practice.

Clinicians employed through NSW Health for example, should currently continue to use consent forms specific to that state.

Potential impact

Australian Genomics mission is to prepare Australia for genomic medicine. A significant element of this mission is to ensure patients understand the risks, benefits and outcomes of testing - all of which are key areas of the consent process.

By creating a product that works satisfactorily across the clinic, laboratory and community, Australian Genomics is leading the way in national collaborative approaches to the delivery of complex genomic information.

The consent materials have received interest from overseas initiatives looking to implement similar documentation in their countries.

Conclusion

The development, consultation and pilot process of these clinical genomic consent materials was a resource-intensive, lengthy process, but an extremely valuable one.

The resulting consent materials will help support standardised testing information to be provided to patients in a clear and concise format, create more consistency in the management of patients and appropriate sharing of information across jurisdictions.

In 2019, the Australian Health Ministers' Advisory Council launched a project led by the NSW Ministry of Health administered by the Project Reference Group on Health Genomics (PRGHG). While the materials developed by Australian Genomics informed this project, the consent materials endorsed by the PRGHG in late 2020 fail to include optional consent for secondary research, and do not explicitly refer to de-identified data sharing.

As part of the Australian Genomics Grant Program 2021 – 2023, we plan to reconvene a National Consent Working Group to review and refine the Australian Genomics materials, informed by the PRGHG products, and also progress development of forms for specific purposes (e.g. mature minors, somatic genomic testing, prenatal genomic testing) as well as translations of forms and materials into multiple languages.

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ACKNOWLEDGEMENT

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We encourage everyone to access the national consent package from our website.
It can be found in tools and resources.

australiangenomics.org.au

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A National Clinical Genomic Consent Process

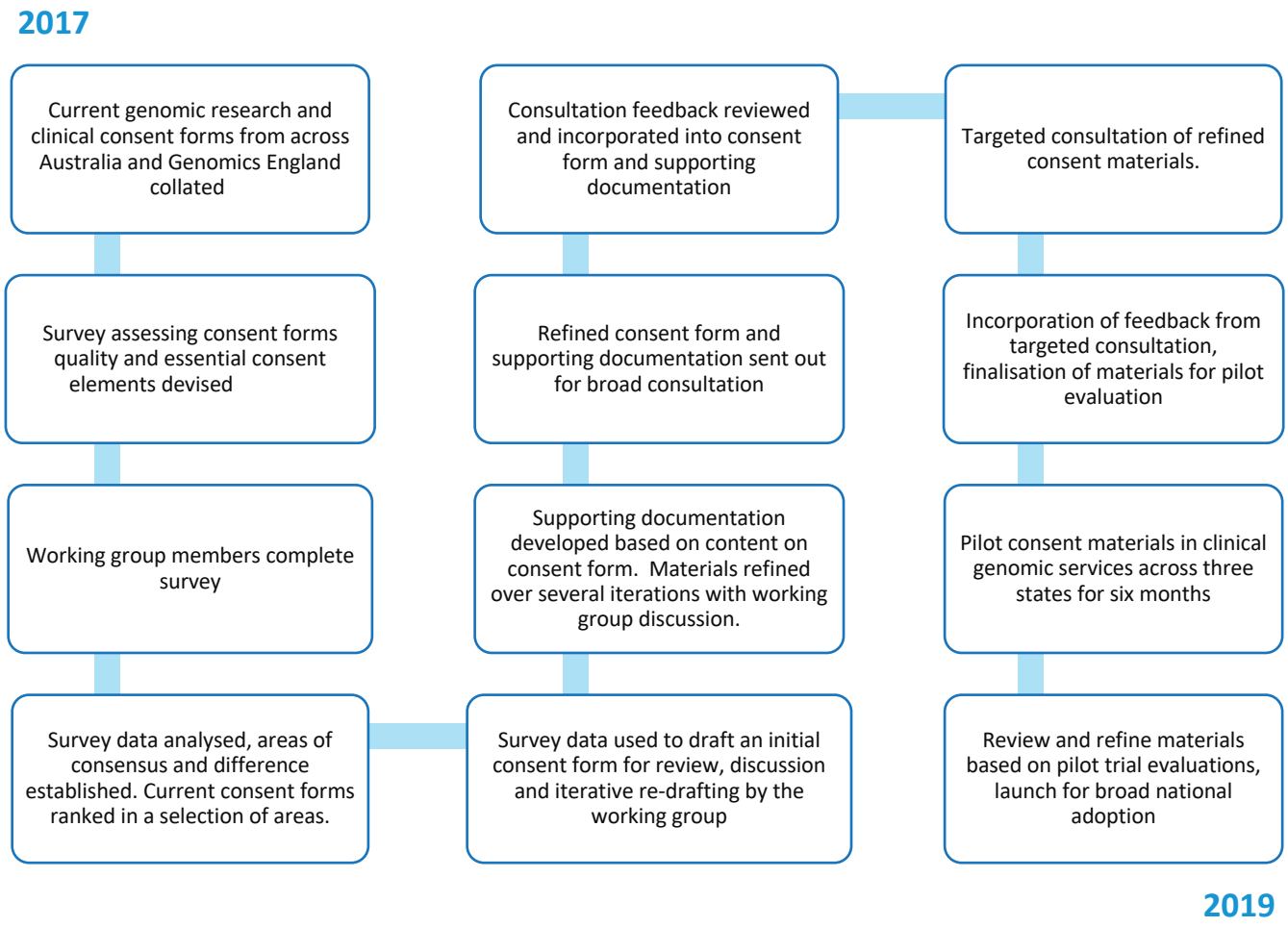

Figure 1. Australian Genomics multi-stage development of a national consent form and factsheet (a consent 'package').