Phase 2 Consultation National Model for Clinical Consent to Genomic Testing

INSTRUCTIONS FOR COMPLETING THE CONSULTATION FORM:

Your feedback will inform the national model for clinical consent to Genomic Testing. As part of this model, a draft consent form template, guidance material for health professionals and patient information has been developed to assist with the process of obtaining informed consent. Include your responses in the sections below.

• Please read the National Model for Clinical Consent to Genomic Testing - draft final report. The document includes the revised consent form template; guidance for health professionals obtaining consent and relevant inclusions for patient supporting materials
• Please return your completed feedback from by **Friday 24 April 2020**
• Please direct your responses and questions regarding this request to Ms Vanessa Fitzgerald, Genomics Principal Project Officer, Strategic Reform and Planning Branch on 9391 9544 or vanessa.fitzgerald@health.nsw.gov.au

DETAILS OF SURVEY RESPONDENT

Name:	Heather Renton
Position:	Chief Executive Officer
Organisation	Syndromes Without A Name (SWAN) Australia
Contact Details (phone, email)	heather@swanaus.org.au

NATIONAL MODEL FOR CONSULTATON

Draft Genomic testing clinical consent form template (page 4)

Field	(Please comment on the numbered sections in the draft consent form)	Further Comments
1. (reason/type of test)	**Type of genomic test** □ Genomic testing by – single genet test, gene panel, exome, genome, other (specify) is being conducted for…. **Reason for genomic test** □ Diagnostic Testing, Predictive Testing, Carrier Testing, Prenatal Testing, Family Studies, Other (with explanations for them all as stated on form. Please note that Pharmacogenomics should be included in predictive testing)	There need to add the headings: Type of Genomic Test and Reason for Genomic Test. These should be 2 separate headings
Need to add a section: About my Genomic Test	□ My blood/saliva/tissue cells sample will be used for genomic testing □ I will be told my test results by a health practitioner (please note a genetic counsellor is a qualified health practitioner) □ My data will be stored…..need to state how and where and for how long for e.g. deidentified	Need to add a section: About my Genomic Test. The general public may not realise a genetic counsellor is a health practitioner
2. (patient primary consent) - Need to reword this heading to read: I understand that that my genomic test could mean:	**I understand that that my genomic test could mean:** □ **My test results are based on current knowledge that may change in the future** □ **My test results may find the cause of my genetic condition** □ **My test may not find the cause of my genetic condition at this point in time** □ **My test results may be of 'uncertain significance', which means they cannot be understood at this point in time** □ **My test results may or may not show other clinically relevant findings (incidental findings)** □ **My test results may have health implications for me or other family members** □ **My test results may or may not show unexpected family relationships** □ **My test results may affect my ability to obtain some types of insurance** □ **My test results may affect the type of employment I can undertake** □ **My test results are confidential and will only be released with my consent or as required or permitted by law.**	Need to reword this heading to read: I understand that that my genomic test could mean. Employment statement needs to be added. Use consistent language used throughout the consent form.
3. (patient optional consent) - Remove the word "optional"	**Additional consent** □ Sharing my results with clinical health team □ Sharing my test results with relevant health practitioners of my choice involved in the care of my genetic relatives (if clinically relevant) □ Sharing my test results with my genetic relatives (if clinically relevant) □ Be contacted in the future regarding participating in relevant ethically approved research studies (please note this will require you to sign a separate research consent form prior to be involved in any research projects) □ Sharing my deidentified and untraceable data for research projects to advance scientific knowledge	
4. (patient declaration)	□ I, insert name of patient / guardian / medical power of attorney ….. consent to genomic testing as discussed with my / the person I am guardian for / the person I have medical power of attorney for, health practitioner……. □ I consent for my results to be given to …….. in the event that I do not have the cognitive capacity to receive them or are deceased.	
5. (health practitioner declaration)	Leave as stated	
Optional additional consent (if applicable)	States: Yes and Not Applicable, yet this is headed as an optional field, so just change this in the heading as I have stated)	
6. (interpreter/liaison)	Leave as stated	
Overall Comment on Consent Form	• There needs to be consistent language throughout the guidelines and consent form • There needs to be consistent plain English language used throughout the consent form. • Neither the consent guidelines nor the consent form has an Easy Read/Easy English version. We need to make the information accessible for people with intellectual disabilities. This will need to be trialled and tested first with people with intellectual disabilities to gauge their level of understanding before any publication is officially adopted.	

Draft guidance material for health professionals (page 5-8)		
Theme	***(Please provide general comment on the guidance material)***	
General Comments	No reference to what accreditation is given to the lab e.g. are they NATA. It should state the accreditation level of the labs who can perform genomic tests.	
Consent requirements	Consent information needs to be provided in accessible format such as through an Easy Read/Easy English documents, document readers or form readers. There is no reference to give people the option to ask for information in other formats and we wonder how many health professionals would think to offer information in accessible formats.	
Consent forms	Was there a digital consent form available for consultation? If this will be an option (and it should be), consumer engagement needs to be undertaken to ensure it meets patient's needs. Patients should always be given the opportunity to discuss consent forms with a health professional.	
Supporting patient information	The option to receive the genomic information and consent form should be given with enough time for patients to read it and process the information so they can discuss their concerns at their genomics appointment.	
Aboriginal and Torres Strait Islander Peoples	Aboriginal and Torres Strait Island Peoples Community need to be included in consumer feedback and consultation groups. Health professionals should receive training on how to best liaise with patients from Aboriginal and Torres Strait islanders, culturally diverse and religious backgrounds.	
Cultural and linguistic diversity	There is always a risk that information is interpreted incorrectly, particularly when there is no equivalent word in the non-English language. Accessible information Easy Read/Easy English genomic information and consent forms need to be made available to patients. Any website which has genomic information should have accessible features incorporated into them to meet the needs of people with disabilities. The statement 'Where a patient is not fluent in English, has deafness or other special communication needs...' should include reference to 'hearing and/or visual impairment' rather than just 'deafness' as both vision and hearing impairment can be the result of genetic conditions.	
Disclosure of results	There needs to be the option to disclose results to another nominated family member or guardian if the patient is incapacitated or has passed away. Timing should be noted, too many times we hear from our community that they get a call saying their geneticists has test results but then they cannot get an appointment for a number of weeks. We also hear that families recoveomg test results over the phone but then have to wait for an appointment to discuss them. This leads to increased anxiety among our members. Patients should be given the opportunity for re-testing or reanalysis of results at a later stage and this should be offered by the health practitioner rather than relying on the patient themselves to make the follow up appointment.	
Insurance	The clinical consent guidelines will need to be updated to reflect any changes to insurance once the Moratorium expires. Consumers need to be informed on the implications genomic testing may have in the future with regards to insurance.	
Employment	There needs to be some reference to the fact that genomic test results may impact a patient's ability to perform certain employment tasks. We believe that employment impacts need to be included in the genomics information sheet and consent form.	
Implications for Family members	Support around implications for family members should be given by a genetic counsellor as often feelings of guilt and anxiety are involved, and patients will need support. The patient may be need referring onto a social worker or psychologist.	
Research	There needs to be a clear understanding on how data will be shared for research and consent forms for specific research projects should be given when the time arises for a patient to be considered for a research project. Patients want to know how and where their data will be stored and how it will be used for research projects. Patients should be given clear descriptions between de-identified, re-identified (traceable) and anonymous data (non-traceable). It should be noted that many SWAN families are only too happy to share data for research in the hope it assists more patients be diagnosed or leads to treatment options and better clinical care or possibly even a cure for their child's genetioc condition. It needs to be made very clear to patients that there is a difference between clinical testing and research testing.	
Data management	There needs to be clear guidelines for health practitioners as to where and how a patients consent form, blood/saliva/tissue samples, test results will be stored. It is worth noting that not all patients are registered for E-Health records. You also want to be able to share data and test results in a secure way between labs and health practitioners/hospitals in different clinical settings. For example, data and results should not be emailed between hospitals as email is considered 'unsafe'. Instead data should always be shared via an encryption method.	
Further testing and analysis	The option of further testing should be offered to patients if no diagnosis can be made. This should be offered by the health practitioner to the patient as to what they would consider reasonably practicable. The request for reanalysis should not be the patient's responsibility, though patients should have the option to request this if they deem it appropriate. e.g. if they are thinking of having another child and it has been 2 years since the original testing sample was analysed. There may be other opportunities to reanalyse the testing sample through research projects both in Australia and overseas.	
Relevant inclusions in patient information materials (page 9)		
Theme	***(Please comment on the inclusions within the patient information material)***	
Genomic testing process	A patient genomic testing information guide needs to be presented in a number of ways in various mediums: •A written plain English guide, including the option for document readers and form readers •A written Easy Read or Easy English. (there is a difference) •Visuals such as series of infographics •Videos •Interactive options on a website or app It is important to be mindful that people learn in different ways and some people are more visual than others. It is important to include clear illustrations along side descriptions. Many members of the general public do not understand medical terms and find genetics and genomic testing very difficult to understand so the concepts should be broken down where possible. Patient genomic testing information guidelines should be given to patients in advance of their health appointment to address the consent form to ascertain that patients have had a chance to read and process the information. The health practitioner should always ask the patient if they understood the guidelines and the consent form. It is important to be mindful that some patients will say 'yes" whether they do or not, so asking questions in relation to their understanding is one way to ensure patients understand what they are consenting to. There have been some great patient resources written by Melbourne Genomics Health Alliance *https://www.melbournegenomics.org.au/patients/community-resources and the* Australian Genomics Health Alliance *https://www.genomicsinfo.org.au/*. These resources should be used to form the patient guide. It would be good to include an updated flow chart e.g. *https://swanaus.org.au/wp-content/uploads/2019/06/SWAN_genetics_flowchart.pdf* in the patient genomic testing information guide. The patient guide should include a glossary of terms. It should also be references to additional reading/resources for patients who would like to improve their knowledge of genomics. It should also have a links to support group bodies, such as the Genetic Support Network Victoria so patients can find support groups when they want further support and information.	

Implications for genetic relatives	This should take into consideration patients cultural, religious and linguistic backgrounds.	
Sharing genomic data	Research is extremely important to SWAN members searching for a diagnosis for their child but also for patients seeking better medical treatment plans and cures for their condition. Many of our SWAN members want to contribute to research if it assists with learning more about their child's condition or helps others gain a diagnosis. Therefore, research questions need to be addressed ahead of insurance questions in the patient genomic testing guide. Most Australians do not have a life insurance policy, so this information is of little concern to them. That is not to say it should not be included in the patient guide. How data will be shared needs to be explained, e.g. deidentified vs reidentifies vs anonymous. How data will be stored and where it will be stored needs to be addressed. The risks and benefits of data sharing need to be explained. It needs to be made clear what the data is being shared. Is it just the blood/saliva/tissue sample that are stored and shared or is phenotypical information stored and shared too? Is the family history shared? Are and behavioural, cognitive, physical traits that might go with a patient's condition shared? Exactly what information can be shared for research needs to documented in the patient guide.	
General Comments		
(Please provide any general comments on the document)		
SWAN represents over 500 members who have gone through a diagnostic journey, many of our members have received multiple single gene tests and genomic tests. Our concerns are around the consent form and genomic testing patient guide are as follows: • There needs to be consistent plain English language throughout the guidelines and consent form (not everyone can understand medical jargon and genomics is not an easy concept to grasp). The information also needs to be accompanied by some visuals illustrating what the text is explaining. • Genomic testing information needs to be offered in more than one medium, e.g. print, video links, animations, and infographics • Any website which has genomic information should have accessible features incorporated into it to meet the needs of people with disabilities. • Neither the consent guidelines nor the consent form has an Easy Read/Easy English version. The information needs to be accessible for people with intellectual disabilities and people who English is not their native language. This will need to be tested first with people with intellectual disabilities to gauge their level of understanding before any publication/guidelines/consent forms are officially adopted. • There needs to be the option to use a document reader on the information sheet and a form reader on the consent form so the information can be read out loud. Readspeaker is an example of a service provider for this service (*https://www.readspeaker.com/blog/industries/health-care/*) and provides software on some government and disability websites. *https://www.ideas.org.au/covid-videos/covid-19-operational-plan-for-people-with-disability-released.html* gives you an example of how this works on a website. • Data sharing and security – who has access to it? • Data sharing for research – how will this be done, is my data safe? • There needs to be increased community consultation with diverse groups from a wide range of demographics. More consultation is required with a diverse population e.g. Aboriginal and Torres Strait Islanders, people with intellectual disabilities and people from non-English speaking backgrounds to ensure the national consent form and patient genomic testing information guide are fit for purpose. • There needs to be some reference in the Health Practitioners guidelines to prompt them about the importance of referring patients on to appropriate patient support groups whether a diagnosis can be made or not. E.g. if the person has epilepsy are they referred on to the Epilepsy Foundation if no gene change for the epilepsy is found or if the consent form is being used for a child/young adult who has a rare genetic condition for which there is no active face to face peer support group for, they could be referred onto Syndromes Without A Name. • It is important to avoid vague language e.g. 'relevant health practitioners' as stated in the summary 3F Stakeholder interview. Many health professionals currently have limited awareness of genomics. It is important that where consent is granted for a genomic test result to be shared with a patient's health practitioners, that a geneticists/paediatrician communicates with them, so everyone receives the same accurate information. A letter written in plain English should also be sent to the patient and where required, a letter written in Easy Read/Easy English should also be written to the patient.	