Consent for genomic testing (trio)

This consent form is to be used in conjunction with additional information provided to me by my genetic healthcare professional.

This consent form consists of a number of sections:

Section 1: Having genomic testing

Section 2: The possible outcomes of genomic testing

Section 3: Additional genomic information that may be identified by genomic testing

Section 4: Additional testing to examine genetic factors that may influence how your body processes medications

Section 5: Sharing genomic information with family members

Section 6: Future use of my/my child's genomic data

Child being tested		
First Name	Date of birth	DD/MMM/YY
Surname	URN	

Mother		
First Name	Date of birth	DD/MMM/YY
Surname		

Father		
First Name	Date of birth	DD/MMM/YY
Surname		

Section 1: Having genomic testing

We have been given information explaining the reasons for testing and the possible outcomes of the test.

We understand that:

1. Undergoing genomic testing is voluntary and we can withdraw at any time before results are reported.
2. We can say yes or no to any of the options in this consent.
3. Genomic testing requires a biological sample (usually blood or saliva) from which my/my child's DNA is obtained. My/my child's DNA will be tested to look for genetic variants associated with

   _____

   (name of condition(s)).
4. Biological samples will be retained by Genome.One in accordance with applicable law and standard laboratory practice.
5. Genomic testing results may affect our ability, or our child's ability, to obtain some types of insurance (such as life insurance and income protection insurance). If we have questions or are concerned, Genome.One recommend we discuss this further with an insurance specialist prior to undergoing genomic testing.

   ☐ Yes ☐ No

Section 2: The possible outcomes of genomic testing

We understand that:

1. Genomic testing may or may not provide a diagnosis for the condition(s) tested for. Our genetic healthcare professional may be able to give an estimate of the chance genomic testing will lead to a diagnosis for the condition(s) tested for.
2. Genomic testing will not identify all possible genetic variants that could contribute to health problems for us, or our child, now or in the future.
3. The possible outcomes of genomic testing are:

(a) One or more genetic variants associated with the condition(s) tested for are identified. This means there is strong scientific or medical evidence that links the genetic variants with disease (this is known as a "pathogenic" or "likely pathogenic" variant).

(b) No genetic variants known to be associated with the condition(s) tested for are identified.

(c) One or more genetic variants are identified, although currently there is not enough scientific/medical evidence to determine if the variant identified is associated with the condition(s) tested for (this is known as a "variant of unknown significance").

We understand that:

1. The Genome.One report is based on information that is current at the time of reporting.
2. Genomics is a rapidly developing field of medicine. Genome.One does not automatically reanalyse or review the results of genomic testing already provided in light of new scientific knowledge (including variants of unknown significance).
3. In the event either of us develop, or our child develops, new symptoms or new health information becomes available, e.g. if someone else in our families develop symptoms, we should contact our genetic healthcare professional so that they can assess whether a reanalysis or review of the results is required.

Section 3:
Additional genomic information that may be identified by genomic testing (Incidental findings)

We understand that there is a small chance (less than 5%) that additional genomic information may be identified through genomic testing. For example, a genetic variant may be identified that is associated with an unrelated condition one of us may develop, or our child may develop, in the future.

1. For our child:

We understand that:
(a) If additional genetic variants are identified from genomic testing that are unrelated to the condition(s) being tested for and those genomic variants are associated with conditions that can develop in childhood (only), we have the choice to receive those findings when the results of the genomic test are reported. We also have the choice not to receive those findings.

If we choose to receive any of these additional findings from genomic testing of our child, we may need to arrange appropriate follow up care with our genetic healthcare professional.

If we change our minds about receiving additional findings from genomic testing of our child before the results of the genomic test are reported, we need to notify our genetic healthcare professional as soon as possible.

We want to know about additional genetic variants identified from genetic testing of our child unrelated to the condition(s) tested for that are associated with conditions that can develop in childhood.

☐ Yes ☐ No

(b) If additional genetic variants are identified from genomic testing of our child that are unrelated to the condition(s) tested for and that are associated with conditions that develop in adulthood, they will not be reported to our genetic healthcare professional or to us.

In this next section, each parent should answer for himself or herself.

I understand that:
(a) If additional genomic variants are identified that are unrelated to the condition(s) my child is being tested for and that are associated with conditions I could develop where there are options for early diagnosis, prevention or medical treatment e.g. certain cancers and heart conditions, I have the choice to receive those findings when the results of the genomic test are reported. I also have the choice not to receive those findings.

If I choose to receive any of these additional findings, I may need to arrange appropriate follow up care with my genetic healthcare professional.

If I change my mind about receiving additional findings from genomic testing before the results of the genomic test are reported, I need to notify my genetic healthcare professional as soon as possible.

2. For the mother:

I want to know about genetic variants identified from genomic testing unrelated to the condition(s) my child is being tested for that are associated with conditions I could develop where there are options for early diagnosis, prevention or medical treatment.

☐ Yes ☐ No

3. For the father:

I want to know about genetic variants identified from genomic testing unrelated to the condition(s) my child is being tested for that are associated with conditions I could develop where there are options for early diagnosis, prevention or medical treatment.

☐ Yes ☐ No

Section 4: Additional testing to examine genetic factors that may influence how your body processes medications

Pharmacogenomics testing examines genetic factors that may influence how your body processes medications. I understand that genomic testing can include pharmacogenomics testing. Pharmacogenomics testing is optional.

We want our child to have pharmacogenomics testing.

☐ Yes ☐ No

For the mother:
I want to have pharmacogenomics testing

☐ Yes ☐ No

For the father:
I want to have pharmacogenomics testing

☐ Yes ☐ No

Section 5: Sharing genomic information with family members

We understand that:

1. The results of genomic testing may have implications for blood relatives (e.g. parents, siblings, children).

   If any of our results, or our child's results, have implications for any blood relative:

☐ We each consent to our own results being given to our own blood relatives and healthcare professionals involved in their care. We each consent to our child's results being given to our child's blood relatives and healthcare professionals involved in their care. If a blood relative wishes to access any of our results, or our child's results, they must contact their own healthcare professional who must make a formal request through Genome.One.

☐ We do not consent to our results, or our child's results, being given to any of our blood relatives.

2. Our own test results, or our child's test results, may be given to a blood relative without consent in accordance with applicable legal guidelines under the Privacy Act 1988 (Cth) where this is necessary to lessen or prevent a serious threat to their life, health or safety.

Section 6: Future use of our genomic data

1. We understand that if we give consent, our child's de-identified information may be placed in reference databases and shared with researchers and clinicians from Genome.One and external organisations for the purpose of research into the genetic causes of disease, to improve genomic pathology services and for the development of drugs and therapies.

We consent to our child's de-identified genetic information being placed in reference databases.
☐ Yes ☐ No

In this next section, each parent should answer for himself or herself.

2. I understand that if I give consent, my de-identified information may be placed in reference databases and shared with researchers and clinicians from Genome.One and external organisations for the purpose of research into the genetic causes of disease, to improve genomic pathology services and for the development of drugs and therapies.

For the mother:
I consent my de-identified genetic information being placed in reference databases.
☐ Yes ☐ No

For the father:
I consent my de-identified genetic information being placed in reference databases.
☐ Yes ☐ No

Participant

- The genetic healthcare professional has discussed the genomic test with us and we each understand the potential benefits, limitations, risks and consequences of the test. We have each been given the opportunity to ask additional questions and we are each satisfied with the explanations. We have each received genetic counselling prior to giving this consent.
- We each request and consent to genomic testing.

Mother

Name (printed)

Signature

Date DD/MMM/YY

Father

Name (printed)

Signature

Date DD/MMM/YY

Health professional

- I have informed both participants about the potential benefits, limitations, risks and consequences of the genomic testing. I have given both participants the opportunity to ask additional questions about genomic testing and those questions have been answered to their satisfaction.
- Each participant has completed the incidental findings section of this consent and has had the opportunity to ask questions about the implications of reporting incidental findings.

Name (printed)

Signature

Specialty

Date DD/MMM/YY