**Participant or Parent/Guardian Information Statement**

**Template for studies offering diagnostic genomic testing**

*[Blue italics prompts for content, including alternative wording for a*

*Participant versus Parent/Guardian Information Statement]*

*[Study Name]*

HREC Number:

Principal Investigator:

Site Principal Investigator:

Version No:

Version Date:

Location:

1. **Introduction**

We are inviting *[you and/or your child]* to participate in a research study that is explained below. Knowing what is involved will help you decide if *[you and/or your child]* want to take part. Please read this Information Statement and the attached fact sheet on genomic testing carefully. You will be given a copy of this information and the consent form to keep.

**Important points:**

* Participation in this research study is voluntary.
* Take the time you need to decide if *[you and/or your child]* want to participate.
* If you have any questions, please get in contact with the study team.
* You can withdraw at any time without this affecting *[your/your child’s]* care.
1. **About this research study**

*[Insert a brief statement about the study.]*

*Example: This research study is looking at how useful genomic testing is for diagnosing and/or managing [insert] medical conditions. This will help to find out when we should use this test and the most appropriate and cost-effective way of providing genomic testing to patients in the future.*

We have invited *[you and/or your child]* to take part in this research study because we are trying to understand if there is a genetic cause for *[your/your child’s]* condition.

1. **Who is funding this research study?**

This research study is being led by *[institution/investigator]*. It is funded by *[funder]*. The health professionals and researchers involved in the research study are all employees of medical research institutes, universities and clinical and diagnostic services.

1. **Are there any costs?**

There will be no out-of-pocket costs to you for tests or appointments associated with participating in this research study, nor will you *[or your child]* be paid. Additional testing that may be suggested by your doctor may not be included as part of this research study. If you choose *[for your child]* to undertake further tests at your doctor’s suggestion, there may be a cost to *[you/the family]* for these tests.

1. **What does participation involve?**

**Genomic test**: Participation involves a genomic test called *[test name e.g. whole exome/whole genome/trio whole genome sequencing]*. The test aims to check if *[you/your child]* may have a genetic condition to explain *[your/their]* health problems. The test is done on a *[sample name]* sample, *[details of how sample will be collected]. [Details on whether the sequencing/result is coming from an accredited or research laboratory. If laboratory/test is not accredited, please confirm if result will be verified or if further verification will be required after the result is returned].*

**Further analysis:** In some cases, *[your and/or your child’s]* sample(s), health data and/or genomic data may be analysed using different approaches or based on new knowledge, to try to find a diagnosis and/or to better understand the health condition. *[Details of type of further analysis ore re-analysis if appropriate; if additional samples might be required; where it is taking place if different to main study; if additional consent will be sought or the participant will be notified prior to further analysis.]*

**Health information:** We will gather information about *[your and/or your child’s]* health, including from *[your and/or your child’s]* hospital/medical records. A member of the study team may also ask you directly for more details.

**Result return:** The results of the genomic test will be provided to you *[details, e.g. in person by a health professional]*. It may take *[turnaround time]* for *[your and/or your child’s]* test results to be available. The genomic test may or may not provide a diagnosis (see section 6). *[Details on whether further confirmation of the test is required by the health care team separate to this research study.]*

Results of any further analysis of *[your and/or your child’s]* sample(s), health data and/or genomic data will be returned to you if relevant to *[your/your child’s]* care. *[Details, e.g. provided in person by a health professional]*. If further analysis does not provide information relevant to *[your/your child’s]* care, this will not be reported to you. It may take *[period of time]* for results to be available. *[Details on whether further confirmation of the test is required by the health care team separate to this research study.]*

**Surveys:** You *[may/will]* also be asked to complete a survey prior to *[your and/or your child’s]* genomic test and *[time period]* after the return of *[your and/or your child’s]* results. *[Details e.g. how surveys will be provided, purpose of surveys, how long they should take].*

1. **What are the possible results of the genomic test?**
* A genetic cause for *[your/your child’s]* condition(s) may be found.
* A genetic cause for *[your/your child’s]* condition(s) may not be found.
* The results may be of ‘uncertain significance’, which means they cannot be understood using current available information.

Genomic test results are based on current knowledge, which may change in the future. This test will also not predict all future health problems.

1. **What are the possible benefits of taking part?**

The results of genomic testing could potentially help health professionals involved in *[your/your child’s]* care to better understand and manage *[your/your child’s]* condition.

Should a genetic cause of *[your/your child’s]* condition be found, this may also help you access support and plan for the future, including assisting with reproductive decision making.

Sometimes, genomic test results may also provide information about the genetic risks of family members related to *[you/your child]* by blood. Where appropriate, this information may be used to help inform genetic counselling and testing of family members.

*[May include information on how communication with family members in such situations will be managed, ensuring consistency with any state-based procedures.]*

1. **What are the possible risks of taking part?**

The test result may affect *[your and/or your child’s]* ability to obtain some types of insurance (such as life insurance, income protection insurance or travel insurance). It does not affect health insurance. More information can be found in the genomic testing fact sheet.

There is a small chance of unexpected findings, such as:

* finding a genetic change related to a different medical condition (incidental finding); or
* showing an unexpected family relationship.

*[Include information on how these situations will be dealt with, e.g. Any unexpected findings will be discussed with your doctor and/or genetic counsellor involved in the study, to ensure appropriate communication of information.]*

Genomic testing and discussion of the results can also be emotional for some people and their families.

1. **What happens to *[my and/or my child’s]* sample(s) and data?**

***[Your and/or your child’s]* sample(s)**

*[Your and/or your child’s]* *[sample name]* sample(s) will be sent directly to the *[clinically accredited diagnostic/research]* laboratory *[if a single site, add location]* for genomic testing and stored as per laboratory guidelines. As part of this research study, *[your and/or your child’s]* sample(s) will be stored indefinitely in case further analysis may be needed to help find a diagnosis and/or to better understand the health condition. Some samples may be used by the laboratory or research study as a control sample and for quality assurance purposes. *[Your and/or your child’s]* sample will not be shared with any person or organisation outside of the research study unless you consent to this. If you would like *[your and/or your child’s]* sample to be destroyed, you can contact the study team and request this.

***[Your and/or your child’s]* data**

All data collected as part of this research study will be stored in secure, controlled-access databases that meet national and international data standards. Stringent security measures will help prevent unauthorised access to or misuse of the data.

*[Your and/or your child’s]* data obtained through this research study:

* will be accessed by those involved in *[your/your child’s]* care and personnel working on this research study;
* may be released to genetic services to help with the care of other family members, without *[your and/or your child’s]* identity being revealed to family members wherever possible;
* will be stored and made available to other research studies if you consent to donate *[your and/or your child’s]* data for this purpose (optional – see section 13); and
* will otherwise remain confidential, except as required or allowed by law.

Personal information (including *[your and/or your child’s]* name, date of birth and address) will be removed and replaced with a unique study code. Only the minimum, necessary data will be shared with study researchers. This maintains *[your and/or your child’s]* privacy, while allowing our study team to link any research findings back to *[you/your child]* if necessary. This will be important if there are findings that have implications for *[your/your child’s]* future health care, so that it may be possible to contact you to return these results.

1. **Using *[your and/or your child’s]* data to advance knowledge**

*[Your and/or your child’s]* anonymised genomic test results and health data obtained through the research study may also be shared with national or international databases. This improves understanding of human genetics by comparing *[your and/or your child’s]* results to those from other people.

In such cases, *[your and/or your child’s]* data will be ‘anonymised’. This means that there will be no personal information or study code attached to the data and it cannot be linked back to *[you and/or your child]*. Therefore, there is no direct benefit to *[you and/or your child]*, but *[your and/or your child’s]*data can support health advances that benefit others.

1. **Publication of results**

The results of this research study may be published and/or presented at scientific and medical meetings. In any publication or presentation, data will be reported in a way that means *[you and/or your child]* cannot be identified.

1. **Additional details**

*[Your and/or your child’s]* health records and any data collected and stored for the research study may be reviewed at any time to make sure we are following correct study procedures. This review may be done by the Human Research Ethics Committee that approved this research study, regulatory authorities, or as required by law. *[Your/your child’s]* health professional may record *[your and/or your child’s]* participation in this research study and genomic test results in *[your and/or your child’s]* local health record.

*[Your and/or your child’s]* participation and the way this research study is conducted abides by relevant Australian and State/Territory privacy laws. In accordance with those and other relevant laws, you have the right to request access to information about *[you and/or your child]* collected and stored by the study team. You also have the right to request the correction of any information you disagree with. Please contact the study team member named at the end of this document if you would like to request access to *[your and/or your child’s]* information.

1. **Donating *[your and/or your child’s]* sample(s) and data for other research studies (optional)**

We ask you below whether you consent to donating *[your and/or your child’s]* sample(s) and data (health-related, genomic and self-reported information) collected in this research study, for use in other research approved by a registered Human Research Ethics Committee. This committee checks that research studies are scientifically and ethically acceptable. This means that the research respects and protects *[you and/or your child]* and the other people who have donated sample(s) and/or data.

If you consent to donating *[your and/or your child’s]* sample(s) and data for other research studies:

* we will remove *[your and/or your child’s]* personal information from the sample(s) and data before sharing them;
* we may share *[your and/or your child’s]* samples(s) and/or data with researchers in Australia or overseas, including at universities, hospitals, medical research institutes, not-for-profits, or for-profit biomedical, pharmaceutical or diagnostic testing companies;
* *[your and/or your child’s]* data (with personal information removed) may also be stored on national or international databases, with access to the data controlled by our Data Access Committee;
* access to *[your and/or your child’s]* sample(s) and/or data will only be granted if approved by our Data Access Committee, a group of people who will consider each application for access to the research study sample(s) and data;
* in most cases, we will not recontact you for further consent;
* the other research studies may or may not be related to this research study;
* research findings from these other studies will generally not be returned to you, and are unlikely to benefit *[you/your child]* directly. However, they will benefit future research; and
* we will not share *[your and/or your child’s]* data for marketing purposes or with organisations (such as insurance companies) that are not connected to research as described above.
1. **Re-contact to participate in new studies (optional)**

There may be opportunities in the future to invite *[you and/or your child]* to participate in new, ethically approved studies. This may involve collecting new information or samples. This is optional and you can indicate below whether or not you consent to be contacted about *[your child]* participating in new studies in the future.

1. **Withdrawal from the research study**

If you decide to withdraw from the research study before genomic testing is performed and data is collected, we will not continue.

If you withdraw after genomic testing is performed and data is collected, you can choose not to be told about the result. However, we will use any sample(s) and data already collected for research purposes unless you tell us not to. If *[your and/or your child’s]* sample(s) or data have already been shared, it may not be possible to retrieve or destroy all *[your and/or your child’s]* sample(s) and data that have been collected as part of this research study.

1. **Further information and who to contact**

If you would like any further information concerning this research study, or to withdraw, you can contact:

*[Name]*

*[Position]*

*[Phone Number]*

*[Email Address]*

This research study has been approved by the Human Research Ethics Committee (HREC) of *[HREC Name]*. This research study will be carried out according to the National Statement on Ethical Conduct in Human Research (updated 2018).

If you have any complaints about any aspect of the research study, the way it is being conducted, or any questions about being a research participant in general, then you may contact:

**Reviewing HREC approving this research and HREC Executive Officer details:**

*[Reviewing HREC Name]*, HREC Manager

Telephone: *[Phone Number]*

Email: *[Email Address]*

**Local HREC Office contact (Single Site – Research Governance Officer)**

*[Name]*

*[Position]*

Telephone: *[Phone Number]*

Email: *[Email Address]*

**Consent Form for Genomic Testing and Participation in Research**

It is my choice *[for my child]* to have genomic testing and participate in the *[insert study name]* research study. I understand that I can say yes or no where options are given on this form.

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(*[patient] or [parent/guardian names]*),

understand that my *[child’s, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (child’s name)]*

DNA will be tested by *[name of test]* to look for changes in genes that may be associated with

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (condition).

**About the test**

* Genomic test results are based on current knowledge, which may change in the future.
* I will be told the test results by a doctor or a genetic counsellor, who will arrange appropriate follow up care as necessary.
* If I change my mind, I can choose not to be told about the test results.

**Potential test results**

* This test might find a cause for the condition(s).
* This test might not find a cause for the condition(s).
* The results might be of *'uncertain significance*’, which means they cannot be understood today.
* There is a chance that this test could find other medical conditions (incidental findings).
* Further analysis may be undertaken to try to find a diagnosis and/or to better understand the health condition.

**Potential outcomes**

* Results may provide information about *[my/my child’s]* condition and its management.
* Results may provide information on the health/genetic risks of family members related to *[me/my child]* by blood.
* Results may affect *[my/my child’s]* ability to obtain some types of insurance.
* There is a chance that results may show unexpected family relationships.

***[My and/or my child’s]* sample and data**

* *[My and/or my child’s]* sample(s) will not be shared with any person or organisation outside of the research study unless I consent to this.
* *[My and/or my child’s]* results will be available to health professionals involved in *[my/my child’s]* care.
* *[My/my child’s]* results may also be used to inform genetic counselling and testing of family members related to *[me/my child]* by blood, without disclosing *[my/my child’s]* identity to them where possible.
* *[My and/or my child’s]* personal information will be kept confidential and will only be accessed as needed by those involved in *[my/my child’s]* care and study members, unless otherwise required or allowed by law.
* *[My and/or my child’s]* genomic data and other data may be combined with other people's data internationally to increase understanding about human genetics. This data cannot be traced back to *[me and/or my child]* and any findings cannot be returned to me.

**In agreeing to participate in this research study, I understand that:**

* I am free to withdraw *[myself and/or my child]* at any time during the study without any impact on *[my/my child’s]* usual care.
* I *[may/will]* be asked to complete survey(s) about *[details, e.g. my understanding and experience of genomic testing and costs associated with living with my condition]*.
* *[Add any other requirements for participants]*
* The health professionals and organisations involved in *[my/my child’s]* care may release information about *[my/my child’s]* health to *[name of institution]* for the purposes of this research study.
* The laboratory undertaking the genomic testing will release *[my and/or my child’s]* test report and genomic data to the study team. *[Name of research study]* will then have responsibility for the data.
* Further analysis may be undertaken to understand *[my/my child’s]* genomic test results and/or the health condition. Additional samples may be requested by the study team to undertake this analysis if required.

**Optional consent for future research**

* I agree to donate *[my and/or my child’s]* sample(s) and study data, with all personal information removed, for use in other ethically approved research studies. I understand that I will not be recontacted for separate consent prior to sharing *[my and/or my child’s]* samples(s) and study data with other ethically approved research studies (see **section 13**).

**□ Yes       □ No**

* I agree to being contacted in the future about participating in new research studies. I understand that if I am interested in taking part, I will be given a separate consent form (see **section 14**).

**□ Yes        □ No**

**Alternative contact for *[my and/or my child’s]* results**

This person can be given *[my and/or my child’s]* results if I pass away, lose decision-making capacity or cannot be contacted. (Leave this blank if you do not wish *[your and/or your child’s]* results to be given to anyone in these circumstances.):

**Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Relationship to you: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­\_­\_\_\_**

**Contact details: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**I have had enough time to consider the information provided to me, and:**

* I have had the opportunity to discuss this research study with a study team member or health professional.
* I have been able to ask questions until I am satisfied with the answers.
* I know how to get in touch if I think of more questions later.
* I have been offered a copy of this consent form.

I provide consent *[for my child]* to have genomic testing and participate in research as summarised in this form.

*[****Participant] or [Parent/Guardian]***

|  |  |
| --- | --- |
| Full Name |  |
| Signature |  | Date of Signature |  |
| *[Child’s]* Date of Birth |  |
| *[Child’s]* Address |  |
| *[Parent/Guardian]*Email |  |

**Study Team Member/Health Professional**

I have explained the research study to the *[participant / parent/guardian]* who has signed above, and believe that they understand the purpose, extent and possible risks of *[their/their child’s]* involvement in this research study.

|  |  |
| --- | --- |
| Full Name |  |
| Signature |  | Date of Signature |  |

**Witness\* – for verbal consent**

I have witnessed the verbal consent of the *[participant / parent/guardian]*, stated above.

|  |  |
| --- | --- |
| Full Name |  |
| Signature |  | Date of Signature |  |

\* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent. Witness must be 18 years or older.

**Additional Family Consent [include if relevant, e.g. Trio testing]**

I consent to:

* Genomic testing on my sample(s) for the purposes of clarifying results of the genomic testing that is being performed on the participant’s sample(s).
* Further analysis of my sample(s) and/or genomic data to try to find a diagnosis for the participant’s condition and/or to better understand the health condition.
* The sharing requirements of my data and sample(s) as part of this research study (stated above).

A separate report may not be issued for family members who have provided a sample(s) for the purpose of interpreting the genomic test result of the participant. However, it may be possible to deduce information about family members from the results of the child.

**Relative 1**

|  |  |
| --- | --- |
| Relationship to Participant |  |
| Full Name |  | Date of Birth |  |
| Signature |  | Date of Signature |  |

**Relative 2**

|  |  |
| --- | --- |
| Relationship to Participant |  |
| Full Name |  | Date of Birth |  |
| Signature |  | Date of Signature |  |

**Relative 3**

|  |  |
| --- | --- |
| Relationship to Participant |  |
| Full Name |  | Date of Birth |  |
| Signature |  | Date of Signature |  |

Note: All parties signing the Consent Form must date their own signature.

NOTE: Copy of this consent is to be sent to testing laboratory with sample.

Affix identifier information

**Form for Withdrawal of Participation**

*[To be provided to participant as required]*

*[Study Name]*

HREC Number:

Principal Investigator:

Site Principal Investigator:

Location:

**Declaration by *[Participant or Parent/Guardian]***

I wish to withdraw *[myself and/or my child]* from participation in the *[insert study name]* research study. I understand that such withdrawal will not affect *[my/my child’s]* usual care, my relationship with those treating *[me/my child]* or my relationship with *[Institution name]*.

If genomic testing has already been performed, I request that the result be disclosed to me:

**□ Yes        □ No**

I agree that *[my and/or my child’s]* sample(s) and any data already collected can continue to be used for research purposes:

**□ Yes        □ No**

I understand that if *[my and/or my child’s]* sample and/or data that has been collected as part of this research study has already been shared, it may not be possible to retrieve or destroy all of *[my and/or my child’s* sample and data.

|  |  |
| --- | --- |
| Full Name |  |
| Signature |  | Date of Signature |  |

*In the event that the [participant’s/ parent/guardian’s] decision to withdraw is communicated verbally, the study team member/health professional must provide a description of the circumstances below.*

|  |
| --- |
|  |

**Study Team Member/Health Professional**

I have explained the process of research study withdrawal to the *[participant / parent/guardian]* who has signed above, and believe that they understood that explanation.

|  |  |
| --- | --- |
| Full Name |  |
| Signature |  | Date of Signature |  |

Note: All parties signing the withdrawal section must date their own signature.