**Participant Information Statement**

**Template for studies offering predictive genomic testing**

*[Includes* ***Option (A)*** *combined participation/testing consent form; or* ***Option (B)*** *separate consent forms to allow individuals to participate in the study but decline genomic testing (e.g. where a decliners’ survey is used)]*

*[Blue italics prompts for content]*

*[Study Name]*

HREC Number:

Principal Investigator:

Site Principal Investigator:

Version No:

Version Date:

Location:

1. **Introduction**

We are inviting you to participate in a research study that is explained below. Knowing what is involved will help you decide if you 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 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 future access to care.
1. **About this Research Study**

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

*Example: This research study is looking at genetic changes which increase people’s risk of developing health problems in the future.*

We have invited you to take part in this research study because *[e.g. we are offering genomic testing to identify people with genetic changes which increase their chance of developing health problems in the future].*

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 be paid. Additional testing that may be suggested by your doctor may not be included as part of this research study. If you choose to undertake further tests at your doctor’s suggestion, there may be a cost to you for these tests.

1. **What does participation involve?**

You will be offered genomic testing as part of this research study.

*[If you intend to survey genomic test decliners: You do not have to have testing. We support either decision and are keen to understand more about people’s decision-making. We may ask you questions to understand your decision-making.]*

**Genomic Test**: The genomic test you will be offered is called *[test name e.g. whole genome sequencing/panel testing/single gene testing]*. The test aims to check whether you may have an increased risk of developing *[health problems / name of condition(s)]* in the future due to changes in your DNA. 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 whether result will be verified or if further verification will be required after the result is returned].*

**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 test results to be available. The genomic test may or may not tell you about increased *[health risks / chance of health problems/condition name]* for you and/or your family members (see section 6). *[Details on whether further confirmation of the test is required by the health care team separate to this research study.]*

**Health Information:** We may gather information about your health, including from your hospital/medical records. A member of the study team may also ask you directly for more details.

**Further analysis:** In some cases, your sample(s), health data and/or genomic data may be analysed using different approaches or based on new knowledge in the future. *[Details of type of further analysis or re-analysis, if relevant to the study; 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.]*

Findings from any further analysis of your sample(s), health data and/or genomic data may be returned to you if they are relevant to your or your family’s health. *[Details, e.g. provided in person by a health professional; whether further confirmation of the test is required by a health care team separate to this research study.]*

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

1. **What are the possible results of the genomic test?**
* We might find changes in your DNA which are known to increase your *[health risks / chance of developing health problems/condition name]* in the future.
* We might not find any changes in your DNA which are known to increase your *[health risks / chance of developing health problems/condition name]*. It is still possible that you have DNA changes that we do not know about or in genes that we did not look at. It is also possible that you could develop *[health problems / condition name or other health conditions]* in the future.
* The results might be of ‘uncertain significance’, which means they cannot be understood using currently available information.

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

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

The results of genomic testing could provide information about your *[health risks / chances of developing health problems/condition name]* in the future. This may empower you to take steps to prevent *[health problems / condition name]* or to detect and treat *[them/it]* early. This testing may also help you access support and plan for the future, including assisting with decisions around reproductive options.

Sometimes, genomic test results may also provide information about the genetic risks of family members related to you 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 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 health condition that wasn’t anticipated; 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 be emotional for some people and their families.

1. **What happens to my sample(s) and data?**

**Your sample(s)**

If you consent to testing, your *[sample name]* sample(s) will be sent directly to the *[clinically accredited diagnostic/research]* laboratory *[if a site single, add location]* for genomic testing and stored as per laboratory guidelines. As part of this research study, your sample(s) will be stored indefinitely in case further analysis may be needed. Some samples may be used by the laboratory or research study as a control sample and/or for quality assurance purposes. Your 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 sample to be destroyed, you can contact the study team and request this.

**Your data**

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

Your data obtained through this research study:

* will be accessed by *[those involved in your 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 identity being revealed to family members wherever possible;
* will be stored and made available to other research studies if you consent to donate your data for this purpose (optional – see section 13); and
* will otherwise remain confidential, except as required or allowed by law.

Personal information (including your 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 researchers. This maintains your privacy, while allowing our study team to link any research findings back to you if necessary. This will be important if there are findings that have additional implications for your future health, so that it may be possible to contact you to return these results.

1. **Using your data to advance knowledge**

Your 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 results to those from other people.

In such cases, your 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. Therefore, there is no direct benefit to you, but your 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 and/or presentation, data will be reported in a way that means you cannot be identified.

1. **Additional details**

Your 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 project, regulatory authorities, or as required by law. Your health professional may record your participation in this research study and genomic test results in your local health record.

Your 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 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 information.

1. **Donating your sample(s) and data for other research studies (optional)**

We ask you in the consent form whether you consent to donating your 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 studies are scientifically and ethically acceptable. This means that the research respects and protects you and the other people who have donated sample(s) and/or data.

If you consent to donating your sample(s) and data for other research studies:

* we will remove your personal information from your data and sample(s) before sharing them;
* we may share your 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 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 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 directly. However, they will benefit future research; and
* we will not share your 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 to participate in new, ethically approved studies. This may involve collecting new information or samples. This is optional and you can indicate on the consent form whether or not you consent to be contacted about participating in new studies in the future.

1. **Withdrawal from the research study**

If you decide to withdraw from the 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 samples(s) and data already collected for research purposes unless you tell us not to. If your data has already been shared, it may not be possible to retrieve or destroy all your samples(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 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 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 to have genomic testing and participate in the *[study name]* research study. I understand that I can say yes or no where options are given on this form.

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(patient), understand that my DNA will be tested by *[name of test]* to look for changes in my DNA that are associated with increased *[health risks / chance of developing health problems/condition name]*.

**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 *[details, e.g. a health professional]*, 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 changes in my DNA which increase my *[health risks / chance of developing health problems/condition name]* in the future.
* This test might not find changes in my DNA which increase my *[health risks / chance of developing health problems/condition name]* in the future.
* The results might be of *'uncertain significance*’, which means they cannot be understood today.
* There is a chance that this test could find a change in my DNA that is related to a health condition that wasn’t anticipated.
* *[Add any other analyses/results that may occur as part of the study, e.g. further analysis might be undertaken to better understand the result or health condition.]*

**Potential outcomes**

* Results could inform me about my *[future health risks / chances of developing health problems/ condition name in the future]*, and possible steps to prevent *[health problems / condition name]* or detect and treat *[them/it]* early.
* Results may provide information on the health/genetic risks of family members related to me by blood.
* Results may affect my ability to obtain some types of insurance.
* There is a chance that results may show unexpected family relationships.

**My sample and data**

* My sample(s) will not be shared with any person or organisation outside of the research study unless I consent to this.
* *[My results will be available to health professionals involved in my care.]*
* My results may also be used to inform genetic counselling and testing of family members related to me by blood, without disclosing my identity to them where possible.
* My personal information will be kept confidential and will only be accessed as needed by *[those involved in my care and]* study members, unless required or allowed by law.
* My anonymised genomic test results and health data may be shared with national or international databases to improve our understanding of human genetics. This data cannot be linked back to me and there is no direct benefit to me of this data sharing.

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

* I am free to withdraw at any time during the study without any impact on my future access to care.
* I *[may/will]* be asked to complete survey(s) about *[details, e.g. my understanding and experience of genomic testing].*
* *[Add any other requirements for participants]*
* The health professionals and organisations involved in my care may release information about my health to *[name of institution]* for the purposes of this research study.
* The laboratory undertaking the genomic testing will release my 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 in the future *[insert details of the type of any further analysis that might be undertaken as part of the study]*.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 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 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 results**

This person can be given my results if I pass away, lose decision-making capacity or cannot be contacted. (Leave this blank if you do not wish your 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 to have genomic testing and participate in research as summarised in this form.

 **Participant**

|  |  |
| --- | --- |
| Full Name |  |
| Signature |  | Date of Signature |  |
| Date of Birth |  |
| Address |  |
| Email |  |

**Study Team Member/Health Professional**

I have explained the research study to the participant who has signed above, and believe that they understand the purpose, extent and possible risks of their involvement in this research study.

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

***Witness\* – for verbal consent^***

 *I have witnessed the verbal consent of the participant, stated above.*

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

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

*[****^Optional.*** *Include if witnessed verbal consent is necessary for the study (e.g. participants cannot read) or the Human Research Ethics Committee allows verbal consent in lieu of written consent under certain circumstances, e.g. during the COVID-19 pandemic.]*

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

**Consent Form for Participation in Research**

It is my choice to participate in the *[study name]* research study.

\*\***This is not consent for genomic testing. There is an additional consent form if you choose to have testing.**

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

* I can choose whether or not to have genomic testing.
* I may be asked to complete a survey(s) as part of my participation, including questions about my reasons for declining genomic testing if I choose not to have testing.
* I am free to withdraw at any time during the study without any impact on my future access to care.
* The study coordinator can contact me at any time during the study if required.
* Data gathered from the research study may be published. My identity will not be revealed in any such publication.

**Optional consent to be contacted about future studies**

* 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**

**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.

**Participant**

|  |  |
| --- | --- |
| Full Name |  |
| Signature |  | Date of Signature |  |
| Date of Birth |  |
| Address |  |
| Email |  |

***Witness\* – for verbal consent^***

 *I have witnessed the verbal consent of the participant, stated above.*

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

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

*[****^Optional.*** *Include if witnessed verbal consent is necessary for the study (e.g. participants cannot read) or the Human Research Ethics Committee allows verbal consent in lieu of written consent under certain circumstances, e.g. during the COVID-19 pandemic.]*

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

**Consent Form for Genomic Testing**

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(patient), understand that my DNA will be tested by *[name of test]* to look for changes in my DNA that are associated with increased *[health risks / chance of developing health problems/condition name]*.

**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 *[details, e.g. health professional]*, 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 changes in my DNA which increase my *[health risks / chance of developing health problems/condition name]* in the future.
* This test might not find changes in my DNA which increase my *[health risks / chance of developing health problems/condition name]* in the future.
* The results might be of *'uncertain significance*’, which means they cannot be understood today.
* There is a chance that this test could find a change in my DNA that is related to a *[health condition]* that wasn’t anticipated.
* *[Add any other analyses/results that may occur as part of the study, e.g. further analysis might be undertaken to better understand the result or health condition.]*

**Potential outcomes**

* Results could inform me about my *[future health risks / chances of developing health problems/ condition name in the future]*, and possible steps to prevent *[health problems / condition name]* or detect and treat *[them/it]* early.
* Results may provide information on the health/genetic risks to family members related to me by blood.
* Results may affect my ability to obtain some types of insurance.
* There is a chance that results may show unexpected family relationships.

**My sample and data**

* My sample(s) will not be shared with any person or organisation outside of the research study unless I consent to this.
* *[My results will be available to health professionals involved in my care.]*
* My results may also be used to inform genetic counselling and testing of family members related to me by blood, without disclosing my identity to them where possible.
* My personal information will be kept confidential and will only be accessed as needed by *[those involved in my care and]* study members, unless required or allowed by law.
* My anonymised genomic test results and health data may be shared with national or international databases to improve our understanding of human genetics. This data cannot be linked back to me and there is no direct benefit to me of this data sharing.

**In agreeing to have genomic testing, I understand that:**

* I am free to withdraw at any time during the study without any impact on my future access to care.
* I *[may/will]* be asked to complete survey(s) about *[details, e.g. my understanding and experience of genomic testing].*
* *[Add any other requirements for participants]*
* The health professionals and organisations involved in my care may release information about my health to *[name of institution]* for the purposes of this research study.
* The laboratory undertaking the genomic testing will release my 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 in the future *[insert details of the type of any further analysis that might be undertaken as part of the study]*.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 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 samples(s) and study data with other ethically approved research studies (see **section 13**).

**□ Yes       □ No**

**Alternative contact for my results**

This person can be given my results if I pass away, lose decision-making capacity or cannot be contacted. (Leave this blank if you do not wish your 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 to have genomic testing and participate in research as summarised in this form.

 **Participant**

|  |  |
| --- | --- |
| Full Name |  |
| Signature |  | Date of Signature |  |
| Date of Birth |  |
| Address |  |
| Email |  |

**Study Team Member/Health Professional**

I have explained the research study to the participant who has signed above, and believe that they understand the purpose, extent and possible risks of their involvement in this research study.

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

***Witness\* – for verbal consent^***

 *I have witnessed the verbal consent of the participant, stated above.*

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

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

*[****^Optional.*** *Include if witnessed verbal consent is necessary for the study (e.g. participants cannot read) or the Human Research Ethics Committee allows verbal consent in lieu of written consent under certain circumstances, e.g. during the COVID-19 pandemic.]*

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**

I wish to withdraw from participation in the *[study name]* research study. I understand that such withdrawal will not affect my future access to care 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 sample(s) and/or any data already collected can continue to be used for research purposes:

**□ Yes        □ No**

I understand that if my sample(s) 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 sample(s) and data.

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

*In the event that the participant’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 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.