*Insert Header with institution’s name or institution’s letterhead*

Patient Information and Consent Form for Future Unspecified Non-Interventional Coronavirus or Related Research

**How can you help us with research in Coronavirus?**

Coronavirus is a new disease with very limited knowledge on how it spreads and how it can be treated. It is very important that we can do research to find a prevention and/or treatment.

Research makes a difference, it can be used to improve quality of care, quality of life, length of life and develop vaccines and better treatments for diseases. In order, to help our wider community it is important to use your health information or laboratory/pathology samples for coronavirus research.

This invitation is seeking your consent for researchers to access your health information and samples for the purpose of approved future unspecified (unknown) coronavirus related research. Looking at your health information and samples can reveal information that can help new diagnostic tests and treatment.

This Participant Information Sheet/Consent Form tells you about this project. It explains the tests and research involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you do not understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local doctor.

Participation is this research is voluntary. If you do not wish to take part, you don’t have to.

If you decide you want to take part in this research, you will be asked to sign the consent section. By signing it you are telling us that you:

* Understand what you have read
* Consent to take part in the research
* Consent to the tests and research that are described
* Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

**What does participation involve?**

If you consent, your health information and samples *[include information on the nature, number of tissue samples to be collected]* will be used in future coronavirus related research projects. The nature of these projects are not known at this point however each individual project will need to be approved by a Human Research Ethics Committee (HREC) and the Health Services involved prior to your information and samples being used.

**What details do researchers want to collect and use for research from your health information?**

We wish to collect information from your health record and/or samples *[include information on type of samples]* that will help us conduct research into Coronavirus. As our knowledge and understanding of this virus is changing quickly, we currently do not know what information and/or samples *[include information on type of samples]* may be relevant for future research. We are therefore asking for your consent to access a broad range of samples and/or information from your health record. Your health information may include medical and personal information in your health record (including information about any psychiatric/psychological issues, sexual health issues, behaviours and drug use), notes from clinicians and test results (including x-rays, and genetic tests) if needed. Health Information is also inclusive of laboratory samples such as blood, tissue and other samples.

**What is the most common way your health information and samples will be used by researchers?**

Future unspecified coronavirus or related research may include reviewing your health information and collecting information about your laboratory/pathology samples. For example, your samples may be used to look at how accurate a coronavirus diagnostic test is. Our laboratories may also store remaining human tissue that has been removed during a medical procedure such as in an operation, a biopsy, or a blood test. This extra tissue is not needed for diagnosis or treatment and will normally be discarded but will form part of your health information.

A broad range of tests may be performed on your samples. We may need to send your samples and data to other Institutions in Australia or Internationally to do these tests. If we transfer your samples to another research institution, we will make sure that this is done in a way so that your samples cannot identify you (be de-identified) and will follow applicable privacy principles to ensure your privacy is protected

The storage of your laboratory samples will be reviewed and approved by a registered Human Research Ethics Committee.

**Are there any direct benefits to you?**

Assisting health research can help to benefit everyone by improving the delivery of care and increasing our understanding of human health and wellbeing, diseases, their treatments and side effects. However, there will be no direct benefits to you from your participation in approved future unspecified coronavirus research or related projects.

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

*[Describe foreseeable risks, side effects, discomforts and inconveniences of the sample collection process. Specifically consider and address the risk of breach of confidentiality which could impact insurance, employment, family plans and family relationships].*

Having a blood/tissue sample taken may cause some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated.

**How is future research approved?**

Once you have consented and signed this document your health information and samples may be made available to researchers to conduct future research into Coronavirus. You will not be contacted again to provide your consent and will not be required to do anything more.

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). Before your health information and samples are released to a researcher the project must first be carefully considered by a HREC and approved as ethically acceptable. This is in accordance with the *National Statement on Ethical Conduct in Human Research (2007) – Updated 2018,* to protect the interests of people who agree to participate in human research studies.

Each research project has different rules and procedures as to how researchers can use and disclose your health information and samples and under what conditions they can do so.

Results from research using your health information and samples will not be given to you or your doctor or recorded in your health records. There will be no cost to you, and you will not be paid for the use of your health information and samples, including if any research results in a commercial product or application.

**How do we protect your privacy?**

The collection, storage, use and disclosure of your health information and laboratory samples, your access to it and your ability to have it amended, is governed by *[include applicable privacy measures]*.

Any research done using your health information and/or samples will be done in a way to protect your privacy to the best of our abilities. This includes de-identifying your data or samples by removing information that can identify you (e.g. name and UR number). We will also make sure that you are not identified in any research publications by ensuring only summary or combined data is published.

**Will your identity be published?**

No. Your health information and samples may be provided to researchers or linked with other data for ethically approved coronavirus or related research. However, any published research papers, including any published results of the research, will not identify you.

**Who will have access to your health information?**

Your health information and samples obtained by authorised researchers for projects approved may also be inspected by relevant authorities and authorised representatives of the Health Service for the purpose of verifying research procedures and data. Additionally, your health information and samples can be used or disclosed if the use or disclosure is authorised or required by law as set out in Health’s Service privacy policies.

**What happens if you do not give your consent?**

If you don’t consent, your care and treatment and your relationships with the Health Service and those treating you will not be affected by your decision. You do not need to provide reasons for not giving your consent.

**How long will your consent last?**

Unless you withdraw your consent while you are alive, your consent will continue for as long as the Health Service holds your health record.

**What if I change my mind?**

You can withdraw your consent for your health record to be accessed at any time by asking a staff member at the Health Service for a *Withdrawal of Consent* form, completing and signing the form and then giving it to a staff member at the Health Service. You do not need to provide reasons for withdrawing your consent.

Your health information and samples will not be available for any future unspecified coronavirus or related projects after the date you withdraw your consent. However, if your health information and samples have already been used in an approved research project, you cannot withdraw your consent for your health information and samples to be used in that project only.

**Further contact with you**

You will not be contacted by the Health Service about your consent to participate in a future coronavirus research project.

**Declaration**

I have read this *Patient Information and Consent Form,* or someone has read it to me in a language that I understand. I understand the information in this *Patient Information and Consent Form,* and I have had the opportunity to ask questions of clinicians about this consent who have answered those questions to my satisfaction.

I understand the purpose of my consent is so my health information and samples will be available to be used by researchers in projects approved by a Human Research Ethics Committee at the Health Service for broad range of health research in coronavirus.

**Consent**

I freely and voluntarily give consent to researchers to access my health information and samples held by the Health Service for the purposes of unspecified future coronavirus research or related research projects that are approved by a Human Research Ethics Committee.

I also agree that my health information and laboratory samples used for those projects may be inspected by relevant authorities and authorised representatives of the Health Service for the purpose of verifying the research procedures and data of the research projects.

I agree that the Health Service or a company or a university may benefit financially from the outcomes of the research projects that have used my health information.

I understand that I am free to withdraw my consent at any time without affecting my future health care but that if I do not withdraw my consent it will continue, even after I have died, for as long as the Health Service holds my health record in accordance with Health Service *Clinical Records Management* policies.

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|  | | | | | | |
|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

*If the participant is unable to read, then, by signing and dating the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the participant and that informed consent was freely given by the participant.*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | |
|  | Name of Witness\* to Participant’s Signature (please print) | |  | | |  | |
|  | | | | | | | |
|  | Signature |  | | Date |  | |  | |
|  | | | | | | | |

\*. If an interpreter is used, the interpreter must not be the witness. The witness must be 18 years or older.

**Declaration by Clinician**

I have given a verbal explanation of the project its procedures and risks and I believe that the participant has understood that explanation. I have assessed the participant’s capacity to consent in accordance with the Health Service policies and I believe that, at the time of this declaration, the participant has capacity to give their consent as documented above.

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|  | Name of Clinician (please print) | |  | | |  |
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|  | Signature |  | | Date |  |  |
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Where the participant is under the age of 18 years, I have assessed the participant’s capacity to consent in accordance with Health Service policies and guidelines and I reasonably believe that, at the time of this declaration, the participant:

* is of sufficient age and mental and emotional maturity to understand the nature of consenting;
* has sufficient understanding, intelligence and maturity to appreciate the nature, consequences and risks of the project and its procedures and the nature, consequences and risks of their participation (that is, I consider the patient to be “*Gillick competent*”). Accordingly, I believe that, at the time of this declaration, the participant has capacity to give their as documented above.

**Declaration by Parent/Guardian – for Parent/Guardian who has read the information**

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|  | Name of Child (please print) | |  | | |
|  | | | | | |
|  | Signature of child (*optional)* |  | | Date |  |
|  | | | | | |
|  | Name of Parent/Guardian (please print) | |  | | |
|  | | | | | |
|  | Signature of Parent/Guardian |  | | Date |  |

**Name of this Health Service**

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|  | (please print) |  |  |
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**Form for Withdrawal of Participation -** *Adult providing own consent*

*It is recommended that this form NOT be included as part of the PICF itself, but that it be developed at the same time and made available to researchers for later use, if necessary.*

|  |  |
| --- | --- |
| **Title** | *[Project Title]* |
| **Short Title** | *[Short Project Title]* |
| **Protocol Number** | *[Protocol Number]* |
| **Project Sponsor** | *[Project Sponsor in Australia]* |
| **Coordinating Principal Investigator/**  **Principal Investigator** | *[Coordinating Principal Investigator/*  *Principal Investigator]* |
| **Associate Investigator(s)**  *(if required by institution)* | *[Associate Investigator(s)]* |
| **Location** *(where CPI/PI will recruit)* | *[Location where the research will be conducted]* |

**Declaration by Participant**

I wish to withdraw from participation in the Non-Interventional Coronavirus or Related Research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with *[Institution]*.

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|  | | | | | | |
|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
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*In the event that the participant’s decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.*

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**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

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|  | Name of Study Doctor/  Senior Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

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