*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 help find a prevention and 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 coronavirus research or related projects.

**Before agreeing to take part, it is important you understand what the different terms mean;**

Health Services routinely collect and analyses information about the health of patients for service delivery and patient treatment purposes this is known in this document as “health information”.

Samples can mean blood, saliva, urine, stool/poo, bone, breast milk or any tissue taken from a participant’s body by a healthcare professional (skin, part of an organ or tumour or other cells in the body).

In this document, when we refer to *“Health Service”* we are referring to a particular “Hospital and Health Service”where you are being treated. When we refer to “*researchers*” we are referring to authorised people who are performing research.

When we refer to “*your health record*” we are referring to the part of the Health Service record containing your health information that is accessible at the health service.

**What details do we collect in your health information?**

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, test results (including x-rays, and genetic tests) and genetic information if needed. Health Information is also inclusive of laboratory samples such as blood, tissue and other samples.

Your health information may also identify other people, such as your family members, as part of your family and social medical history.

**What does participation involve?**

If you decide to consent, your health information and samples will be used in an approved future unspecified coronavirus research or related projects.

The type of consent this Health Service is asking you for is known as unspecified consent, or broad consent, because we would like your consent to provide your health information and samples to researchers for future projects, which have not yet been developed, in coronavirus related research.

**How is future research approved?**

Before your health information and samples are released to a researcher the project must first be carefully considered by a registered Ethics Committee and approved as ethically acceptable in accordance with the *National Statement on Ethical Conduct in Human Research (2007) – Updated 2018,* to protect your interests.

Once consented your health information and samples will be available to researchers through an ethically approved research project and you will not be required to do anything more.

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 the Health Service “*privacy policies*”.

**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 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 validate coronavirus diagnostic tests. Our laboratories may 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 but will form part of your health information.

Laboratory samples that are chosen to be part of a research project are stored under the National Association of Testing Authorities (NATA) and National Pathology Accreditation Advisory Council (NPAAC) requirements.

A broad range of tests may be performed on your samples and any material or material transfers will be de-identified and follow applicable privacy principles.

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

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

If you don’t consent, this consent form cannot be used to make your health information and samples available to researchers for unspecified future Coronavirus related research. Your care and treatment and your relationships with the Health Service and those treating you will not be affected by your decision to participate or not. You do not need to provide reasons for not giving your consent.

Please note that even if you do not consent to the use of your health information and samples for research purposes through an approved future unspecified coronavirus research or related project there are other lawful ways that researchers can gain access to your health information for use in research **without** your consent. – refer to the *Health Records Act 2001* (Vic) – Statutory Guidelines on Research.

**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. Also, no one else can withdraw your consent on your behalf, even after your death.

**Further contact with you**

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

**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, must not be capable of identifying you.

**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 including financially, regardless of the outcomes of the research projects. The Health Service or a company or a university may benefit financially from the outcomes of research projects that have used your health information an ethically approved 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 registered 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 registered 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 the 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 the consent given by the participant and documented above.

Where the participant is under the age of 18 years, I have assessed the participant’s capacity to consent in accordance with the 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 to the disclosure;
* 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 the consent given by the participant and documented above.

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|  | Name of Clinician (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
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**Name of this Health Service**

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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.