Participant Information Sheet and Consent Form

Title	Immuno-Metabolic Phenotyping in Adults following COVID-19: Long-term patterns of change in Western Australia **(IMPALA)**
Protocol Number	Version 1.2 12 August 2022
Name of Researcher	Professor Toby Richards

Why are we doing this research project?

There is a lot that we don't yet understand about existing COVID-19 infections and the long-term effects of COVID-19. This research project will gain important information about your COVID-19 infection so we can try to find better ways to manage and treat this infection in the future.

What does your participation involve?

You will be asked to:

- Complete an online survey (5 minutes duration) and details about your COVID-19 infection
- Provide a blood and urine sample each year for up to five years

Do you have to take part in this research project?

No, participation in this research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage by contacting the research team.

What are the possible benefits of taking part?

There will be no clear direct benefit to you from your participation in this research project however, your participation will contribute to the advancement of research into COVID-19.

Where appropriate, if any test results with potential relevance to your medical care are identified you will be informed.

What are the possible risks and disadvantages of taking part?

Inconvenience

- Participation in this research project involves an annual visit to a blood and urine sample collection site (Clinipath Pathology sites in WA (including UWA and Curtin University) or Harry Perkins South in Murdoch), the time involved in completing this may be an inconvenience.

Phlebotomy (Blood Sample Collection)

- Phlebotomy can be associated with pain at the draw site and rarely with infection. Discomfort will be minimised by having expert staff obtain blood samples.

Incidental Findings

- This research project includes blood testing to identify potential markers of disease progression or severity. There is a very small chance that these tests may result in the incidental discovery of information that is relevant to your health. Since the samples will be de-identified and analysed in batches, and generally in non-clinical laboratories with investigational techniques, data will be de-identified. If deemed medically relevant the research team will re-identify and inform you of any results.

What will happen to your blood and urine samples and information?

All information about you will be kept confidential by those working on this research project, and your name or other identifiers will not be used in any reports about this research project. The research team will use your name and contact details to contact you about this research project, updates and results, to oversee the quality of the project, and to keep you informed about any future relevant studies. They will keep identifiable information about you from this study according to local policies.

Data protection regulation provides you with control over your personal data and how it is used.

We will use the blood and urine samples to look at how the body has responded to COVID-19. This study will enable us to look at the 'phenome' this is the participants chemical response i.e. the 'fingerprint' and include analysis of lipids, amino acids and other markers of disease. We are looking to explore if there is a pattern of changes (or not) seen in people after COVID-19 and if this may change over time. Some of the tests may be done in different countries.

All electronic data will be de-identified and stored safely and securely at the University of Western Australia (UWA) repository and kept for the duration of the research project and at maximum to 20 years following the completion of the study. All samples will be labelled with only research identifiers for storage (no personal information) and will be kept in University of Western Australia (UWA) storage at the Harry Perkins Institute of Medical Research for the duration of the research project and at maximum to 20 years.

The information collected about you and the samples collected will be 'de-identified'. This de-identified data will be used for research now and in the future and may be shared with

other scientific organisations such as, (but not exclusively) University of Western Australia and the Australian National Phenome Centre at Murdoch University and researchers working with our team to allow more detailed or complimentary analyses to be done. Access to samples for further projects will be governed by a committee comprising the lead investigator, and comply with UWA open access policies. No data or samples will be released to a third party unless it is to carry out research that has been approved by a Human Research Ethics Committee, or if disclosure is required by law.

Keeping you updated about the research project

If you consent, we will keep your contact details (email) so we can keep you updated on the research project's progress each year, final results, and opportunities to participate in other relevant research projects or trials.

What happens if you decide to withdraw?

If you choose to withdraw (which you can do at any time), we will ask that the data and samples already collected to date are retained in the research project. However, these samples can be disposed of if you request it. Please contact the research team should you wish to discuss this further.

Who is paying for this research?

This research project is being conducted by Professor Toby Richards from the University of Western Australia, supported by a grant from the Medical Research Future Fund.

Who has reviewed this research project?

The ethical aspects of this research project have been approved by the Human Research Ethics Committee (HREC) of the University of Western Australia (Project ID No 2022/ET000468).

Further information and who to contact

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project you can contact the Coordinating Principal Investigator/Lead Researcher:

Coordinating Principal Investigator/Lead Researcher

Name	Professor Toby Richards
Position	Professor of Vascular Surgery UWA
Telephone	(08) 6151 1152
Email	toby.richards@uwa.edu.au

If you have any complaints about any aspect of the project, 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	The University of Western Australia Human Research Ethics Committee
HREC Executive Officer	Executive Officer
Telephone	(08) 6488 3703
Email	humanethics@uwa.edu.au

Approval to conduct this research has been provided by the University of Western Australia, in accordance with its ethics review and approval procedures. Any person considering participation in this research project, or agreeing to participate, may raise any questions or issues with the researchers at any time. In addition, any person not satisfied with the response of researchers may raise ethics issues or concerns, and may make any complaints about this research project by contacting the Human Ethics Office at the University of Western Australia on (08) 6488 3703 or by emailing to humanethics@uwa.edu.au. All research participants are entitled to retain a copy of any Participant Information Form and/or Participant Consent Form relating to this research project.

Consent Form (eConsent)

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Coordinating Principal Investigator	Professor Toby Richards

Declaration by Participant

- I have read the Participant Information Sheet or someone has read it to me in a language that I understand.
- I understand the purposes, procedures and risks of the research described in the research project.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.
- I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to the University of Western Australia concerning my condition and treatment for the purposes of this project. I understand that such information will remain confidential.
- I understand that data will be collected from my medical records, including medications and laboratory results by study staff during the study. I agree that these individuals may have access to my research records and their study results.
- I understand that my information can be collected, analysed, reported, and shared internationally with others as part of this research project. I understand that my name will not be used, and I will not be identified.
- I agree that my blood and urine samples will be analysed to explore potential markers of disease progression or severity.

1. Do you agree to the 8 points above (please select) **Yes** **No**
2. I agree that my samples, or those already taken as part of my routine care, and any samples left-over after tests requested by my doctor, may be used in additional research in the future, if necessary, in different parts of the world, as long as appropriate ethical approval is in place. **Yes** **No**
3. I agree that my contact details (email) can be used to keep me updated on the research project's progress each year, final results, and for opportunities to participate in other relevant research projects or trials. **Yes** **No**

Name of Participant (please print) _____

Signature _____ Date _____