Participant Information Sheet/Consent Form - for adults providing own consent.

Title	Test Evaluation, development and implementation (TEDI) study
Short Title	TEDI
Protocol Number	HREC MH2020.384
Project Sponsor	ZiP Diagnostics
Principal Investigator (PI)	Associate Professor Joe Sasadeusz
Associate Investigators	Dr Jennifer Audsley Assoc Prof Jonathan (Jack) Richards
Research nurse co-ordinator	Joanne Patterson
Locations	VIDS Outpatient Department Royal Melbourne Hospital ZiP Diagnostics Laboratory 24 Cromwell St, Collingwood, Victoria, Australia, 3066

Part 1 What does my participation involve?

1. Introduction

You are invited to take part in this research and development project, “Test Evaluation, development and implementation (TEDI) study”. This project aims to develop new point-of-care infectious diseases tests for ZiP Diagnostics Pty Ltd, an Australian diagnostic test manufacturer.

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

Please read this information carefully. Ask questions about anything that you do not understand or want to know more about. If you do not wish to participate, you do not have to.

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

- Understand what you have read
- Consent to take part in the research and development project
- Consent to the tests and research that are described
- Consent to the use of your personal information as described

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

2. What is the purpose of this research and development project?

The ability to provide a rapid and accurate diagnosis at point-of-care (PoC) is a global challenge. "Point-of-care" testing allows diagnoses in the health care worker's clinic, an ambulance, the home, the field, or in the hospital. The results of care are timely and allow rapid treatment to the patient. Such PoC tests are critically needed in remote settings, especially in low-middle income countries, where people may need to travel great distances for healthcare. At ZiP Diagnostics, we are developing a range of PoC diagnostic tests targeting the most detrimental and widespread infectious diseases including respiratory diseases (e.g. SARS-CoV-2, influenza, respiratory syncytial virus, tuberculosis, sexually transmitted diseases (e.g. chlamydia, gonorrhoea), viral hepatitis (e.g. hepatitis B, hepatitis C) and vector-borne diseases (e.g. malaria).

For our diagnostic test development, we require the use of human samples to ensure the compatibility of our diagnostic tests with a range of samples such as swabs, blood and urine. Human samples contain a range of cells, DNA/ RNA, proteins, fats, sugars and other compounds that may contaminate, inhibit or confound diagnostic tests. Obtaining fresh samples is especially important in developing PoC tests, because these tests are designed to use clinical samples freshly taken and provide test results in less than 30 minutes. Samples collected for this study will be "spiked" with infectious disease agents (have bacteria or viruses added) to then use as known positive samples to evaluate and optimise PoC test development

This research is being conducted and sponsored by ZiP Diagnostics Pty Ltd.

3. What does participation in this research involve?

If you agree to participate in this study, you will need to sign the consent form before any study procedures will be performed.

Once you sign the consent form, you will receive emails from the Study co-ordinator no more than once a week to let you know that samples are required for test development, what type of samples are needed and what days they are needed. This study will continue for 12 months, and you will be contacted about donating samples for the duration of this study. There will be many weeks in which samples are not required, and some weeks you may be asked to donate samples on more than one day in a given week, or more than one sample type in a given week. The types of samples that may be collected can include:

- Nasal swab (not deep nasal) (maximum 2 swabs per day; maximum 3 sampling days in any week)
- Throat swab (maximum 2 swabs per day; maximum 3 sampling days in any week)
- Saliva (spit) (maximum 20 mls, or about 1 tablespoon per day; maximum 3 sampling days in any week)
- Vaginal swab (female participants only) (maximum 2 swabs per day; maximum 3 sampling days in any week)
- Urine (maximum 200 mls, or a bit less than 1 cup per day, maximum 3 sampling days in any week)
- Blood (maximum 20 mls, or about 1 tablespoon per day; maximum 3 sampling days in any week)

On any occasion you can choose to donate one sample type but refuse to provide another sample type; or choose to donate on one day but refuse on another; or choose to donate on one week but refuse on another.

All swabs (nasal, throat and vaginal), saliva and urine will be self-collected either at the Royal Melbourne Hospital (RMH) or at your own home. This means that you collect the sample yourself. Blood samples will be taken by a registered nurse at the VIDS Outpatient Department, RMH. This may involve a finger-prick blood collection or a blood draw using a needle and syringe. These blood collection visits may take up to about half an hour.

We do not collect any clinical information from you.

If you need to travel to RMH to participate in this research you will be reimbursed for parking costs (an RMH car park voucher) if travelling by car, or a Myki card if travelling by public transport. Additionally, on completion of your participation in the 12-month study, you will be given a $100 Coles-Myer gift voucher.

4. What do I have to do?

If you agree to participate in this research project, you do not need to do anything differently than you would if you did not participate in the study.

5. Other relevant information about the research and development project

We are planning to recruit up to 50 participants for this research and development project.

We think that all participants will be negative for the infectious diseases targeted by the tests under development. In the unlikely event that your sample is positive (this might occur if no infectious disease agent is added to the sample but a positive test result occurs), the Study Coordinator will be notified that that there is an unexpected positive test result. The test result will only be linked to a coded Sample ID number. The Study Coordinator will then “decode” the Sample ID number to identify the study participant. The Principal investigator will then contact you to discuss confidentially the result and arrange follow-up with the you for formal clinical testing and clinical management. You may prefer to see your own GP after the test results has been confirmed. If the positive result shows Hepatitis or Covid-19, or any other reportable diseases, the Principal investigator is required by law to notify government health authorities.

6. Do I have to take part in this research and development project?

Participation in any 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.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your treatment or employment at RMH. No employees or management at ZiP Diagnostics will have access to your files.

7. What are the possible benefits of taking part?

Providing a sample will help advance the research and development for ZiP Diagnostics tests. You will not receive any specific benefits from being a participant in research and development project for ZiP Diagnostics tests.

8. What are the possible risks and disadvantages of taking part?

There is very little risk associated with participating in the study, except the potential risks that may occur from sample collection. For swabs, you may experience mild discomfort when taking the swab. For blood tests, you may experience some discomfort, bruising, minor infection or bleeding at the needle insertion site. If this happens, it can be easily managed by the registered nurse.

If you become upset or distressed as a result of your participation in the research, the Study Coordinator or Principal Investigator will be able to arrange for counselling or other appropriate support for you.

9. What will happen to my test sample(s)?

Your sample(s) will be collected for research and development testing of a ZiP Diagnostics test compatible with the sample type provide. All your sample(s) will be coded with a unique Sample ID number. No other identifying details will accompany your sample to the ZiP Diagnostics laboratories. Your sample will then be used to add a range of potential infectious agents. This may include SARS-CoV-2 virus (inactivated), chlamydia, gonorrhoea, or other infectious agents. These artificially spiked samples (and negative controls without the added infectious agents) will be used to test sample processing workflows, to optimise test composition and to test new cartridge-instrument platforms.

Your personal details will not appear on the samples. The samples will be labelled with the unique Sample ID number.

10. How long will my samples be kept?

It is intended that your samples will be used for immediate testing because this type of sample processing is likely to be critical for point-of-care test systems. If there is excess sample available, then your samples may be stored at the ZiP Diagnostics laboratory for up to 5 years and used for test development as required. They may be used for other research and development test studies that are consistent with the sample type collected.

Part 2 How is the research project being conducted?

11. What will happen to information about me?

By signing the consent form, you consent to the Principal Investigator or research nurse collecting your name, contact details, age and sex. No other information will be collected. The Research Nurse Coordinator will maintain a confidential enrolment log, listing your name and contact details. The log will be kept in a password protected data base. This confidential data will be stored as a hard copy in a locked cupboard and as an electronic record that will be password protected on a fire-wall protected server. Because the results from the research are for test development only, it is not intended that you will be informed about specific test results. Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

12. Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the Study Coordinator or Principal Investigator as soon as possible. You will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

13. Who is organising and funding the research?

This research project is being conducted by Associate Professor Joe Sasadeusz and is being sponsored and funded by ZiP Diagnostics.

ZiP Diagnostics may benefit financially from this research project if, for example, the project assists them to obtain approval for a new POC test.

By taking part in this research project you agree that samples of your blood or tissue (or data generated from analysis of these materials) may be provided to ZiP Diagnostics.

You will not benefit financially from your involvement in this research project even if, for example, your samples (or knowledge acquired from analysis of your samples) prove to be of commercial value to ZiP Diagnostics.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to ZiP Diagnostics, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

Melbourne Health will receive a payment from ZiP Diagnostics for undertaking this research project.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

14. Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Melbourne Health.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

15. Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning participation or if you have any medical problems which may be related to your involvement in the project, you can contact the principal study doctor A/Prof Joe Sasadeusz.

Clinical contact person

Name	A/Prof Joe Sasadeusz
Position	Study principal Investigator
Telephone	9342 7200
Email	j.sasadeusz@mh.org.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	Director Research Governance and Ethics
Position	Complaints Manager
Telephone	(03) 9342 8530
Email	research@mh.org.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	Melbourne Health Human Research Ethics Committee
HREC Executive Officer	Manager
Telephone	(03) 9342 8530
Email	research@mh.org.au

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Short Title	TEDI
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Project Sponsor	ZIP DIAGNOSTICS
Principal Investigator (PI)	Associate Professor Joe Sasadeusz
Associate Investigators	Dr Jennifer Audsley Assoc Prof Jonathan (Jack) Richards
Locations	VIDS Outpatient Department, Royal Melbourne Hospital ZiP Diagnostics Laboratory, Collingwood

Consent Agreement

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 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 any relationship with Melbourne Health.

I agree to provide samples as described in Section 3.

I understand that I will be given a signed copy of this document to keep.

I agree that if I decide to stop providing sample(s) that information (name and contact details) and data about me and any sample(s) collected, up to the point when I withdraw, may continue to be used.

Declaration by Participant -for participants who have read the information

Name of Participant (please print)

Signature Date

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research and development project, its procedures and risks and I believe that the participant has understood that explanation.

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

Signature Date

† A senior member of the research and development team must provide the explanation of, and information concerning, the research project. Note: All parties signing the consent section must date their own signature.