School of Public Health and Community Medicine
Faculty of Medicine

PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

University student travel-health and immunity study
Dr Anita Heywood

The research study is being carried out by the following researchers:		
Role	**Name**	**Organisation**
Chief Investigator	Dr Anita Heywood	University of New South Wales
Co-Investigator/s	Dr Holly Seale Professor Raina MacIntyre Professor William Rawlinson Professor Nick Zwar Dr Bill Kefalas	University of New South Wales University of New South Wales SEALS Microbiology, Prince of Wales Hospital, Randwick University of New South Wales University of New South Wales
Research Funder	This research is being funded by GSK	

What is the research study about?

You are invited to take part in this research study. You have been invited because you are an enrolled student aged 18-27 years at UNSW and your contact details were obtained from the online Travel Health Survey that you completed or you attended the Health Clinic at UNSW.

To participate in this project you need to meet the following inclusion criteria:

- Provide informed consent;
- Complete the online Travel Health Survey, if you have not done so already;
- Complete an additional 5 minute questionnaire about your vaccination history; and
- Provide 10mL blood sample (one blood collection tubes)

Students who have received transfused blood products in the previous three months, who are currently taking prescription medication that lowers their immune system and those who a condition that lowers their immunity are not eligible to participate in the study.

The research study is aiming to determine the immunity to a range of vaccine preventable diseases in a young adult population (a "serosurvey") and use this data to evaluate travel vaccination recommendations, to compare these results to self-reported vaccine uptake and evaluate Australia's immunisation program..

Do I have to take part in this research study?

Participation in this research study is voluntary. If you don't wish to take part, you don't have to. Your decision will not affect your relationship with The University of New South Wales.

This Participant Information Statement and Consent Form tells you about the research study. It explains the research tasks 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 don't 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 or friend.

If you decide you want to take part in the research study, you will be asked to:

- Sign the consent form ;
- Keep a copy of this Participant Information Statement;

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What does participation in this research require, and are there any risks involved?

If you decide to take part in the research study, a trained staff member will take 20mL of blood (two blood collection tubes). We will use this blood to test for antibodies to measles, mumps, rubella, varicella (chickenpox), hepatitis A, hepatitis B and dengue. We will not use your blood for any other purposes without your written consent. Once your blood is tested we will provide you with the results. You will also be provided with information about you test results that you can read and a results record that you can provide to your GP. Blood collection is a very safe procedure, and complications are rare. However, there is a small risk of bleeding from the site of blood collection, mild bruising or haematoma (a small lump under the skin). Some people may feel faint or dizzy; this is common in people with a fear of needles or the sight of blood. If you have any ongoing symptoms you should speak to the trained staff member or arrange to see a GP.

For students who have not previously completed the Travel Health Survey we will ask you to complete the survey using an iPad at the time of blood collection. This will take approximately 10 minutes to complete. The survey will ask you questions about your recent travel history, uptake of vaccination and your attitudes towards different travel health risks.

We also ask that you complete a short 5 minute questionnaire which includes questions on your vaccination and disease history and your perceptions regarding risk.

We would also like to seek your permission to contact your GP. We would like to confirm your vaccination history against the records that your GP may have.

Will I be paid to participate in this project?

There are no costs associated with participating in this research study, nor will you be paid. However, if you consent, your name will be entered into a prize draw. The first prize is a MacBook valued at $1200 and second prize is one of two iPad minis valued at $250 each. The winners will be selected at random by a person not connected to the project. To be eligible for the prize, you will need to supply a blood sample and provide your student email address.

What are the possible benefits to participation?

There are benefits for taking part in this study. The Australian Government recommends being up to date with standard vaccinations recommended for your age. For young adults this includes MMR (measles-mumps-rubella) and varicella. Hepatitis A and hepatitis B vaccination is also recommended for high-risk groups, which includes travellers to high risk countries.

By taking part in this study, you will be told if you are immune to the included diseases. This will be useful when making a decision with your doctor about your risk and whether you need a vaccine. The presence of antibodies indicates immunity to these diseases due to prior vaccination or past history of the disease and a vaccine is not required. The absence of antibodies indicates no detectable immunity to these diseases and a vaccine may be required. There is no current vaccine for dengue, the presence of antibodies to dengue indicates past infection only. In some people, infection with the hepatitis B virus can last for many years and cause damage to the liver and be transmitted to other people. We will also test for antibodies to the hepatitis B virus that are not contained in the vaccine and therefore indicate past or present infection. If we detect this antibody we will provide the results to your nominated GP for follow-up. No vaccines will be provided as part of this study.

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What will happen to information about me?

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission, except as required by law. If you give us your permission by signing this document, we plan to publish a summary of the participants' results. In any publication, information will be provided in such a way that you cannot be identified.

To ensure that all participants are aware of their results and understand what they mean, we would like to obtain your permission to provide your results to your nominated doctor. Your preferred doctor will be provided with information on why your blood was tested for this study and the results.

You have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. You can do this by contacting a member of the research team.

How and when will I find out what the results of the research study are?

You have a right to receive feedback about the overall results of this study. In addition to your own test results, a summary of the study will be distributed to students through the UNSW Newsroom. No identifiable information will be included in this summary. You will receive this feedback after the study is finished.

What if I want to withdraw from the research study?

If you do consent to participate, you may withdraw at any time. If you do withdraw, you will be asked to complete and sign the 'Withdrawal of Consent Form' which is provided at the end of this document. Alternatively you can ring the research team and tell them you no longer want to participate.

You are free to stop the interview or the blood collection at any time. If you decide to leave the research study, the researchers will not collect additional information from you. Unless you say that you want us to keep them, any information or blood samples you have provided will not be included in the study results. You may also refuse to answer any questions that you do not wish to answer during the interview.

Submitting your completed questionnaire or providing a blood sample is an indication of your consent to participate in the study. You can withdraw your responses if you change your mind about having them included in the study, up to the point that we have analysed and published the results.

What should I do if I have further questions about my involvement in the research study?

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact the following member/s of the research team:

Research Team Contact

Name	Dr Anita Heywood
Position	Senior Lecturer
Telephone	02 9385 3667
Email	a.heywood@unsw.edu.au

If at any stage during the project you become distressed or require additional support from someone not involved in the research please call:

Contact for feelings of distress

Name/Organisation	UNSW Health Service
Telephone	(02) 9385 5425
Address	Ground Floor Quadrangle Building UNSW

What if I have a complaint or any concerns about the research study?

If you have any complaints about any aspect of the project, the way it is being conducted, then you may contact:

Complaints Contact

Position	Human Research Ethics Coordinator
Telephone	+ 61 2 9385 6222
Email	humanethics@unsw.edu.au
HC Reference Number	HC15205

Consent Form – Participant providing own consent

Declaration by the 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, study tasks 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 study as described and understand that I am free to withdraw at any time during the project and withdrawal will not affect my relationship with any of the named organisations and/or research team members;
- ☐ I understand that I will be given a signed copy of this document to keep;

Participant Signature

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

Declaration by Researcher*

- ☐ I have given a verbal explanation of the research study, its study activities and risks and I believe that the participant has understood that explanation.

Researcher Signature*

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

[+]An appropriately qualified member of the research team must provide the explanation of, and information concerning the research study.

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

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Form for Withdrawal of Participation

I wish to **WITHDRAW** my consent to participate in the research proposal described above and understand that such withdrawal **WILL NOT** affect my relationship with The University of New South Wales.

Participant Signature

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

The section for Withdrawal of Participation should be forwarded to:

CI Name:	Dr Anita Heywood
Email:	a.heywood@unsw.edu.au
Phone:	(02) 9385 3667
Postal Address:	School of Public Health & Community Medicine Level 3, Samuels Building UNSW AUSTRALIA