**Participant Information Sheet**

**Project Title: Long-term persistence of antibodies following Japanese encephalitis virus vaccination in adults residing in a non-endemic area**

**Researchers:**

This study will be conducted by researchers at the Australian National University (ANU), the University of Queensland, Queensland Institute of Medical Research (QIMR) Berghofer and Dr Deb – The Travel Doctor clinic. The study will be led by Dr Ramona Muttucumaru, who is a post-graduate student at ANU. The following researchers will be conducting the study:

* **Dr Ramona Muttucumaru,** Masters of Applied Epidemiology scholar, National Centre for Epidemiology and Population Health, Australian National University (ANU)
* **Dr Deborah Mills,** Medical Director, Dr Deb – The Travel Doctor
* **Dr Luis Furuya-Kanamori,** NHMRC Early Career Fellow, University of Queensland Centre for Clinical Research
* **A/Prof Mark Chatfield,** Biostatistician, Centre for Health Services Research, Faculty of Medicine, UQ
* **Dr Narayan Gyawali,** Postdoctoral research fellow in the Mosquito Control Laboratory, QIMR Berghofer
* **Adjunct A/Prof Leon Hugo,** Mosquito Control Laboratory, QIMR Berghofer
* **Associate Professor Gregor Devine,** Group Leader of the Mosquito Control Laboratory, QIMR Berghofer
* **Dr Emma Field,** Research Fellow, National Centre for Epidemiology and Population Health, ANU
* **Professor Colleen Lau,** Professorial Research Fellow, School of Public Health, University of Queensland, Honorary Professor, National Centre for Epidemiology and Population Health, ANU

**General Outline of the Project:**

* **Description and Methodology:**

*Background*

Japanese encephalitis (JE) is a viral infection that is transmitted by mosquitoes and is widespread throughout Asia and in parts of the Western Pacific. Most people infected with JE virus have no symptoms but, in some cases, an infected person can go on to develop inflammation of the brain, which is called encephalitis, which can cause death or permanent disability.

Until recently, JE virus cases in Australia have been rare, occurring mainly in travellers returning from overseas. In early 2022, a multi-state outbreak of JE virus was detected in Australia.

In Australia, there are 2 approved vaccines directed against JE virus:

* inactivated Vero cell-derived vaccine (JEspect®), which is administered as an injection into the muscle or *intra-muscularly*
* live attenuated recombinant vaccine (Imojev®), which is administered as an injection into the fat layer just underneath the skin or *subcutaneously*

Some vaccines can be administered *intra-dermally (ID)*, meaning that the vaccine is given into the top layer of the skin. ID-administered vaccines have several advantages, including they can be given at smaller doses than intramuscular or subcutaneous vaccines, which makes ID vaccine costs less and means that vaccine supplies can be extended. A recent study at this travel clinic has looked at the level of protective antibody in response to ID-administered Imojev® vaccine.

Studies have shown that both vaccines JEspect® and Imojev® are effective in inducing protective antibody responses, however, there are relatively few studies that have examined how long these antibody responses persist following vaccination, particularly in adults living in countries like Australia where the JE virus is not widespread.

This study will look at the antibody levels in people who have completed the following vaccination schedules 2 or more years ago:

1. Imojev® - single dose
2. JEspect® - two or more doses
3. JEspect® two or more doses plus Imojev single dose
4. Imojev® - intradermal dose

Your assistance with this study will help doctors understand how long the protection lasts following vaccination against JEV.

* **Participants:**

Participants will be recruited from the Dr Deb – The Travel Doctor clinic in Brisbane. Patients who were vaccinated against JEV two or more years ago will be contacted and invited to participate in the study. If you agree to participate in the study, a clinic doctor will complete a questionnaire with you to gather some basic demographic information and some information about your medical and travel history. This information will be collected as it will be important for researchers being able to account for other potential factors that may affect your JE virus antibody levels other than your vaccination course. Clinic staff will then draw a blood sample which will be sent for antibody testing. It is anticipated that approximately 230 participants will be recruited for this study.

* **Use of Data and Feedback:**

Your data from the questionnaire and the blood test for JEV-specific antibodies will be de-identified and then collated with those of other participants for statistical analysis. Findings from this study may be published in scientific journals or presented at conferences. A non-technical summary report of the research findings will be emailed to you by the research team when the analysis has been completed.

* **Project Funding:** There is no specific funding for this project, which is being conducted at the clinic’s own cost, with the aim of increasing our understanding of how well JE vaccines work, and improving clinical practice.

**Participant Involvement:**

* **Voluntary Participation & Withdrawal:**

Taking part in the study is voluntary. Should you change your mind about wanting to be involved, you may withdraw from the study at any time with no questions asked. There are no negative consequences if you decide not to participate, and you will continue to receive the usual high standard of pre-travel and post-travel care from the doctors and nurses at the clinic. If you decide to withdraw from the study before it is published, your data will be deleted and excluded from the pooled results. However, once the results of the study are published, it will not be possible to withdraw your de-identified data.

* **What does participation in the research entail?**

If you decide to participate in the study, the medical or nursing staff will assist in completing a questionnaire that includes questions about your age, sex, past travel and vaccination history. Some limited information about your medical history will also be collected. Once the questionnaire is completed, clinic staff will draw 10mL of blood, which will be sent to a laboratory at the Queensland Institute of Medical Research (QIMR) Berghofer, where researchers will conduct testing for JE antibody levels. When the results of testing are available, clinic staff will contact you to inform you of your blood test results. This testing may take weeks or months as the test is a special technically difficult test that must be done in batches.

* **Location and Duration:**

If you decide to participate, a consultation visit will take place at Dr Deb – The Travel Doctor clinic in Brisbane, 5/247 Adelaide Street, Brisbane City. The consultation will involve completing a questionnaire and having blood drawn for testing, which may take approximately 15-20 minutes.

* **Remuneration:** Taking part in the study will cost you nothing apart from your time. The cost of blood tests will be covered by the study. There is no special payment or remuneration for being a participant in this study.
* **Risks:** The only potential side effects that you may experience are those related to having blood drawn. These include pain and bruising at the site of blood collection.
* **Benefits:** It is unlikely that you will personally benefit from participating in this study, however, we expect that the results of this study will confirm that antibody responses persist for 2 or more years following JE vaccination. This will help future people who need protection from JE virus.

**Exclusion criteria**:

* **Participant Limitation:**

You will not be eligible to participate in the study if you have:

* a past history of infection with JE virus
* lived in a JE virus endemic area for 12 months or more (cumulatively) BEFORE being vaccinated

**Confidentiality:**

* **Confidentiality:**

Any information you provide as part of this study will only be accessible to the staff at Dr Deb’s - doctors, nurses, and researchers directly involved in this study. Your name and contact details will be recorded by clinic staff so that they can contact you to advise you of your results. Research staff will de-identify your personal information before it is used for analysis and publication purposes. All data collected as part of this study will be held securely.

**Privacy Notice:**

In collecting your personal information within this research, the ANU must comply with the Privacy Act 1988. The ANU Privacy Policy is available at <https://policies.anu.edu.au/ppl/document/ANUP_010007> and it contains information about how a person can:

* Access or seek correction to their personal information;
* Complain about a breach of an Australian Privacy Principle by ANU, and how ANU will handle the complaint.

**Management of biological samples:**

If you consent to participate in this study, your blood will be collected by a clinic staff member, and sent to QIMR Berghofer for testing. The testing will involve examine if your blood contains antibodies that are directed against JE virus. Samples will be tested in batches. Samples will be stored in a secure -20C freezer in a laboratory in QIMR Berghofer that is only accessible to researchers directly involved in the study. The samples will be stored for 5 years after the completion of the study. After this period of time, the samples will be destroyed according to QIMR procedures. The samples will not be used for any other studies other than the one you have consented to be involved in.

Samples will be stored and disposed of in accordance with policies for the management of biological samples outlined by the National Health and Medical Research Council, QIMR Berghofer and ANU.

**Data Storage:**

* **Where:**

Clinic staff will record your name, contact details and information about your medical and travel history on a paper questionnaire. This paper questionnaire will be stored at the clinic and will not be made available to other researchers involved in the study. Your name and contact details will be recorded on the paper questionnaire so that clinic staff can later contact you to advise you of your blood test antibody result. A unique identifier will be created for each study participant, which will be used to label blood tubes and collect the data in an electronic form. Your identifying information such as your name and data of birth will not be shared with QIMR or other organisations involved in this study. The results of laboratory testing, which will be de-identified, will initially be recorded in lab books at QIMR and subsequently on spreadsheets that are stored on secure QIMR servers.

The data from the questionnaire and blood test will be deidentified and entered into a secure electronic platform. De-identified data sets will be stored securely on password-protected computers owned by the clinic, the Australian National University, the University of Queensland and research data management systems. De-identified data from both the questionnaire and the blood tests will be made available to researchers at ANU, UQ, QIMR Berghofer and Dr Deb the Travel Doctor clinic who are involved in the study.

* **How long:** Data will be stored for a period of at least 5 years from the date of any publication arising from the research. The raw laboratory data recorded in laboratory books will be held for at least 7 years following the publication of research arising from the study.
* **Handling of Data following the required storage period:** After 5 years, de-identified research data will be archived in a secure online data archiving platform at UQ. Researchers at UQ, ANU, QIMR Berghofer or Dr Deb The Travel Doctor clinic may use this de-identified data in future studies, if you provide consent to do so. If you do not want your de-identified data to be archived for possible future use in research studies, you may refuse consent for this purpose.

**Queries and Concerns:**

* **Contact Details for More Information:**

If you have any questions, concerns or complaints relating to the research, please contact one of the following researchers:

* Dr Ramona Muttucumaru (email: Ramona.Muttucumaru@anu.edu.au or telephone : 0421 989 799)
* Professor Colleen Lau (email: colleen.lau@uq.edu.au or telephone; 07 3346 4747)

**Ethics Committee Clearance:**

The ethical aspects of this research have been approved by the ANU Human Research Ethics Committee (Protocol 2022/433). If you have any concerns or complaints about how this research has been conducted, please contact:

Ethics Manager
The ANU Human Research Ethics Committee
The Australian National University
Telephone: +61 2 6125 3427
Email: Human.Ethics.Officer@anu.edu.au