**Participant Information Sheet**

JEVID **- J**apanese **E**ncephalitis **V**accination via **I**ntra**D**ermal route

**Outline of the project**

*Background*

It is estimated that are more than 100,000 cases of Japanese encephalitis (JE) cases and 25,000 deaths worldwide per year. JE is endemic in Asia and Papua New Guinea, and outbreaks have occurred in the Torres Strait Islands. Travellers spending one month or more in endemic regions are recommended to receive JE vaccine. Effective JE vaccines with very few adverse events are currently available, but uptake of JE vaccines by travellers remain low, with the high cost of vaccines (approx. AU$ 300 for Imojev® in Australia) being one of the main reasons.

JE vaccines are licensed to be administered via subcutaneous (SC) or intramuscular (IM) injections; however, intradermal (ID) administration of vaccines using smaller doses have been shown to be as effective as SC administration for other vaccines, e.g. yellow fever and rabies. ID injections are shallow injections into the dermis (the most superficial layer of the skin). The needle is inserted at approximately 5 degree angle in the skin of the upper arm and 0.1mL of JE vaccine will be administered. The ID route uses a smaller volume of vaccine, thus it is less expensive than the SC and IM routes of administration, and could potentially enable more travellers to afford the vaccination. Therefore, we aim to investigate whether ID could potentially be an economical yet effective route of administration for JE vaccine.

*Use of data and feedback*

It is anticipated that the results of the study will provide valuable information to support the use of ID administration of JE vaccine, making it affordable for more travellers. On completion of the study, the research team plans to publish the results in an internationally recognised medical journal, so that this important information can be shared with the medical and scientific community to improve the health of travellers worldwide. Individuals will not be identified when results are presented (e.g. conferences) or published (e.g. journal articles). A summary of the results will be posted in the clinic, on the website of the travel medicine clinic ([www.thetraveldoctor.com.au](http://www.thetraveldoctor.com.au)), and distributed to participants.

**Participant involvement**

*Participants*

Participants will be recruited from our specialist travel medicine clinic: Dr Deb - The Travel Doctor in Brisbane, the study will be promoted through the clinic’s patient database (i.e. patients who expressed their interest in receiving the vaccine during a prior pre-travel consultation), and its website. Adult Australian residents between 18 and 45 years of age, who have never received JE vaccine will be invited to participate. The study aims to recruit 50 participants.

*Voluntary participation & withdrawal*

Taking part in this study is entirely voluntary. 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 advice from the doctors and nurses. The study involves 2 questionnaires and 3 visits to the clinic to collect blood samples. You will be requested to participate in both questionnaires, but you may decline to answer particular questions. You may decline to participate or decide to withdraw until the work is prepared for publication without having to provide an explanation. If you decide to withdraw, your data will be destroyed and excluded from the pool of results. However, once the results have been published, we will not be able to withdraw your de-identified data from the overall findings. We recommend that you read this document carefully, and discuss any questions with the medical staff, or with the Dr Deborah Mills, Dr Luis Furuya-Kanamori, or Prof Colleen Lau. Contact details are provided at the end of this document.

*What does participation in the research entail?*

* *Day 0:* To participate in the study, the medical staff will assist you to fill out the first questionnaire with basic demographic details. The nurse will draw 10mls of blood, which will be sent to Queensland Institute of Medical Research (QIMR) Berghofer to test for JE antibodies (we expect that you will not have antibodies at this stage). Once the blood sample has been collected, the nurse will give you a single dose of ID JE vaccine.
* *Day 10:* The nurse will call you to ask if you have experienced any side effects from the vaccine.
* *Day 28 and 56:* You will need to return to the clinic for a second and third blood test, respectively.
* *Day ~74:* You will be rung by a nurse and be given the results of your blood tests.

*Location and duration*

The consultation will take place at Dr Deb The Travel Doctor clinic in Brisbane. The first visit may take 45 minutes (including 30 minutes of observation after receiving the vaccine). The second and third visits will take about 30 minutes.

*Remuneration*

Taking part in the study will cost nothing apart from your time. The cost of the blood tests and the JE vaccine will be covered by the study. You will not receive any special payments for being part of this research study.

*Project funding*

This project is being conducted at the clinic’s own cost, with the aim of improving clinical best practice in travel medicine.

*Vaccine*

Imojev® will be used for this study. Imojev® is a live attenuated JE vaccine, and it is approved for use in Australia in people aged ≥9 months. Each 0.5 mL reconstituted dose contains 4.0–5.8 log plaque-forming units of live attenuated recombinant JE, mannitol, lactose, glutamic acid, potassium hydroxide, histidine, and human serum albumin. The medical staff will determine if you do not have contraindications for this vaccine.

*Risks*

The most common side effects of blood collection are a sore arm and bruising at the site of the blood collection. The side effects of JE vaccine are a red, sore and itchy injection site. Very occasionally persons vaccinated may experience fever, a rash or fatigue. Clinic staff are on call for our patients by phone 24 hours a day. In the event that you experience an adverse reaction to the vaccination, we would like to contact your doctor and provide medical details about the side effects or other problems. We will seek your consent to do this in the consent form. Any serious adverse events will be reported to the Therapeutic Goods Administration (https://www.tga.gov.au/reporting-adverse-events).

*Benefits*

We expect that the results from this study will confirm that a single ID dose of JE vaccine is an effective and economical route of administration. If it is shown to be successful, you will be protected against JE.

**Exclusion criteria**

You will not be able to participate in this study if:

* You are under 18 or over 45 years
* You have lived in a JE risk area for 12 months or more
* You have had dengue fever
* You have previously had vaccines against JE, yellow fever, or dengue fever or are planning to have yellow fever or dengue vaccines during the next two months
* You have contraindications to the JE vaccine or live vaccines
* You are pregnant, planning to get pregnant, or breastfeeding
* You are have a disease or are on any medication that depresses your immune system (e.g. cancer or on chemotherapy)
* You are travelling or planning to travel to areas of high risk for JE within the next two months

**The medical staff will assist you to determine if you are eligible to participate in the study or not.**

**Confidentiality**

The information provided by you will only be accessible by your travel medicine doctors and nurses, and the researchers. We will need to record your name and contact details, so that we can contact you for the follow-up questionnaires. We need to record your date of birth on the blood test form as it will form part of your usual medical record as it will be important for your future medical care for your treating doctors to have access to this information. We will keep your participation in this research study confidential to the extent permitted by the law. For publication, the results of all participants will be pooled, and no individual will be identified.

**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.

**Data Storage**

Research records will be kept at the travel medicine clinic. Electronic data will be stored in password-protected computers owned by the clinic, the Australian National University, and the researchers. Data will be stored for a period of at least five years from the date of any publication arising from the research. After 5 years, the research data will be completely de-identified (name and date of birth of the participants will be deleted from the dataset) and archived in the servers of the Research School of Population Health at the Australian National University.

**Queries and concerns**

*Contact details for more information*

You have the right to ask any questions about this research. If you have questions, complaints or concerns related to this research, please contact one of the following people:

Dr. Deborah Mills Email: email@drdeb.com.au Phone: (07) 3221 9066

Dr. Luis Furuya-Kanamori Email: luis.furuya-kanamori@anu.edu.au Phone: (02) 6125 2145

Prof. Colleen Lau Email: colleen.lau@qu.edu.au Phone: (07) 3221 9066

**Ethics Committee Clearance**

The ethical aspects of this research have been approved by the ANU Human Research Ethics Committee (Protocol 2020/708). 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

**Researchers**

This study is being conducted at Dr Deb The Travel Doctor Clinic in Brisbane. The laboratory analyses will be carried out at the QIMR Berghofer. The researchers conducting this study are:

* **Dr Luis Furuya-Kanamori**, NHMRC Early Career Fellow, Research School of Population Health, ANU College of Health and Medicine, Australian National University.
* **Dr Deborah Mills**, Medical Director of Dr Deb The Travel Doctor Clinic.
* **Professor Colleen Lau**, NHMRC Fellow, School of Public Health, Faculty of Medicine, University of Queensland, and travel medicine doctor at Dr Deb The Travel Doctor Clinic.
* **Associate Professor Gregor Devine**, Group Leader of the Mosquito Control Laboratory at QIMR Berghofer.
* **Dr Leon Hugo,** Senior Research Officer in the Mosquito Control Laboratory at the QIMR Berghofer.
* **Dr Narayan Gyawali,** Postdoctoral research fellow in the Mosquito Control Laboratory at the QIMR Berghofer.