Day 0

BORS Participant Information Sheet (PIS)

Boostability of One priming dose IM Rabies vaccine especially in Senior age groups

Researchers:

This study is being conducted at Dr Deb The Travel Doctor Clinic in Brisbane. The researchers conducting this study are:

- **Dr Deborah Mills**, Medical Director of Dr Deb The Travel Doctor Clinic in Brisbane.
- **Dr Colleen Lau**, an academic researcher at the Research School of Population Health at the Australian National University. Dr Lau has over 15 years of experience as a travel medicine doctor, and has conducted many research projects on travel vaccinations and travellers' health.
- **Dr Luis Furuya-Kanamori**, NHMRC Fellow, Research School of Population Health, ANU

The ethical aspects of the study have been approved by the Human Research Ethics Committee of the **Australian National University**.

Project Title:

Boostability of One dose IM Rabies vaccine, especially in Senior age groups (BORS)

General Outline of the Project:

A. Description and Methodology:

Rabies is a fatal disease, present in most countries outside Australia, so poses a risk to Australian travellers. Although deaths in travellers are rare (60 reported cases 1990 – 2012), rabies risk exposures are relatively common (2-13/1000 travellers per month). In travellers who are aware the horrors of this untreatable disease, a potential rabies exposure can be stressful, and cause major disruption to travel plans in the quest for appropriate treatment.

Pre-exposure rabies vaccination (PrEP) simplifies the treatment of animal exposures if they should occur during travel. The standard recommendations for rabies PrEP is to give 2-3 doses of vaccine prior to departure

The Australian recommended PrEP is one dose of Rabies vaccine given on day 0,7,and 21-28. Many travellers are leaving at short notice and do not have time to complete this pre departure rabies vaccine course. Recent research has suggested that two doses or even one dose may be sufficient to prime the immune system, and simplify the post exposure treatment of at risk animal exposures. Much of the research in the past has be done on young soldiers etc.

There is very limited research in persons over the age of 50 years to confirm that persons in this age group mount an adequate immune response to lower doses of rabies vaccine.

B. Participants: Participants will be recruited from our specialist travel medicine clinic: Dr Deb - The Travel Doctor in Brisbane. Adult Australian residents between 18 and 99, with 50% participants over 50 years of age, who have never received a course of rabies vaccine will be invited to participate. The study aims to include approximately 100 travellers.

C. Use of Data and Feedback: It is anticipated that the results of the study will provide valuable information to support the long term effectiveness of shorter PrEP for rabies prevention. 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 world-wide. Individuals will not be identified when results are presented or published. A summary of the results will be posted on the clinic website www.thetraveldoctor.com.au.

D. Project Funding: This project does not have any specific funding. It is being conducted by the doctors and nurses at the participating clinics at their own cost, with the aim of improving clinical best practice in travel medicine.

Participant involvement:

A. 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 - one in the clinic and one 74 days later by phone. You will need to participate in both questionnaires but you may decline to answer particular questions. You may decline to participate or decide to withdraw at any time 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 Dr Colleen Lau, or Dr Deborah Mills. Contact details are provided at the end of this document.

B. What does participation in the research entail?

To participate in the study, the nurse will assist you to fill out the first questionnaire with basic demographic details. You will then be requested to have 10 mls of blood drawn for rabies serology. On that day, you will be given a single intramuscular rabies vaccine. 60 days later you will be asked to return for a further rabies vaccine. On day 63 you will be given a third and final rabies vaccine. A blood sample will be taken at 67 days from the start. You will be rung at approximately 74 days to ask about side effects from the vaccine and be given the results of your blood tests. If your level is less than necessary, you will be offered a final blood test at day 81.

Trial DAY	0		60	63	67	74	81
Vaccine	IM Rabies		IM Rabies	IM Rabies			
Test	Serology		Serology		Serology		Serology if needed
Location	Clinic		Clinic	Clinic	Lab or clinic	Phone	

C. Location and Duration: The consultation will take place at Dr Deb The Travel Doctor clinic in Brisbane. The standard pre travel consultation with the doctor and nurse may take up to an hour, about the same time as a standard pre-travel consultation even if you do not want to participate in the study. For the second and third doses of vaccine, the visit will take about 10-20 minutes.

D. Remuneration: Taking part in the study will cost nothing apart from your time. The cost of the blood tests and the rabies vaccine will be covered by the study. You will not receive any special payments for being part of this research study. You will have 3 doses of rabies vaccine and two blood tests.

E. 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 rabies boosters are a red, sore and itchy injection site. Very occasionally persons vaccinated may experience a rash or fatigue. If this happens it would be treated in the usual way for all vaccine side effects. Clinic staff are on-call 24 hours for access to information about vaccine side effects. You can ring on our normal clinic phone number 0732219066 Also our clinic uses the SMARTVAX active surveillance system for monitoring for vaccine side effects and participants will receive a text message 2-3 days after vaccination asking about potential side effects, - these replies are notified to clinic staff during business hours

F. Benefits: We expect that the results from this study will confirm that a single dose of vaccine provides priming of the immune system, and the findings could provide support for more widespread use of a single dose of rabies vaccine being given to persons who must travel overseas at short notice.

Exclusion criteria:

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

- You are under 18 years of age
- You have previously had any rabies vaccine.
- You are pregnant
- You are on any medication that depresses your immune system
- Travelling to areas of high risk for rabies within 90 days where an unusual PrEP schedule may cause difficulty in the event of an animal exposure that requires PEP.

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 have 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 to know how best to treat you in the event of a rabies risk exposure on an overseas trip or in Australia if handling flying fox, however, the research will only include an identifier. We will keep your participation in this research study confidential to the extent permitted by the law. However, it is possible that other people may become aware of your participation in this study. For example, The University's Human Research Ethics Committee might inspect records pertaining to this research, but the university will ensure that your information personal remain confidential. 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: Medical and research records will be kept at the travel medicine clinics. Electronic data will be stored in password-protected computers owned by the clinics, 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 and archived at computers at the Australian National University, but your medical records will continue to be kept at the travel medicine clinics.

Queries and Concerns:

A. 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. Colleen Lau (Primary Investigator) Email: colleen.lau@anu.edu.au Phone: (07) 3221 9066

Dr. Deborah Mills (Brisbane) Email: email@drdeb.com.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 2019/451). 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