



Participant Information Sheet

Title	Boostability of One visit Rabies IntraDermal vaccination (BORID)
Protocol Number	2025_HE002460
Project Sponsor	The University of Queensland
Coordinating Principal Investigator	A/Prof Luis Furuya Kanamori
Coordinating Centre	The University of Queensland
Principal Site Investigator	Dr Deborah Mills
Location	Dr Deb The Travel Doctor
Ethics approval	University of Queensland Human Research Ethics Committee
Participant Information Sheet version	1.1

Part 1 – What does my participation involve?

1. Introduction

Thank you for your interest in participating in this research project.

Please read the following information about the project so that you can decide whether you would like to take part in this research. Please feel free to ask any questions you might have about your involvement in the project. You can also talk to someone you trust, like a family member or friend, or your medical practitioner, before deciding if you want to participate.

You are invited to take part in this research project because you are either already seeking rabies pre-exposure vaccination at Dr Deb The Travel Doctor clinic, or you have expressed interest in participating specifically in this study. You may be eligible to join a research project that is evaluating a simplified rabies vaccination schedule. Participation in this research 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 stop at any time, and you would not need to give any explanation for your decision to stop participating.

If you decide to take part, you will be asked to sign a Consent Form and will be given a copy of that signed form and this Participant Information Sheet to keep. Your decision whether you take part, or not to take part, or to take part and then withdraw, will not affect your usual care at Dr Deb The Travel Doctor or any future clinical care will not be affected, or your relationship with the University of Queensland.

2. What is the purpose of this research?

Rabies is a potentially deadly disease caused by a virus that mainly attacks the central nervous system. People can catch it from the bite or scratch of an infected animal, usually dogs. Once symptoms start, rabies is almost always fatal. The good news is that rabies can be prevented with wound care and vaccines after an exposure.

Another way to be prepared is to have some rabies vaccine before exposure or travel (this known as pre-exposure prophylaxis [PrEP]). This ‘trains’ the immune system so that if a risky exposure (such as a bite) ever occurs, you will only need two more doses of vaccine to stop the rabies virus.

If your immune system has not been ‘trained’ in advance, you will need 4-5 rabies vaccines and a special injectable medication (rabies immunoglobulin [RIG]) after a rabies risk exposure. This RIG is often a blood product and can be unavailable in many countries where rabies is present. Pre travel vaccination saves a lot of trouble in the event of a bite, scratch or lick.

Currently, this immune ‘training’ for rabies/PrEP is given over two visits (Days 0 and 7-14), which can be problematic for last-minute travellers and during periods of vaccine shortage. Recent studies suggest that single-visit PrEP—using either intradermal (ID) or intramuscular (IM) vaccination—may ‘train’ the immune system sufficiently, but more evidence is required, especially for ID vaccination.

ID vaccination means giving the vaccine into the surface layers of the skin rather than deeper into the muscle. There are more immune cells in that layer so a smaller dose of vaccine can be used when vaccines are given that way. Many studies have shown that for certain vaccines and circumstances, ID and IM vaccines give very similar results. The particular question about whether one dose is enough in this situation has not been answered. This BORID study will evaluate whether single-visit PrEP schedules are safe and effective. This research is conducted by The University of Queensland in collaboration with Kansas State University and Dr Deb The Travel Doctor. The study vaccine (Verorab®) and funding for study operations are provided through an investigator-initiated agreement with Sanofi Pasteur.

3. What does participation in this research involve?

If you agree to take part, you will be participating in a research project assessing single-visit rabies PrEP schedules in adults. Your involvement will involve having registered vaccine and blood tests and attending between 4-5 clinic visits over approximately 12 weeks, all conducted at Dr Deb The Travel Doctor clinic in Brisbane.

Participants will be randomised to 4 groups/schedules of the study:

- Group 1: Single ID dose on day 0
- Group 2: 2-site ID dose on day 0
- Group 3: Single IM dose on day 0
- Group 4: 2-visit IM on days 0 and 7 (the ‘standard’ schedule)

At no time will you be exposed to any rabies virus or risk of catching rabies – in fact you must not have any possible rabies risk exposures until the end of the study (e.g., travelling to high rabies risk countries). This is because the outcome of this research is not yet known.

Before any study procedures take place, you will be provided with this Participant Information Sheet and Consent Form, and the study doctor will answer your questions and confirm whether you are eligible to take part. The table below summarises all visits and procedures in this study.

Visit (Timing)	What Happens	Who Attends
Clinic visit 1: Enrolment & PrEP dose (Day 0)	Discuss study and ask questions Confirm eligibility Sign consent Medical history & questionnaire Pregnancy test (if applicable) Blood test (baseline) Randomisation Rabies PrEP vaccine 15-minute observation	All participants
Clinic visit 2: Second PrEP dose (Day 7)	Second IM vaccine dose (0.5 mL)	Only some participants will have this visit, those randomised to group 4 (standard IM schedule)
Phone call follow-up (PrEP safety) (Day 7-14)	Review of any symptoms or side effects after PrEP dose(s)	All participants
Clinic visit 3: First PEP dose (Day 56 ± 7)	Blood test Rabies PEP IM vaccine 15-minute observation	All participants

Clinic visit 4: Second PEP dose (Day 59 ± 7)	Rabies PEP IM vaccine 15-minute observation	All participants
Clinic visit 5: Blood test (Day 63 ± 7)	Blood test	All participants
Phone call follow-up (PEP safety) (Day 63-70)	Final review of any symptoms or concerns after PEP	All participants
Extra clinic visit (if needed) (Day 77)	Repeat blood test if antibody levels were low at Day 63	Only some participants will require an extra test

You will need your enrolment visit plus usually 3 or 4 extra clinic visits and 2 phone calls

4. What do I have to do?

You do not need to change your lifestyle, diet, or activity. Simply attend the study visits, answer the phone calls, and follow instructions from the research team.

Please inform the team early if you plan to travel during the study so appointments can be scheduled appropriately.

If you choose to take part, we ask you to:

- Attend all scheduled study visits (enrolment plus usually 4 more visits)
- Inform the research team about any changes to your health
- Tell the team if you start any new medicines or receive any vaccinations
- Report any side effects, even if mild
- Immediately report any rabies vaccines outside the study protocol
- Provide accurate information during follow-up calls and visits

5. Am I eligible to take part?

Healthy adults aged 18 years and older may participate in this trial. To take part, you must be able to read and understand English well enough to understand the study information, ask questions, and provide informed consent.

You must NOT take part if you:

- have previously received any rabies vaccine, including PrEP or PEP
- plan to travel to a rabies-endemic country during the study period
- work with live lyssaviruses and require rabies IM PrEP for occupational reasons
- are taking immunosuppressive medication or have conditions affecting normal immune function
- have received blood products or immunoglobulins in the past 3 months
- are pregnant, breastfeeding, or planning pregnancy during the study
- have a known allergy to any component of the rabies vaccine
- have an acute febrile illness or active infection on the day of enrolment

If you agree to participate, the study doctor will review these criteria with you in detail to confirm the trial is suitable for you.

6. Can I take part if I am pregnant or become pregnant during the study?

You cannot participate in this study if you are pregnant or breastfeeding.

Because the effects of rabies vaccination during early pregnancy are not fully understood, participants are advised to avoid becoming pregnant during the study. If you become pregnant during the study, or think you may

be pregnant, you should inform the study doctor or research team as soon as possible so that appropriate advice and follow-up can be provided.

7. How will the study vaccines be given?

Rabies vaccines in this study can be given in two different ways, depending on the group you are randomised to:

- Intramuscular (IM) injection: given into the deltoid muscle of the upper arm
- Intradermal (ID) injection: given just under the skin of the upper arm.

You may choose which arm you prefer for each vaccination.

After each vaccination, you will be asked to remain at the clinic for 15 minutes so staff can monitor you for any immediate reactions. This is standard practice for all vaccines.

8. What rabies vaccines will be used in this study?

All participants will receive Verorab[®], a licensed, inactivated (dead) rabies vaccine used in Australia. You will be randomly assigned—by chance, like flipping a coin—to one of four PrEP schedules/groups. A computer will randomly assign you to one of these four groups. You cannot choose your schedule. PrEP schedules (Day 0 ± Day 7) are:

- Group 1: *Single ID dose*
One × 0.1 mL ID administered on Day 0
- Group 2: *2-site ID dose*
Two × 0.1 mL ID (two ID injections) administered on Day 0
- Group 3: *Single IM dose*
One × 0.5 mL IM administered on Day 0
- Group 4: *2-visit IM*
One × 0.5 mL IM on Day 0 AND One × 0.5 mL IM on Day 7

The PrEP schedule will be followed by a 'simulated post-exposure prophylaxis'.

9. What is 'simulated post-exposure prophylaxis (PEP)'?

In this study, simulated PEP means receiving two additional rabies vaccine doses only. This does not involve exposure to rabies virus, live virus, or any infectious material. The additional vaccine doses are given to help researchers understand how well your immune system responds to a booster after the earlier vaccinations (i.e., PrEP schedule).

10. What should I do if I am bitten or scratched by an animal during the study?

If you are bitten or scratched by an animal at any time during the study, you must seek urgent medical care immediately for rabies post-exposure prophylaxis (PEP). You should not wait for a scheduled study visit.

After you have sought medical care, please inform the study team as soon as possible, so they can record the event and advise you about any study-related procedures.

11. Other relevant information

This study aims to recruit 200 adults (50 in each group) at this single study site in Brisbane. All vaccines used are licensed in Australia. All injections will be given by qualified medical practitioners or registered nurses.

12. Do I have to take part?

No. Taking part in this research is entirely voluntary. You can choose not to participate or to withdraw at any time without affecting your medical care.

Standard rabies vaccination, including the usual two-visit schedule, is available without joining this study. Your decision about participation will not affect your relationship with your doctor, clinic, or The University of Queensland

13. What are the possible benefits of taking part?

You may or may not receive a personal health benefit.

However:

- You will receive rabies PrEP using licensed vaccines
- At the end of the course you will have had full pre-exposure vaccination
- Your involvement will help improve rabies prevention for travellers

14. Will I be reimbursed?

You will receive a \$50 gift card to help cover time and travel costs related to study visits. This will be provided after your final study visit. This payment is not linked to your test results and is not a benefit for taking part.

15. What are the possible risks and disadvantages?

Vaccine side effects: Common reactions to rabies vaccines include: Pain, redness, itch, swelling at the injection site, mild fever, headache, fatigue, muscle aches. Injection-site reactions may be more visible with intradermal injections. Serious allergic reactions are rare but possible. Staff are trained to manage them.

Blood tests: Blood draws may cause temporary pain, bruising, light-headedness (rare), infection (very rare).

Time commitment: Participation requires attending 4-5 appointments in the city. Blood tests must be done during the visits, not at pathology collection centres.

Privacy: As with all studies, there is a very small risk of data breach; all data protection measures follow the University of Queensland [Research Data Management Policy](#) and Australian standards.

This study does not involve exposure to live rabies virus at any time. All testing is performed on your blood samples only.

If you ever feel uncomfortable, you may decline any procedure or withdraw at any time.

16. What if I am injured because of the study?

If you are injured as a result of taking part in this research, you should seek appropriate medical care. The University of Queensland holds insurance that may cover study-related injury in accordance with its legal obligations. You do not give up any legal rights by taking part. If you wish to make a claim or obtain further information, you may contact the research team using the details below.

17. What will happen to my test samples and data?

By signing the Consent Form, you consent to UQ collecting, using, and (where applicable) disclosing your blood sample information as set out in this Participant Information Statement and the Consent Form. Information obtained in connection with this project will be retained and disposed of in accordance with relevant University of Queensland policies and State and National regulations. For further information regarding the management of research data and information, you may refer to UQ's [Research Data Management Policy](#).

Any information obtained in connection with this research project that can identify you will remain confidential. Confidentiality will be maintained by replacing your name with a study code on all samples and test results and by keeping the document that links your name to that code in a separate, secure location. Electronic records are

kept on password-protected systems with audit trails. Only authorised members of the study team can see your identifiable details, and they use them only to conduct the study—for example, to contact you about appointments/visits. Your coded information and samples may be sent to approved laboratories or partners for testing or analysis; if this occurs, we use secure methods and agreements to protect your privacy. We retain research records for as long as required by university policy and Australian law and then dispose of them securely. It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified. In practical terms, your blood samples will be:

- Labelled with a study code, not your name
- Tested at Sullivan Nicolaides Pathology using ELISA
- Transported to the USA and tested at Kansas State University using the RFFIT assay

Samples will be stored securely and never sold.

18. Who will have access to my information?

Access to identifiable participant information will be strictly limited to authorised personnel and oversight bodies, for purposes related to study conduct, safety monitoring, regulatory compliance, and data integrity.

The following parties may access identifiable information:

Authorised study personnel:

- Chief Investigator and co-investigators listed in the proposal
- Site investigator and delegated clinical staff at Dr Deb The Travel Doctor clinic

Data management and monitoring personnel:

- Authorised monitors appointed by the Sponsor (UQ)
- Contracted data management staff (BytesBrain Pty Ltd), under formal data processing agreements

Auditors and regulatory authorities:

- UQ internal auditors
- HREC representatives
- Regulatory authorities (e.g. TGA)

The funder, Sanofi Pasteur, may receive summary (aggregated) results or de-identified study data to help understand the overall findings of the research. No information that identifies you (such as your name, contact details, or individual test results linked to you) will be provided to the funder.

19. What if you find any unexpected health issues?

The blood samples collected as part of the study will be tested ONLY for rabies virus antibodies.

Clinically relevant incidental findings from this study are unlikely. If any unexpected finding arises that may be important for your health, a study clinician will explain this to you and, where appropriate, recommend or refer you for relevant clinical care.

20. Will my samples or data be used for future research?

The collected samples and data may be used again for secondary/future research if you agree to this. Identifiable data will not be used in this way without your permission. This future use must be approved by an ethics committee. The consent form will describe situations where collected samples and data may be used again.

21. How will my personal information be used, stored, and protected?

UQ is the data custodian for this research project. This means UQ is responsible for how your study data are collected, stored, used, protected, retained, and securely destroyed. Your information will be managed in

accordance with UQ's Research Data Management Policy, Information Security Policy, and Privacy Management Policy, as well as Australian privacy law and the National Statement on Ethical Conduct in Human Research.

Use: Your personal information will be used for the purpose of the research project and any other purpose described in this Participant Information Sheet and the Consent Form.

Storage and security: Your personal information will be maintained confidentially by ensuring appropriate access and security is applied to the research project data. Your personal information will be accessed by authorised research staff, authorised staff of UQ (for the purposes of managing data holdings) and third parties as described in this Participant Information Sheet and the Consent Form.

Disclosure: Your personal information will only be disclosed in a manner consistent with this Participant Information Sheet and the Consent Form. Your personal information will remain confidential and will not be disclosed to a third party without your agreement, or as required by law.

Any information obtained during the research project is subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of The University of Queensland, or as required by law. Designated University individuals (data stewards or custodians) may also have access to the information for the purposes of ensuring long-term retention and disposal. By signing the Consent Form, you authorise the release of, or access to, this confidential information to the relevant research personnel and authorities as noted above.

You have the right to request access to the personal information about you that is collected and stored by the research team. If you are seeking to update or correct any information, it is recommended that you liaise with the research team in the first instance (see contact details at the top of this information sheet).

You are also able to request an amendment via a University of Queensland Right to Information and Privacy officer (rti@uq.edu.au). For further information regarding the management of your personal information, please refer to UQ's [Research Data Management Policy](#), [Privacy Management Policy](#) and [Privacy Management Procedure](#).

22. Can I find out the results of this research?

Yes. You may choose to receive a summary of the study results. You can indicate your preference at enrolment or by contacting the research team. The summary is expected to be available within approximately 6-12 months after the study is completed.

You will not be named or identified in any report, publication, or presentation.

23. What if new information arises?

If new information becomes available that may affect your participation, the research team will inform you promptly. You may choose to continue or withdraw.

24. Can I have other treatments during the research?

Yes, you can continue all routine medications and treatments.

The following must be immediately reported during the study by phoning the clinic during business hours:

Immunosuppressive medications (unless already discussed with the study doctor)

Blood products or immunoglobulins

Any rabies vaccines outside the study

You must inform the study team about any new treatments you receive.

25. What if I withdraw?

Your participation in this research is voluntary, and you are free to withdraw without needing to provide an explanation. If you withdraw from this study, you will not have any consequences, and your consultation, planned

treatment, and follow-up at Dr Deb The Travel Doctor clinic will be guaranteed. If you decide to withdraw, you can tell any member of the study team by phone or email that you wish to withdraw. If you prefer, we can provide a simple Withdrawal of Consent form. Once you let us know, we will confirm your decision in writing and stop scheduling further study activities.

If you decide to withdraw, we will not collect additional data or information from you. Any data, samples and information already collected may be retained as described in this Participant Information Sheet and the Consent Form to ensure that the results of the research project can be measured properly and to comply with relevant regulations.

If you decide to withdraw, the samples and data already collected are usually kept and used. If you would like us to destroy any stored samples that are still identifiable and not yet fully tested, please let us know, and we will arrange this where possible. Laboratory tests that have already been completed cannot be undone. If your information has already been combined with other participants' data, de-identified, or included in analyses, it may not be possible to remove it. We will explain what is possible in your situation.

26. Could this research project be stopped early?

It is very unlikely, but possible reasons could include: Safety concerns, funding or regulatory issues, or insufficient recruitment. You will be informed promptly if this occurs.

Part 2 – How is this research being conducted?

27. What will happen to information about me?

The University of Queensland will collect, store, and use your information according to:

- Australian privacy law
- UQ Research Data Management Policy
- Good Clinical Practice (GCP)

Your identifiable information (e.g., name, contact details) will be stored separately from your study data.

Only authorised staff will have access to identifiable information. Your coded data may be shared with approved research partners for analysis but will not include your identity.

You may request access to, or correction of, your information at any time.

Information collected for this study will be stored securely by UQ for at least 15 years after the study is finished. After this time, the information will be securely destroyed in accordance with the university policy and Australian regulations.

28. Complaints and compensation

If you are injured as a result of this study, contact the study doctor immediately.

You do not waive any legal rights by participating.

If you have concerns about the study, contact:

UQ Human Research Ethics Team

Email: humanethics@research.uq.edu.au

Phone: see <https://research-support.uq.edu.au/research-support/ethics-integrity-compliance/contacts>

29. Who is organising and funding the research?

This is an investigator-initiated study conducted by:

- The University of Queensland

- Kansas State University
- Dr Deb The Travel Doctor

Funding and study vaccine are provided by Sanofi Pasteur. Sanofi does not influence study conduct, data collection, analysis, or publication.

30. Who has reviewed the research?

This study has been reviewed and approved by The University of Queensland Human Research Ethics Committee (Project #2025/HE002460).

31. Further information and who to contact

Questions about the nature of this project and participation in it should be directed to the research team.

Clinical contact (study doctor)

Dr Deborah Mills

Dr Deb The Travel Doctor

Telephone: (07) 3221 9066

Email: clinic@thetraveldoctor.com.au

Sponsor representative

A/Prof Luis Furuya-Kanamori

UQ Centre for Clinical Research

Email: l.furuya@uq.edu.au

Complaints contact (independent of study team)

UQ Human Research Ethics Team

Email: humanethics@research.uq.edu.au

This study adheres to the principles of the National Statement on Ethical Conduct in Human Research. The study has received ethics approval in accordance with the review processes of The University of Queensland. You are free to discuss concerns regarding this study or your participation in it with the research team, but if you would like to speak to an officer of the University not involved in the study, you may contact the Human Research Ethics Team via email humanethics@research.uq.edu.au or phone (see contact details at: <https://research-support.uq.edu.au/research-support/ethics-integrity-compliance/contacts>).

BORID Research Schedule

Days	Day 0	Day 7	Day 7-14	Day 56±7	Day 59±7	Day 63
Participant info sheet	✓					
Participant summary	✓					
Eligibility assessment All	✓					
Written consent All	✓					
Questionnaire All	✓					
Randomisation# All	✓					
Group 1	Vaccine 0.1mL ID			Vaccine 0.5mL IM	Vaccine 0.5mL IM	
Group 2	Vaccine Two 0.1mL ID			Vaccine 0.5mL IM	Vaccine 0.5mL IM	
Group 3	Vaccine 0.5mL IM			Vaccine 0.5mL IM	Vaccine 0.5mL IM	
Group 4	Vaccine 0.5mL IM	Vaccine 0.5mL IM		Vaccine 0.5mL IM	Vaccine 0.5mL IM	
Blood test	✓			✓		✓
Safety follow-up			✓ Phone Call			✓ In-clinic
						\$50 Voucher