Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

Western New South Wales Local Health District

Title	**Japanese encephalitis vaccine via intradermal route in children and adults (JEVID-2)**
Short Title	JE vaccine via intradermal route in children and adults (JEVID-2)
Protocol Number	JEVID-2
Project Sponsor	Sydney Children's Hospitals Network
Coordinating Principal Investigator	Professor Nicholas Wood
Coordinating Centre	Sydney Children's Hospitals Network
Principal Investigators	Professor Colleen Lau Dr Luis Furuya-Kanamori
Associate Investigator	Ms Priscilla Stanley
Location	Bathurst, Western NSW Local Health District

Part 1 What does my participation involve?

1 Introduction

This is an invitation for you to take part in this research project because you are at potential risk from Japanese encephalitis virus (JEV) infection and may benefit from the Japanese encephalitis (JE) vaccine.

This research project aims to test the immune responses and safety of the JE vaccine (Imojev®) in children (aged from 5 years) and adults when delivered by intradermal (ID) injection using a traditional needle and syringe. We would like to compare the immune responses and safety of ID injections with the standard subcutaneous (SC) injection. This is why you are being invited to participate.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments 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 do not understand or want to know more about. Before deciding whether or not you can take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you do not wish to take part, you do not have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section.

By signing it you are telling us that you:
• Understand what you have read
• Consent to taking part in the research project
• Consent to have the tests and treatments that are described
• Consent to the use of your personal and health information as described

Please note, this consent form is to be completed by adults (≥ 18 years) that are participating in this study. A Young Person information sheet and separate parental consent form is to be completed for any participants under the age of 18

You will be given a copy of this Participant Information Sheet and Consent Form to keep.

2 What is the purpose of this research?

JE is a rare but serious illness caused by the JEV. It is spread to humans by infected mosquitoes. It is spread when a mosquito bites an animal (such as pigs or waterbirds) that has the JEV and then this mosquito bites a human.

Australia is on the cusp of a potential outbreak of JE viral infections as we move into spring and summer and having back-to-back La Niña seasons. Before this year, JEV had rarely been found in Australia with previous cases noted only in Northern Australia, Cape York and the Torres Strait. It is not known how JEV came into mainland Australia, but the movement of infected mosquitoes or migratory water birds may have played a part in the virus' spread, combined with significant rain events. JEV has now been detected in pigs and humans in Western and Southern NSW, as well as in Queensland, Victoria, the Northern Territory and South Australia.

Most JEV infections are asymptomatic; however, those with severe infection (less than one per cent) may develop encephalitis which may lead to death or permanent disability. There is no treatment for JE viral infections. One recent study suggests that as much as 3% of the Australian population may be at risk of JEV exposure. Of the 6 JEV deaths recorded in 2022, one was an infant.

There are effective and safe JE vaccines which are licensed for children over 2 months old and given by subcutaneous (SC) injection.

JE vaccination is currently recommended for people who at higher risk of JE infection because they:

- work, live or regularly visit a piggery, including farm workers and their families (including children aged 2 months and older) living at the piggery, pig transport workers, veterinarians (including veterinary students and nurses) and others involved in the care of pigs.
- work directly with mosquitoes **OR**
- are diagnostic or research laboratory workers who may be exposed to the virus.

The vaccine is also recommended for people aged 2 months or older who live or routinely work in specific Local Government Areas **AND**:

- spend significant time outdoors (four hours per day), for unavoidable work, recreation, education, or other essential activities, **OR**
- are living in temporary or flood-damaged accommodation that place them at increased risk of exposure to mosquitoes, **OR**
- are engaged in outdoor recovery efforts (clean up) of stagnant waters following floods.

People who do **not** meet the above criteria are considered at lower risk of JE infection and not currently recommended to be given JE vaccine.

There is shortage of JE vaccines in Australia. Intradermal (ID) vaccine administration, whilst more painful than a subcutaneous vaccine, only uses 1/5 of the subcutaneous dose and is therefore "dose sparing" enabling more people to be vaccinated from each vaccine vial. ID administration of other vaccines using smaller doses have been shown to be as effective as SC administration for other viruses, e.g. yellow fever and rabies. ID administration is widely used for BCG (protects against tuberculosis) and rabies vaccines, and is now recommended for monkey pox vaccination.

ID JE vaccination has found to be safe and result in strong antibody responses in adults; however, it has not yet been tested in children and adolescents, and older (>50 years) populations.

The aim of this project is to study the immune responses and safety of JE viral vaccine (Imojev®) given ID using traditional needle and syringe in children and adults and to compare safety and immune responses with Imojev® given subcutaneously. The results will be very useful to inform vaccination programs if there is a significant JE virus outbreak and especially if we have insufficient supplies of JE vaccines in Australia to vaccinate our most at risk populations, including children.

This research has been initiated by Associate Professor Nicholas Wood at the National Centre for Immunisation Research and Surveillance (NCIRS) in conjunction with Professor Colleen Lau and Dr Luis Furuya-Kanamori at the University of Queensland.

3 What does participation in this research involve?

You will be participating in a clinical vaccine trial and will be given the JE vaccine (Imojev®) if you pass the screening tests as outlined below. This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way.

Healthy children (aged >5 years) and adults who are interested in receiving the JE vaccine can take part in this trial. The participant must **NOT**:

- have previously had JE disease
- have previously had the JE vaccine
- have received dengue or yellow fever vaccines, or are planning to have any of these vaccines in the next 2 months
- had a history of dengue fever
- have contraindications to JE vaccines
- have (or have a family member who has) had a severe reaction to a live attenuated viral vaccine, or are related to someone with known IFNAR1 deficiency
- be taking immunosuppressive medication or have medical conditions that impaired the normal functioning of the immune system

If you agree to participate in this study, we will first check in more detail whether the study is suitable for you.

The study doctor will review your personal risk for JE infection. If you are considered by the study doctor to be at higher risk of JE infection because of where you live, your work or recreational activities you **will not be able to participate** in this study. You should get the JE vaccination at your local vaccine clinic.

If you are considered by the study doctor to be at a lower risk of JE infection because of where you live, your work or recreational activities you **will be able to participate** in the study and will be randomised to be given either ID or SC vaccination. Being randomised means you will not be able to choose which vaccine you are given but it is decided by chance, like flipping a coin. The NHMRC Clinical Trials Centre, based in Sydney, will perform the randomisation for this study.

If the study is suitable for you and you agree to participate you will be asked to sign the Participant Consent Form before any study-related procedures can commence. You will be in the study for 12 months, during which we will see you on five occasions. Your study doctor may inform your local doctor of your participation in this study. Please advise your study doctor if you do not wish this to occur.

Visit 1: On the first visit we will ask about your health and medical conditions, your history of JE vaccination or disease. We will collect a blood sample (5-7mls for adults).

Females of childbearing potential will be asked to take a urine pregnancy test prior to the vaccine being given to make sure they are not pregnant. As JE vaccination is not routinely recommended during pregnancy and its safety has not been established, thus we do not want to give the JE vaccine to any female who may be pregnant. Females should avoid becoming pregnant for 28 days after Imojev® vaccination.

You will be randomised to receive either ID or SC vaccination. An authorised immuniser will then perform the vaccination. The vaccine will be given in your upper arm (in the deltoid region) for the SC vaccination (Figure 1a) and either in the forearm or upper arm for the ID vaccination (Figure 1b). You can choose which arm you would prefer the vaccine to be given.

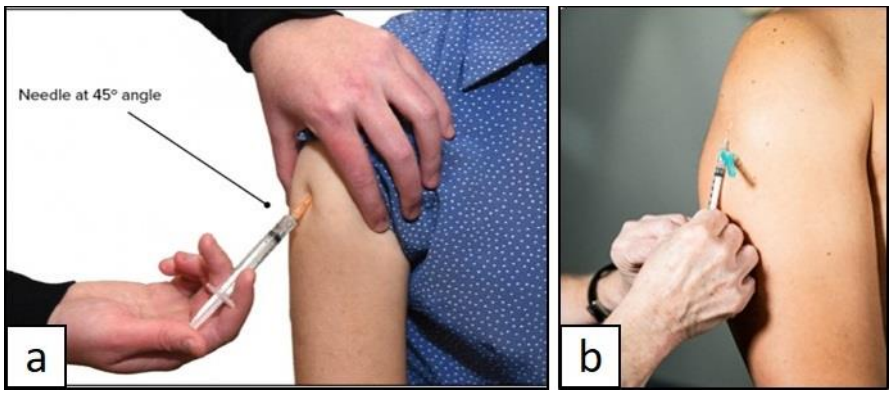

Figure 1: Administration of a) subcutaneous (SC) vaccine and b) intradermal (ID) vaccine

You will be asked to remain at the clinic for half an hour for observation after vaccination.

Following vaccination, we will give you a diary card to complete describing your symptoms for the next 7 days after vaccination. We will explain how to use this paper or electronic diary card. We will ask you to measure your temperature under the armpit each evening and to look at the arm where the vaccine was given for any redness or swelling and measure it with a ruler we provide.

This visit will take 1-2 hours.

Visit 2: At the second visit which takes place 7-10 days after vaccination, we will ask about potential adverse events, review your diary card and look at the injection site. This visit will take around 30 minutes.

A subset of participants (aged over 10 years) will be asked at Visit 2 if they agree to provide a blood sample (5-7mls for adults) in addition to having their diary card and injection site reviewed. For these participants the visit will take around 30 minutes.

Visit 3: At the third visit, which takes place at 28-35 days after vaccination, we will review your medical history, ask about any potential adverse events and collect a blood sample (5-7mls for adults). This visit will take around 30 minutes.

Visit 4: At the fourth visit, which takes place at 180-210 days after vaccination, we will review your medical history, ask about any potential adverse events and collect a blood sample (5-7mls for adults). We will discuss your serology results from Visit 3 with you. This visit will take around 30 minutes.

Visit 5: At the fifth visit, which takes place at 12-13 months after vaccination, we will review your medical history, ask about any potential adverse events and collect a blood sample (5-7mls for adults). This visit will take around 30 minutes.

The following table describes the study visits. All visits will be conducted by study staff at relevant medical facility.

Visit intervals and procedures

Visit Number (Timing)	**Study procedure**
Baseline visit 1 (Day 0)	Explanation and discussion of the study Sign consent form Medical history review Blood sample collection (5-7mls for adults) Urine pregnancy test only for females (childbearing potential) Randomisation to ID or SC vaccination Imojev® vaccine administration Observed for ½ hour post vaccine
Visit 2 (7-10 days post visit 1)	Check post-vaccination adverse events diary Medical history review In a subset of participants (aged over 10 years) a blood sample will be taken (around 5-7mls for adults). This is optional at this visit.
Visit 3 (28-35 days post visit 1)	Check post-vaccination adverse events Medical history review Take blood sample (around 5-7mls for adults)
Visit 4 (180-210 days post visit 1)	Check post-vaccination adverse events Medical history review Take blood sample (around 5-7mls for adults) Discuss the Visit 3 serology results
Visit 5 (12-13 months post visit 1)	Check post-vaccination adverse events Medical history review Take blood sample (around 5-7mls for adults)

We may also need to contact you at a later time in order to ask additional questions related to the study.

Diary card
We will give you either a paper or electronic diary card asking you to record any redness or swelling at the injection site and other symptoms you may have after vaccination. You will be given a thermometer to record your temperature each evening measured under the armpit.

Blood tests
The blood samples are taken by an experienced blood collector, nurse immunisation specialist or paediatrician. We will need to take about 5-7mls for adults of blood from a vein in your arm. This can be painful and bruising can occur.

We take the blood to measure the level of antibody to JEV. You will be given your individual results and their meaning.

Study costs
The vaccination, tests and medical care required as part of the research project will be provided to you free of charge. There are no additional costs associated with participation in this research project, nor will the participant be paid for taking part in the study.

You will be compensated for your time and travel in the form of a voucher (for example Coles or Woolworths or other voucher). This will be provided as a $75 voucher at Visit 3 (after the completion of Visits 1, 2 and 3), a $25 voucher at Visit 4 and a $25 voucher at Visit 5.

4 What do I have to do?

It is important that the diary card is completed as accurately and timely as possible and that all study visits are completed. You do not have to change any part of your lifestyle. There are no restrictions on your diet or exercise. You are allowed to take your routine medications.

You are not allowed to have received dengue or yellow fever vaccines, or have any of these vaccines in the 2 months after the JE vaccination. This is because we want to measure for any side effects after the JE vaccine and if another vaccine is given close in time to the JE vaccine it can be hard to know which vaccine may have caused the side effects.

5 Other relevant information about the research project

A total of 900 children (>5 years of age) and adults in Australia are planned to take part in this JE vaccine trial. This trial is being conducted by a collaborative research group and involves paediatricians, vaccine trial specialists and experts in public health. It is being supported by NSW Health, Queensland Health and Victoria Health.

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide that you want to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide that you want to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision to take part or not, or to withdraw at any time point, will not affect your routine treatment, relationship with those treating you, or the relationship with The National Centre for Immunisation Research and Surveillance (NCIRS) or Western NSW Local Health District.

7 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, likely benefits include protection from JE disease. We know that the JE vaccine is around >95% effective when given subcutaneously in preventing children and adults from JE disease.

We will discuss your serology results with you and advise whether your immune system has adequately responded. This will primarily be based on the blood test you have at Visit 3 and discussed at Visit 4. The doctor will discuss recommendations based on this result.

8 What are the possible risks and disadvantages of taking part?

You will know whether you have been given the Imojev vaccine by the subcutaneous (SC) or intradermal (ID) route. Serology testing is not normally performed to check vaccine responses to the subcutaneous Imojev vaccine and it is assumed that you are protected. In this study we will test your seroconversion at Visit 3 (Day 28-35) and you will be told your serology results at Visit 4 (180-210 days after vaccination). If you have been given the Imojev vaccine by the SC route you are considered to be protected even if your blood result at Visit 3 does not show seroconversion. This is current clinical care.

If you have been given the ID Imojev vaccine and your blood result at Visit 3 shows you have seroconverted then you are considered to be protected.

If you have been given the ID Imojev vaccine and your blood result at Visit 3 shows you **have not** seroconverted the study doctor will discuss this result with you. If your risk of being infected by JE virus increases due to changes in your work, travel or recreation then you can receive the Imojev vaccine via the recommended SC route at least 6 months after you received the Imojev vaccine via the ID route in this study.

Medical treatments often cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or you are worried about them, talk with the study doctor. The study doctor will also be looking out for side effects.

Tell the study doctor immediately about any new or unusual symptoms that you get and they can discuss the best way of managing any side effects with you.

The JE vaccine is safe, effective and has been used extensively over many years in Australian Defence Force personnel, residents of the Torres Strait Islands and many travellers to Southeast Asia.

When the vaccine is given by the intradermal route, it is more painful than when administered subcutaneously.

As with most vaccinations, there are some common side effects. Common side effects of JE vaccines given subcutaneously are:

- pain
- tenderness
- redness
- swelling where the vaccine was given.

Fever may occur, more often in children. Headache or muscle aches can also occur, mainly in adults.

These side effects usually go away within a few days.

A study of the JE vaccine given intradermally to 50 adults in Queensland showed that the vaccine was safe. Only four participants (7.8%) reported local reactions, including redness (n=3, 5.9%), swelling (n=2, 3.9%), and pain at the site of injection (n=1, 2.0%). Seven participants (13.7%) reported systemic reactions, the most common were fatigue (n=4, 7.8%) and headache (n=2, 3.9%).

For intradermal administration, multi-dose vials will be handled in accordance with strict infection control and ATAGI guidelines in which circumstances the risk of acquiring a serious bacterial infection or blood-borne virus is thought to be extremely low.

Severe reactions to JE vaccine are very rare. As with any medicine, there is a very small chance of a vaccine causing a severe allergic reaction or side effect.

Reproductive risks

It is not known whether this vaccine (Imojev) can cause foetal harm when administered to a pregnant woman. Therefore, if you are of childbearing age, you must have a negative pregnancy test before entering this study and confirm that you do not intend to become pregnant for 4 weeks after vaccination. If sexually active, a form of birth control approved by the study doctor or member of the study staff is recommended to be used for 4 weeks following the study vaccination. Medically acceptable methods of birth control include hormonal contraceptive (such as oral, injection, trans-dermal patch, implant, cervical ring); Barrier methods (condom or diaphragm); intrauterine device (IUD) and abstinence. If you think you might be pregnant, you must contact the study doctor immediately. If you become pregnant during the study, you will continue to be followed up for the outcome of the pregnancy and for safety assessments.

9 What will happen to my test samples?

This study is an investigator-initiated study. Your blood sample will be sent to the QIMR Berghofer Medical Research Institute in Brisbane for JEV antibody testing. This laboratory will be analysing the de-identified blood samples to check your antibody levels. They are a specialist reference laboratory that has extensive experience in the conduct of JEV serology in Australia. The analysis and interpretation of results will be performed by study investigators

Your samples will never be sold. You will not benefit financially if this research leads to development of a new treatment or medical test.

If you provide consent for your samples to be used in future research, this will allow us to utilise the blood samples in studies we conduct on vaccine preventable diseases. Any such future research must be approved by the ethics committee (who will be made aware that we wish to use the existing samples) before we will include your sample.

10 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the study doctor will tell you about it.

11 Can I have other treatments during this research project?

Whilst you are participating in this research project, you will be able to take all of the medications or treatments you have been normally taking for your condition or for other reasons. It is important to tell the study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments.

You should also tell the study doctor about any changes to these during your participation in the research project.

12 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. If you do withdraw during the research project, the study doctor and relevant study staff will not collect additional personal information, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time of withdrawal will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

13 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:
• Unacceptable side effects
• Decisions made by local regulatory/health authorities

Part 2 How is the research project being conducted?

14 What will happen to information about me?

Your individual serology results will be given to you with an explanation of the meaning of the results.

By signing the consent form, you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

All data collected will be held in strict confidence to protect your privacy. All information about you (including your name, email address and mobile phone number) will be stored securely with access restricted to authorised members of the research team from the National Centre for Immunisation Research and Surveillance (NCIRS), University of Queensland (UQ), and University of Sydney (NHMRC CTC), and research teams at your study site. Only these people will access your personal data as they need to manage your participation in the trial. Personal data will be kept separate to your de-identified health data.

No material which could personally identify you will be used in any reports on this study. Results from the analysis will be stored in computer files and in written form in locked cabinets at the local research site and the coded data will be stored by the NHMRC Clinical Trials Centre at the University of Sydney in a secure database.

The study data will be kept, for a minimum of 15 years, OR until the youngest participant turns 25 (whichever is the later) after which time the information will be destroyed securely. You may ask to see or correct your data. We will give you a written copy and explanation of your immune responses once they have been tested. The data obtained from this study may be used in future related or unrelated research by principal investigators.

In accordance with relevant Australian and State privacy and other relevant laws, you have the right to request access to your information collected and stored by the study team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this form if you would like to access your information.

Your health records and any information obtained during the study are subject to inspection and monitoring, both remotely and at the location where it is held (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the Sydney Children's Hospitals Network, University of Sydney NHMRC Clinical Trials Centre, the Australian Therapeutic Goods Administration and other relevant regulatory authorities, the approving Human Research Ethics Committee (HREC) and Western NSW Local Health District, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

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, except with your permission

The date and batch number of the JE vaccine you will receive as part of this research project will be recorded in the Australian Immunisation Register.

15 Complaints and compensation

If you suffer any injuries or complications as a result of this study, you should contact the study doctor as soon as possible who will assist you in arranging appropriate medical treatment.

You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if the injury or complication is sufficiently serious and is caused by unsafe drugs or equipment, or by the negligence of one of the parties involved in this study (for example, the researcher, the hospital or the treating doctor). If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies. You do not give up any legal rights to compensation by participating in this study.

If you are not eligible for compensation for the injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for the injury or complication free of charge as a public patient in any Australian public hospital.

16 Who is organising and funding the research?

This research project is being conducted by the above named investigators in conjunction with the NHMRC Clinical Trials Centre (University of Sydney). The study is being funded by the NSW Ministry of Health. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

17 Who has reviewed the research project?

The conduct of this study has been also authorised by The Sydney Children's Hospitals Network Human Research and Ethics Committee. If you have any concerns about the conduct of the study, or your rights as a study participant, you may contact: the Secretary of the Ethics Committee (phone 02 9845 3017) and quote reference 2022/ETH02471.

The conduct of this research in the Western New South Wales Local Health District has been authorised by the Research Governance Officer (RGO). Anyone with any concerns or complaints about the conduct of this study may contact the RGO on (02) 6330 5948 WNSWLHD-EthicsCommittee@health.nsw.gov.au and quote reference: 2023/STE03436.

18 Further information and who to contact

You have the right to ask questions at any time about this study or the potential risks associated with it. You will be informed of any significant new information pertaining to your safety.

Clinical contact person

Name	Professor Nicholas Wood
Position	Staff specialist
Telephone	02 9845 1434
Email	nicholas.wood@health.nsw.gov.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	Phil Sanders
Position	Manager, Research Ethics and Governance
Telephone	(02) 6330 5948
Email	Phil.Sanders@health.nsw.gov.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Sydney Children's Hospitals Network
HREC Executive Officer	Caitlin Braude
Telephone	02 9845 3017
Email	SCHN-Ethics@health.nsw.gov.au

Consent Form - *Adult providing own consent*

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Short Title	JE Vaccine via intradermal route in children and adults (JEVID-2)
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Project Sponsor	Sydney Children's Hospitals Network
Coordinating Principal Investigator	Professor Nicholas Wood
Coordinating Centre	Sydney Children's Hospitals Network
Principal Investigators	Professor Colleen Lau Dr Luis Furuya-Kanamori
Associate Investigator	Ms Priscilla Stanley
Location	Bathurst, Western NSW Local Health District

Declaration by 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, procedures and risks of the research described in the project.

I give permission for doctors, other health professionals, hospitals or laboratories outside this hospital to release information to the National Centre for Immunisation Research and Surveillance (Sydney Children's Hospitals Network) concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

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 project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Under certain circumstances (see Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 at 4.8.9*) a witness* to informed consent is required.*

Name of Witness* to Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Consent to Future Use of Samples

I consent to the storage and use of blood and tissue samples taken from me for use, as described in the relevant section of the Participant Information Sheet, for:

- This specific research project
- Any future ethically approved research relating to vaccine preventable diseases.

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* to
Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning the research project.

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

Form for Withdrawal of Participation - *Adult providing own consent*

Title	**Japanese Encephalitis Vaccine via intradermal route in children and adults (JEVID-2)**
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Associate Investigator	Ms Priscilla Stanley
Location	Bathurst, Western NSW Local Health District

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with the National Centre for Immunisation Research and Surveillance (Sydney Children's Hospitals Network) or Western NSW Local Health District.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

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