

DRAFT

Appendix 1: Participant information sheet: Participants within Dili

Local Study Coordinator Name, National Health Laboratory, Dili, Phone: TBC; Email: TBC

SEROLOGICAL STUDY OF VACCINE-PREVENTABLE DISEASES IN TIMOR-LESTE**This is for you to keep / *Ida ne'e fó ba ita bo'ot atu rai***

You are being invited to take part in a study about vaccine-preventable diseases, which include COVID-19, Hepatitis B, Measles, Rubella and Dengue.

Participation: Taking part in this project is entirely voluntary. You can withdraw from the study at any time. You do not have to explain why you want to withdraw from the study, and there are no negative consequences if you withdraw. If you have any questions, please discuss them with members of our team.

Partispasaun: Partisipa iha projetu ida ne'e completamente voluntariu. Ita bo'ot bele sai husi estudu iha kualker tempu. Ita bo'ot la presiza atu esplika razaun tamba saida, no sei la iha konsekuensia negativu karik ita bo'ot sai. Karik ita bo'ot iha kualker pergunta, favor bele hato'o ba membru husi ami nia ekipa.

What are vaccine preventable diseases? Vaccine preventable diseases are infectious diseases which can be prevented through vaccination. These include COVID-19, Hepatitis B, Measles, Rubella and Dengue.

COVID-19 is the disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which is a type of coronavirus. The virus was first identified in December 2019 and is new for humans. Coronavirus is spread from person to person mostly by droplets and contaminated surfaces. Coronavirus can cause both mild and severe disease, especially in older people and people with medical conditions. Some people with coronavirus may have no symptoms. Common symptoms of coronavirus are fever and cough. Other symptoms include headache, sore throat, tiredness, shortness of breath, sore muscles, loss of taste and smell, chills and vomiting.

COVID-19 started spreading in Timor-Leste in February 2021, and vaccines have been available since April 2021.

Hepatitis B is a virus which is spread by contact with blood. This usually occurs from mother to child (during childbirth), but can also occur by contaminated needles or blood transfusions. In some people the virus causes a short infection, the goes away. In other people, the virus causes a long-lasting infection, which can cause damage to the liver over time. Vaccines are given to new-born babies in Timor-Leste, to prevent them from getting Hepatitis B.

Measles and rubella are infections which can cause outbreaks in children. They usually cause fever and rash, and can occasionally cause serious illness. Vaccines are given to young children to prevent them from getting measles and rubella.

Dengue is a virus spread by mosquitoes which can cause illness in children and adults. Usually it causes fever with headache and rash, sometimes the illness can be serious. Currently vaccines are not used against dengue in Timor-Leste.

DRAFT

Who is organising the project? The study is a collaboration between:

[Se mak organiza projetu ida ne'e?](#) Estudu ida ne'e kolaborasaun entre:

- Ministry of Health, Timor-Leste / [Ministeriu da Saúde, Timor-Leste](#)
- Menzies School of Health Research, Australia
- National Health Laboratory, Dili / [Laboratóriu Nasional Saúde, Dili](#)
- National Centre for Immunisation Research and Surveillance, Australia / [Sentru Nasional ba Peskiza no Vigilansia Imunizasaun, Australia](#)

Approval for this project. This study has been approved by the National Institute of Health, Timor-Leste (Instituto Nacional da Saúde; INS) and the Human Research Ethics Committee of the Northern Territory Department of Health and Menzies School of Health Research in Australia.

[Aprovasaun ba projetu ida ne'e.](#) Estudu ida ne'e hetan ona aprovasaun husi Institutu Nasional da Saúde (INS), Timor-Leste no Human Research Ethics Committee of the Northern Territory Department of Health no Menzies School of Health Research iha Australia.

Informed Consent Information / Informasaun Konsentimentu ne'ebé mak Informadu

Section 1: Purpose of the study.

The main purpose of this study is to see how many people in Timor-Leste have antibodies against different vaccine-preventable diseases. If a person has antibodies to a particular infection, it means they have either been exposed in the past, or have been vaccinated. It sometimes means that the person has protection against the infection ('immunity').

We will test the blood for antibodies against COVID-19, hepatitis B, measles, rubella and dengue. These tests will be done in the laboratory in Dili (National Health Laboratory)

Approximately 5600 people in Timor-Leste will be invited to participate in the project.

Section 2: Procedures. For each person, we will:

[Seksaun 2: Prosedimentu.](#) Ba kada partisipante, ami sei:

- Ask some **QUESTIONS** including name, age, gender, contact details, occupation, vaccination details.
- Take a **BLOOD SAMPLE** (5mL). The blood samples will be used to test for previous exposure or vaccination against COVID-19, hepatitis B, measles, rubella and dengue. The blood sample will also be used to test for hepatitis B infection, and to validate check the accuracy of different tests.
- Take a **DRIED BLOOD SPOT** (3 drops of blood). This will be made by applying drops of blood to a small piece of filter paper, then drying.
- The **blood samples may also be used for validating different tests, and for potential future use to answer medical research questions relating to communicable or non-communicable diseases in Timor-Leste.** All results will be de-identified, and only grouped results will be reported. Anonymized blood samples will be stored at the National Health Laboratory for 10 years before being disposed of.

Section 3: Duration of Procedures. Collection of the blood sample will take less than 10 minutes. The questionnaire should take about 5 minutes to complete and can be answered in Tetun or English.

[Seksaun 3: Durasau ba Prosedimentu.](#) Koleksaun ba amostra ran sei uza tempu pelu menus minutu 10. Kuestionariu sei uza tempu durante minutu 5 hodi kompleta, no bele resposta uza lian Tetun ou Ingles.

DRAFT

Section 4: Potential benefit to you and others. / [Seksaun 4: Benefisiu potensial ba ita bo'ot no ema seluk.](#)

The blood tests for COVID-19, measles, rubella and dengue provides evidence of past infection or vaccination, but do not test for current infection. There is no need for any treatment if these tests are positive. The blood test for hepatitis B will check for active infection. If this is positive, you will be offered assessment and management (which may include treatment) at the hepatology clinic at Hospital Nacional Guido Valadares (NHGV).

The results of the study will provide important and useful information for Timor-Leste on the success of managing patients with COVID-19 in health care facilities without the transmission of coronavirus transmission.

Section 5: Discomforts and Risks. The potential risks of collecting a venous blood sample include temporary discomfort from the needle, bruising, bleeding, and very rarely, infection. Experienced doctors, nurses, or laboratory technicians will take the blood samples. The risk of problems is very small. In the unlikely event of any significant injury because of the blood collection procedure, the study team and/or the Ministry of Health will arrange necessary medical treatment without financial cost. However, no financial compensation will be given in case of any study-related injury.

[Seksaun 5: Deskonfortus no Risku.](#) Potensia ba risku husi kolekta ran venozu sei inklui mos deskonfortu temporariu husi daun, kulit mean (bubu), ran sai, no infeksaun raramente. Doutor, enfermeiru/a, ou tekniku laboratoriu sira ne'ebé mak iha ona esperiensia mak sei foti amostra ran. Risku ba problema ne'e kiik tebes. Karik mosu kualker prejuizu signifikante relasiona ho prosedimentu ba koleksaun ran nian, ekipa estudu/Ministeriu Saude sei aranja tratamentu medikal ne'ebé mak nesasariu sem kustu finansial. No entantu, sei la iha kompensasaun finansial ba kualker injuria ne'ebé mak mosu relasiona ho prosesu estudu.

If you are found to have active hepatitis B, you will be referred to the hepatology clinic and you will be offered further tests to see if any treatment is required.

Section 6: Costs for participation. Taking part in the project will cost nothing apart from your time.

[Seksaun 6: Kustu ba partisipasaun.](#) Partisipasaun iha projetu ida ne'e, sei la kobre kustu ruma exeptu ita bo'ot nia tempu.

Section 7: Compensation for participation. You will not receive any payments for being part of this project.

[Seksaun 7: Kompensasaun ba Partisipasaun.](#) Ita bo'ot sei la simu kualker pagamentu ba partisipasaun iha projetu ida ne'e.

Section 8: Study funding. This study is funded by the Australian Government Department of Foreign Affairs and Trading (DFAT). The Ministry of Health, Timor-Leste has been closely involved in the planning and development of this study and is involved in undertaking this study. The collaborators do not have any conflict of interests to declare.

[Seksaun 8: Finansiamentu ba estudu.](#) Estudu ida ne'e hetan finansiamentu husi Departamentu Asuntu Estranjeiru no Komersiu, Governo Australia (DFAT). Ministeriu Saude Timor-Leste, proximamente involve ona iha planeamentu no dezentvolvimentu ba estudu ida ne'e no envolve ba implementasaun estudu ida ne'e. Kolaboradores sira la iha kualker konfliktu interese atu deklarara.

Section 9: Voluntary participation. Taking part in this project is your choice, and you will have the right to stop at any time. If individuals or communities decide not to participate or decide to stop taking part at any time, there will be no penalties.

[Seksaun 9: Partisipasaun Voluntariu.](#) Partisipa iha projetu ida ne'e ita bo'ot mak hili, no ita bo'ot sei

DRAFT

iha direitu atu hapara/sai iha kualker tempu. Karik individual sira ou comunidade decide atu la partisipa ou decide atu sai husi partisipasaun iha kualker tempu, ida ne'e sei la iha penalidade ruma.

Section 10: Delivery of results. If your blood test shows that you have active hepatitis B, you will be contacted and offered assessment and management (which may include treatment) at the hepatology clinic at Hospital Nacional Guido Valadares (NHGV).

You will not be contacted with results of the other blood tests (COVID-19, measles, rubella and dengue antibodies). This is because we are planning on testing 5600 people, the tests may take several months to complete, and it would be very difficult to contact everyone. Additionally, these tests are not for active infections, so there is no need for any treatment if they are positive.

Results for the whole study will be written-up and may be published. It may be used by the Ministry of Health to plan additional vaccines and other disease-control activities in Timor-Leste. During this whole process, individual results will remain strictly confidential.

Section 11: Privacy and confidentiality. A unique code will be used to identify and link the questionnaire data and blood sample results. Study records and completed questionnaires will be reviewed, stored, and analyzed on a computer at the Menzies office in Dili and will be kept in secured areas and password protected computers. Blood samples collected for laboratory testing will be labeled with the unique code and securely stored at the National Health Laboratory in Dili, Timor-Leste. The list that matches participants' names with unique codes will be kept in a password protected file on a computer in the Menzies office in Dili. No personally identifiable information will be shared in any project reports, publication, or presentations. We will keep each individual's participation in this project confidential to the extent permitted by law. However, it is possible that other people may become aware of their participation in this study, e.g. the following people/groups may inspect project records:

- The Instituto Nacional da Saúde; INS and the Ministry of Health, Timor-Leste
- Human Research Ethics Committee of the Northern Territory Department of Health and Menzies School of Health Research in Australia

Seksaun 6: Privacidade no Konfidensialidade. Sei uza kodigu uniku hodi identifika no liga dados husi kuestionariu no rezultadu amostra ran. Registrus no kuestionariu ne'ebé kompleta ona husi estudu sei reviza, armazena, no halo analizaun uza komputador iha Menzies nia office Dili, no sei rai iha area seguru no iha komputador ne'ebé mak proteje uza password. Amostra ran ne'ebé mak koletadu hodi halo teste iha laboratoriu sei tau rotulagem/label ho kodigu uniku no seguramente sei rai iha Laboratoriu Nasional Saude, Dili Timor-Leste. Lista ne'ebé mak kombinadu ho partisipante nia naran ho kodigu uniku ne'e sei rai iha arkivu 1 protektidu ho password iha komputador iha Menzies nia Office, Dili. Kualker informasaun personal ne'ebé mak identifikavel sei la kompartilha iha kualker projetu nia relatoriu, publikasaun, ou apresentasaun sira. Ami sei mantein kada individual nia partisipasaun iha projetu ida ne'e konfidensial tuir lei haruka. No entantu, iha possibilidade ba ema balu atu notifika konaba ita bo'ot sira nia partisipasaun iha estudu ida ne'e, por ezemplu ema/grupu hirak hanesan tuir mai ne'e sei bele halo inspeksaun ba projetu nia registrus:

- Instituto Nacional da Saúde (INS) no Ministeriu Saude, Timor-Leste
- Human Research Ethics Committee of the Northern Territory Department of Health no Menzies School of Health Research, iha Australia

Some of these records could contain information that tells them who participated in the project. However, the results of blood test and answers to the questionnaires will not be linked to this information. Your test results, including the hepatitis B results will not be shared with any person outside the study team.

Husi registrasaun sira ne'e balun sei inklui informasaun ne'ebé mak sei informa konaba partisipante sira iha projetu ida ne'e. No entantu, rezultadu teste ran nian no resposta iha kuestionariu sira, sei la

DRAFT

inklui iha informasaun refere. Ita bo'ot nia rezultadu teste, inklui rezultadu hepatitis B sei la kompartilha ho kualker ema ne'ebé mak laos ekipa estudu.

Section 12: Contact information for questions or concerns. You have the right to ask any questions you may have about this study. If you have questions, complaints or concerns or believe you may have developed an injury related to this study, please contact **Local Study Coordinator Name, National Health Laboratory, Dili, Phone: TBC; Email: TBC**. If you have questions regarding your rights as a study participant or concerns regarding the ethical conduct of the project, please contact Secretario ethiku, Komisaun etiku peskija komite tekniku INS (Ph +670 7708 7665) or the Northern Territory Department of Health and Menzies School of Health Research Human Research Ethics Committee (Phone +618 8946 8600; Email ethics@menzies.edu.au). If you have any medical problems associated with this study, such as a pain from where your blood was collected or feeling unwell, please contact the above phone numbers or attend your local hospital or clinic if urgent.

Seksaun 12: Informasaun kontaktu karik iha pergunta ou preokupasaun ruma. Ita bo'ot iha direitu hodi husu kualker pergunta ne'ebé mak relasiona ho estudu ida ne'e. Karik ita bo'ot iha pergunta, reklamasau ou preokupasaun ou karik ita bo'ot hetan injuria relasiona ho estudu ida ne'e, favor kontaktu **Local Study Coordinator Name, National Health Laboratory, Dili, Phone: TBC; Email: TBC**. Karik ita bo'ot iha pergunta relasiona ho ita bo'ot nia direitu nudar partisipante ou preokupasaun relasiona ho projetu nia étika konduta, favor kontaktu Sekretariu étiku, komisaun etika peskija komite tekniku INS (Ph +670 7708 7665) ou Northern Territory Department of Health no Menzies School of Health Research Human Research Ethics Committee (telemovel +618 8946 8600; Email ethics@menzies.edu.au). Karik ita bo'ot iha kualker problema mediku ne'ebé mak asociadu ho estudu ida ne'e, por ezemplu hanesan moras iha fatin hasai ran ou sente la saudavel, favor kontaktu ba numeru ne'ebé mensiona iha leten ou konsulta iha hospital lokal ou klinika sira karik urgente.

Section 13: Consent to participate in project. Before making the decision about participating in this study you should have:

- Discussed this project with a member of the study team
- Read and understood the information in this form
- Had the opportunity to ask any questions that you may have
- Had time to consider whether to take part
- Information about who to contact in case you have any further questions or problems

Seksaun 13: konsentimentu atu partisipa iha projetu. Antes foti desizaun atu partisipa iha estudu ida ne'e ita bo'ot tenke:

- Diskute uluk konaba projetu ida ne'e ho membru husi ekipa estudu nian
- Le'e no komprende informasaun iha formulariu ida ne'e
- Iha oportunidade hodi husu kualker pergunta ne'ebé mak ita bo'ot iha
- Iha tempu hodi hanoin antes decide atu partisipa
- Infomasaun konaba se mak ita bo'ot atu kontaktu, kuandu ita bo'ot iha tan pergunta ou problema ruma.

Section 14: Ethics Committee Clearance. The ethical aspects of this research have been approved by the National Institute of Health, Timor-Leste (Instituto Nacional da Saúde; INS) and the Human Research Ethics Committee of the Northern Territory Department of Health and Menzies School of Health Research in Australia (Protocol HREC-2021-4064). If you have any concerns about this research, please contact: Secretario ethiku, Komisaun etiku peskija komite tekniku INS (Ph +670 7708 7665) or the Northern Territory Department of Health and Menzies School of Health Research Human Research Ethics Committee (Phone +618 8946 8600; Email ethics@menzies.edu.au).

DRAFT

Seksaun 14: Lisensa Komite Étika. Aspektu etikal husi peskiza ida ne'e hetan ona aprovasaun husi Institutu Nasional Saude Timor-Leste (INS) no Human Research Ethics Committee of the Northern Territory Department of Health no Menzies School of Health Research, iha Australia (Protokolu HREC-2021-4064). Karik ita bo'ot iha kualker preokupasaun konaba peskiza ida ne'e, favor kontaktu: Sekretariu Étiku, Komisaun Étiku Peskija Komite Tekniku INS (Telemovel +670 7708 7665) ou the Northern Territory Department of Health no Menzies School of Health Research Human Research Ethics Committee (Telemovel +618 8946 8600; Email: ethics@menzies.edu.au).

DRAFT

Appendix 2: Consent form**Appendix 2: Formuláriu Konsentimentu**

Local Study Coordinator Name, National Health Laboratory, Dili, Phone: TBC; Email: TBC

SEROLOGICAL STUDY OF VACCINE-PREVENTABLE DISEASES IN TIMOR-LESTE**Informed Consent / Assent Form**

This means you can say NO /

PRINCIPAL INVESTIGATOR / INVESTIGADOR PRINSIPAL: Dr Nelson Martins
STUDY COLLABORATORS / KOLABORADORES BA ESTUDU:
<ul style="list-style-type: none"> Ministry of Health (MOH), Timor-Leste / Ministeriu da Saúde, Timor-Leste Menzies School of Health Research, Australia National Health Laboratory, Dili, Timor-Leste / Laboráriu Nasional Saude, Dili, Timor-Leste National Centre for Immunisation Research and Surveillance, Australia / Sentru Nasional ba Peskiza no Vigilansia Imunizasaun, Australia

I understand the aim of this research study is **to improve understanding of the number of people who have been exposed and/or vaccinated against infectious diseases in Timor-Leste**. Details of the study have been explained to me, and I have been provided with a written information sheet and given the opportunity to ask questions.

I acknowledge that: / [Hau rekonhese katak:](#)

- Any risks and possible effects of having a **venous blood test** have been explained to my satisfaction; [Kualker risku no efeitu ne'ebé mak posivel atu hetan tamba teste ran venozu nian, esplika ona mai hau nia satisfasaun;](#)
- Taking part in this study is voluntary and I am aware that I can stop taking part at any time without explanation or prejudice and to withdraw any unprocessed data I have provided; [Partisipasaun iha estudu ida ne'e voluntariu no hau hatene katak hau bele hapara hau nia partisipasaun iha kualker tempu sem explikasaun ou prekonseitu, no dada fila fali hau nia dadus ne'ebé mak seidauk prosesa](#)
- Any information I give will be kept strictly confidential and that no names will be used to identify me in this study without my approval. [Kualker informasaun ne'ebé mak hau fó, sei rai estreitamente konfidensial no sei la uza kualker naran hodi identifika hau iha estudu ida ne'e sem hau nia aprovasaun](#)

By providing my name and signature, I agree to:

[Liu husi fó hau nia naran no asinatura, hau konkorda atu:](#)

A venous blood test for past exposure or vaccination against COVID-19

Yes
Sim

No
Lae

A venous blood test for past exposure or vaccination against measles

[Teste ran venozu hodi hatene hau nia imunidade ba Sarampo](#)

Yes
Sim

No
Lae

DRAFT

A venous blood test for past exposure or vaccination against rubella Teste ran venozu hodi hatene hau nia imunidade ba rubella	<input type="checkbox"/>	Yes Sim	<input type="checkbox"/>	No Lae
A blood test for past exposure to dengue	<input type="checkbox"/>		<input type="checkbox"/>	
A venous blood test for past exposure to hepatitis B and active infection with hepatitis B Teste ran venozu hodi hatene hau nia imunidade ba hepatitis B no infeksaun	<input type="checkbox"/>	Yes Sim	<input type="checkbox"/>	No Lae
My blood being used to make a 'dried blood spot'	<input type="checkbox"/>		<input type="checkbox"/>	
The anonymised blood sample and 'dried blood spot' being stored for 10 years and being used to validate tests for infections, and potentially tested for other communicable or non-communicable diseases	<input type="checkbox"/>	Yes Sim	<input type="checkbox"/>	No Lae
Completing a questionnaire with the help of a research assistant Kompleta kuestinariu ho ajuda husi assistente peskiza nian	<input type="checkbox"/>	Yes Sim	<input type="checkbox"/>	No Lae
Being contacted again about vaccine-preventable diseases	<input type="checkbox"/>	Yes Sim	<input type="checkbox"/>	No Lae
Being contacted again about my hepatitis B results	<input type="checkbox"/>	Yes Sim	<input type="checkbox"/>	No Lae

Name of participant / Naran partisipante: (printed)	Unique identifier: / Identifikador uniku:
Signature of participant or parent/guardian:	Date / Data:
Name of witness/interpreter: / Naran testemunha/tradutor: (printed)	Signature of witness/interpreter: / Asinatura husi testemunha/tradutor:
Name of researcher / Naran peskizador: (printed)	Signature of researcher / Asinatura husi peskizador: