Study Information Sheet for Consent

Study Title: A prospective validation of a laser anthropometric device for measuring height and length of children less than 60 months in Vietnam

Principal Investigator: PI Diane Baik MSc, PGDipPH, PhD Candidate at London School of Hygiene and Tropical Medicine

Funding Source: World Vision Korea

Introduction and Study Overview:

Hello. My name is _____. I am part of the research team. We would like to invite you to take part in our research study. Joining the study is entirely up to you, before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through this information sheet with you to help you decide whether or not you would like to take part and answer any questions you may have. We suggest this should take 10 mins. Please feel free to talk to others about the study if you wish.

The first part of the Participant Information Sheet tells you the purpose of the study and what will happen to you if you take part. Then we give you more detailed information about the conduct of the study. Do ask if anything is unclear.

1. **Why is this research being done?**
   We are testing a new laser device to measure the height or length of children less than 60 months of age. Accurate measurement is important to know whether a child is growing well or may be malnourished. The current wooden measuring boards are heavy, expensive, and difficult to use in the community. This research will help us understand whether the laser device is just as accurate and easier to use. If successful, it could make child growth monitoring faster, more reliable, and easier for health workers and families.

2. **What will happen in the study?**
   This study looks at how well the new laser device works in measuring children's height or length compared to the standard wooden board (ShorrBoard). Your child will be measured using both devices by trained teams. The measurement is safe, non-invasive, and similar to what is done in regular growth monitoring. You will be asked a few questions about your child's age and background. Participation is voluntary, and you can stop at any time without any consequences.

3. **Who can take part?**
   Children aged 0 to 59 months who live in selected villages in Quang Nam Province are eligible to take part, with the consent of their parent or caregiver.

4. **Where will the study take place?**
   The study will take place in twelve villages in Quang Nam Province during the government's regular growth monitoring activities.

5. **How long will the study last?**
   The study will run for approximately 3 months. Data collection will take place for 2 weeks, starting on May 28, 2025 to June 2, 2025. The full study will be completed on September 30, 2025. Each child's participation will take less than one hour on a single day.

Detailed Information:

Your child will be measured 4 times using the wooden height board and 4 times using the laser device by experts and community health workers. Measurements will be recorded using pen and paper and using a mobile phone or tablet.

Risks and Discomforts

There are minimal risks from your participation in this survey. One of the main risks is the breach of confidentiality ie. if any of the study reports or data reveals your name or identity. However, our study team will avoid recording your name and your child's name

by de-identifying all information and storing the data in secured facilities and computers. All research involving human participants is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by The London School of Hygiene and Tropical Medicine Ethics Committee and Hanoi University of Public Health.

Benefits

Participation in this survey is not designed to benefit you directly. However, with the information you and your community members provide; we hope that the findings from this study may benefit your community to improve the accuracy of measuring children's heights and length to improve accuracy of identifying malnourished children. There are no costs for you to participate in this study.

Compensation

You will not be offered payment for being in this study, but children will receive snacks as they wait.

Confidentiality

We will keep your personal information and data for the research confidential and secured and will not share it with anyone. Names will be de-identified from reports (a code rather than your name will be used on study records for analysis). Your name and other facts that might point to you will not appear when we present this study or publish its results. At any point, if you withdraw from the study, we will keep and continue to use all your previously collected data. We will, however not collect any further data about you.

Contact Information

If you have questions about your role in the research, your rights as a research participant, or if you have questions, concerns or complaints about the research in general, you may contact the following:

Name: Nguyen Anh Vu, MD, MPH, PhD (Vietnamese)
Address: World Vision International, Vietnam
Tel: +84 2439439920
Email: Nguyen_anh_vu@wvi.org

Name: Diane Baik, MSc (English)
Tel: +1 929-225-4075
Email: diane.baik@lshtm.ac.uk

<to be read in conjunction with guidance >
V3.0; April 24, 2025

Participant Information Sheet

Title of Project: Testing a laser device for measuring height and length of children less than 60 months in Vietnam

Introduction

We would like to invite you to take part in a research study. Joining the study is entirely up to you. Before you decide, you need to understand why the research is being done and what it would involve. One of our team will go through this information sheet with you, and answer any questions you may have. Ask questions if anything you read is not clear or you would like more information. Please feel free to talk to others about the study if you wish. Take time to decide whether or not to take part.

What is the purpose of the study?

The London School of Hygiene and Tropical Medicine (LSHTM) are conducting research in testing a new laser device to measure the height and length of children less than 60 months of age to see if it could be used in replacement of our standard wooden height board.

Why have I been asked to take part?

You have been invited because you have a child less than 60 months of age and we would like to test the device on your child. Accurate measurement is important to know whether a child is growing well or may be malnourished. The current wooden measuring boards are heavy, expensive, and difficult to use in the community. This research will help us understand whether the laser device is just as accurate and easier to use. If successful, it could make child growth monitoring faster for you and your child, more reliable, and easier for health workers and families.

Do I have to take part?

No. It is up to you to decide to take part or now. If you don't want to take part, that's ok. Your doctor will still care for you and your decision will not affect the quality of care you receive.

We will discuss the study together and give you a copy of this information sheet. If you agree to take part, we will then ask you to sign a consent form.

What will happen to me if I take part?

Your child will be measured 4 times using the wooden height board and 4 times using the laser device by experts and community health workers. Measurements will be recorded using pen and paper and using a mobile phone or tablet. Your child will wait in the play area when they are not being measured where they could play with toys, sing and color pictures and snacks will be provided.

What will I have to do?

You will have to bring your child to be measured 8-12 times (height/length), which could possibly take about 1-2 hours today.

What are the possible risks and disadvantages?

There are minimal risks from your participation in this study. One of the main risks is the breach of confidentiality. For example, if any of the study reports or data reveals your name or identity. However, our study team will avoid recording your name and your child's name by de-identifying all information and storing the data in secured facilities and computers. All research involving human participants is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by The London School of Hygiene and Tropical Medicine Ethics Committee and Hanoi University of Public Health. In addition, the child could be distressed because we are measuring him/her 8-12 times, but we will try our best to keep the child happy and measure quickly. You could also feel distressed seeing your child crying and you could always ask us to stop at any time.

What are the possible benefits?

We cannot promise the study will help you but the information we get from the study will help our knowledge and understanding of this research area may benefit your community to improve the accuracy of measuring children's heights and length to improve accuracy of identifying malnourished children. There are no costs for you to participate in this study.

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions <contact number>. If you remain unhappy and wish to complain formally, you can do this by contacting <if LSHTM is the sponsor: The Research Governance and Integrity Office (RGIO) at rgio@lshtm.ac.uk or +44 (0) 20 7927 2626>

The London School of Hygiene and Tropical Medicine holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you may be eligible to claim compensation.

Can I change my mind about taking part?

Yes. You can withdraw from the study at any time. You just need to tell your doctor that you don't want to be in the study anymore. Your doctor will still care for you.

You can withdraw from treatment but keep in contact with us to let us know your progress. Information collected may still be used.

How will we use information about you?

We will need to use information from your child for this research project.

This information will include you're your WV identification number.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

World Vision Korea is the sponsor of this research, and is responsible for looking after your information. We will keep all information about you safe and secure by:

- *Names will be de-identified from reports (a code rather than your name will be used on study records for analysis).*

- *Your name and other facts that might point to you will not appear when we present this study or publish its results.*
- *All data will be stored on a laptop that is password protected and will be transferred with encryption*

As a university, we use personally identifiable information to conduct research to improve health, care and services. As a publicly funded organisation, we have to ensure that it is in the public interest when we use personally identifiable information from people who have agreed to take part in research.

International transfers

We may share data about you outside the UK for research related purposes to:

- *Analyze the data further*

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

- *World Vision*

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- Vietnam and US are the two countries that your data will be shared with and they have adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- We use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website
- We do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- We need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- We have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for the minimum period of time required by we will keep your study data for a maximum of 10 years. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have
- **You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study.**
- If you agree to take part in the study, you will have the option to take part in future research using your data saved from this study. The study's anonymised data will be made publicly available on LSHTM Compass

Where can you find out more about how your information is used?

You can find out more about how we use your information

- *At www.hra.nhs.uk/patientdataandresearch*
- *by asking one of the research team*
- *by sending an email to DPO@lshtm.ac.uk*

What will happen to the results of this study?

The study results will be published in a medical journal so that other doctors can learn from them. Your personal information will not be included in the study report and there is no way that you can be identified from it.

Who is organising and funding this study?

<London School of Hygiene & Tropical Medicine is organizing the research and World Vision Korea is funding it. LSHTM is the sponsor for the research and they have full responsibility for the project including the collection, storage and analysis of your data, and will act as the Data Controller for the study. This means that we are responsible for looking after your information and using it properly.

Who has reviewed this study?

All research involving human participants is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by The London School of Hygiene and Tropical Medicine Research Ethics Committee. The Hanoi University of Public Health Ethics Committee has also reviewed the study and have agreed that it is okay for us to ask people to take part.

Further information and contact details

Thank you for taking time to read this information sheet. If you think you will take part in the study please read and sign the consent form.

If you would like any further information, please contact the research coordinator who can answer any questions you may have about the study.

Contact details: ***Nguyen Anh Vu, MD, MPH, PhD*** *Nguyen_anh_vu@wvi.org; +84 2439439920*

CONSENT FORM FOR PARTICIPANT AND REPRESENTATIVE

Title of Project: A study testing a laser device for measuring height and length of children less than 60 months in Vietnam

Name of PI/Researcher responsible for project: Diane Baik

Statement	**Please initial or thumbprint* each box**
I confirm that I have read and understood the information sheet dated April 24, 2025 for the above named study. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.	
I understand that my consent is voluntary and that I am free to withdraw this consent at any time without giving any reason and without my/the participant's medical care or legal rights being affected.	
I understand that the data collected during the study may be looked at by authorised individuals from London School of Hygiene and Tropical Medicine, World Vision, Ministry of Health and CDC Vietnam, where it is relevant to the participant's taking part in this research. I give permission for these individuals to have access to these records.	
I understand that data about my child may be shared via a public data repository or by sharing directly with other researchers for this study or future studies, and that your child will not be identifiable from this information	
I agree to my child taking part in the above named study.	

Printed name of participant/Representative	Signature of participant/Representative (or thumbprint/mark if unable to sign)	Date
Printed name of person obtaining consent	Signature of person obtaining consent	Date

The participant/representative is unable to sign. As a witness, I confirm that all the information about the trial was given and the participant/representative consented to taking part *(*only required if the participant/representative is unable to read or write)*

Printed name of impartial witness*	Signature of impartial witness*	Date

[*Only required if the participant is unable to read or write.]

A copy of this informed consent document has been provided to the participant.

Centre Number:
Study Number:
Participant Identification Number: