Clinicaltrials.gov: NCT04144166
Title: Informed Consent Form for CS-011-004 IRB#: 19-0726
Date: 27 Sep 2019

Northwell Health
Campus: North Shore University Hospital
Consent for Participation in a Research Study

Study Title: Evaluation of Capillary Refill Index

Principal Investigator: Timmy Li, PhD

Sponsor: Nihon Kohden Corporation

About this research
You are being asked to participate in a research study because you are a patient in the Emergency Department or the Intensive Care Unit at North Shore University Hospital.

This consent form will give you information about the research study to help you decide whether you want to participate. Please read this form before agreeing to be in the study. If you have any questions about or are not clear about something in this form, you should ask the study doctor or study staff. You should also discuss your participation with anyone you choose in order to know about this study and your options.

Important Information
This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

Why am I being asked to provide my consent?	This is a research study, which is different than personal medical care. Scientists do research to answer important questions which might help change or improve the way we do things in the future.
Do I have to join this research study?	No. Taking part in this research study is voluntary. You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled.
Why is this research study being done?	The purpose of this research study is to measure Capillary Refill Index (CRI) and Capillary Refill Time (CRT), a measurement of how quickly blood returns to your fingertip after being compressed. Capillaries are the smallest blood vessels in the body, found in places such as the fingertip. The researchers believe that the CRI method may be more accurate in assessing perfusion than the typical manual method called CRT which is the time required for a fingertip to regain its color after being compressed. We are conducting this research that CRI can be used as a marker for bodily injuries, allowing for earlier identification and action in clinical practice.
What will happen to me during the study?	First, your index (pointer finger) or middle fingertip will be compressed (squeezed) by the clinician for 5 seconds to measure CRT. When the clinician stops squeezing your finger, we will use a stopwatch to count the time (in seconds) that it takes for your fingertip to regain its color.

	This measurement will be repeated 3 times. Next, the clinician will attach a standard Food and Drug Administration (FDA) cleared pulse oximeter sensor to your index or middle fingertip of the same hand. The sensor will be connected to our study device (OLV-4201A Pulse Oximeter, provided by Nihon Kohden Corporation, Tokyo, Japan) which is investigational and not FDA cleared. After we attach the sensor to your finger, the clinician will squeeze your fingertip for 5 seconds and release. Then, the study device will digitally measure the CRI. This measurement will be repeated 3 times. If you are wearing nail polish or rings, you will be asked to remove them for research purposes in order to get a concise measurement.
How long will I participate?	The study will be completed within approximately 15 minutes during your hospital visit. This study does not require you to follow-up with the research team after the measurements is complete.
Will taking part expose me to risks?	There are no physical risks associated with the device and the procedures to measure CRT and CRI. There is a risk of breach of confidentiality. The research team will take all reasonable measures to minimize this risk from occurring. This includes de-identifying collected information and securely storing it with access limited only to researchers participating in this study.
Are there any benefits to participation?	This research will not benefit you directly. By conducting this research, we hope to understand if the device can be used to help providers understand how well the blood is being delivered to the vessels of the body in clinical settings. This is called the perfusion assessment. In the long term, this research could lead to the use of CRI as a marker for bodily injuries. This can help providers identify bodily injuries earlier and take immediate action in clinical practice.

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research.

Introduction
You are being asked to join a research study. The purpose of a research study is to answer specific questions.

Participating in a research study is not the same as getting regular medical care. The purpose of regular medical care is to improve your health. The purpose of a research study is to gather scientific information.

This consent form will explain:
- The purpose of the study
- What you will be asked to do
- The potential risks and benefits

It will also explain that you do not have to be in this study to receive medical care. You should ask questions before you decide if you want to participate. You can also ask questions at any time during the study.

This study is sponsored and funded by Nihon Kohden Corporation, a group doing doing clinical research in the field of capillary refill.

Why is this research study being done?
The purpose of this research study is to determine the effectiveness of a new method, called Capillary Refill Index (CRI) created by Nihon Kohden Corporation, for assessment of finger blood perfusion. This is a measurement of how quickly blood returns to your fingertip after being compressed. The researchers believe that this method may be more accurate in the perfusion assessment than the typical manual method called Capillary Refill Time (CRT). CRT is the time required for a fingertip to regain its color after being compressed. If so, it can be used as a marker for bodily injuries, allowing for earlier identification and action in clinical practice. You are being asked to participate in this study because you are a patient in the Emergency Department or the Intensive Care Unit at North Shore University Hospital.

How many people will take part in this study?
This research study hopes to enroll 60 patients who present to the Emergency Department or who are admitted to the Intensive Care Unit at North Shore University Hospital.

How long will you be in this study?
If you choose to take part in this study, study procedures will take approximately 15 minutes.

What will happen in this research study?
If you participate in this study, we will measure CRI and CRT, a measurement of how quickly blood returns to your fingertip after being compressed.

First, a clinician will measure CRT. Your index or middle fingertip will be compressed by the clinician for 5 seconds. When your finger is released from the compression, we will use a stopwatch to count the time (in seconds) that it takes for your fingertip to regain its color. This measurement will be repeated 3 times.

Next, we will attach a standard Food and Drug Administration (FDA) cleared pulse oximeter sensor to your index or middle fingertip of the same hand, and the sensor will be connected to our study device (OLV-4201A Pulse Oximeter, provided by Nihon Kohden Corporation, Tokyo, Japan) which is not FDA cleared. The device is a noninvasive pulse oximeter; it passes light through your fingertip to detect oxygen levels in your blood. The device is equivalent to clinically available pulse oximeters, except for the new CRI measurement function. With the sensor on it, the clinician will compress your fingertip for 5 seconds and release, and then CRI will be digitally measured by the device. This measurement will be repeated 3 times.

The study will be completed within approximately 15 minutes during your hospital visit. This study does not require you to follow-up with the research team after the measurements is complete.

What are the risks of the research study? What could go wrong?

Procedure Risk

The investigators that will compress your finger to measure CRT and CRI are licensed healthcare providers (physicians, physician assistants, or registered nurses). These healthcare providers perform this examination routinely as part of their clinical practice. The device is noninvasive and equivalent to clinically available pulse oximeters. There are no physical risks associated with the device and the procedures to measure CRT and CRI.

Confidentiality Risk

There is a risk of breach of confidentiality. The research team will take all reasonable measures to minimize this risk from occurring. This includes de-identifying collected information and securely storing it with access limited only to researchers participating in this study.

What are the benefits of this research study?

This research will not benefit you directly. By conducting this research, we hope to understand if the device can be used to improve the perfusion assessment in the clinical settings. In the long term, this research could lead to the use of CRI as a marker for bodily injuries, allowing for earlier identification and action in clinical practice.

Are there any costs for being in this research study?

You will not have any added costs from being in this study.

Will you receive any payments for participating in this research study?

You will receive a $15 gift card as compensation for participation in this study.

If the total payment you receive from Northwell Health, during this year, is equal to $600 or more, the payment is required to be reported to the IRS. Although this study does not pay $600, if you participate in other Northwell Health studies, it is possible your payment could end up totaling $600. If this occurs, the payment you receive on this study will be reported to the IRS. In this case, you will be issued a 1099 form and be required to provide your social security number at that time for reporting purposes. You will also be responsible for reporting this income while filing your tax return.

If the research produces marketable products, will I receive payment?

If this research produces a marketable product, there are no plans for you to receive any money.

What are your rights as a research participant?

Your participation in this project is voluntary. The quality of your medical care will be the same, whether you join, refuse to join, or decide to leave the study.

If you do not join the study, you will not be penalized or lose benefits to which you are entitled. If you join the study you may withdraw at any time without prejudice to your future care at Northwell Health.

Could you be taken off the study before it is over?
It is also possible that your participation in this study may end without your consent. This decision may be made by a researcher or the Institutional Review Board (IRB- the committee that oversees research at this institution).

Reasons for withdrawal may include:
- You feel discomfort/pain from the study procedures
- It is not in your best interest to continue on this study, or
- The study is stopped.

If you withdraw from this study or if you are withdrawn from the study, any data (or samples) already collected will continue to be used. However, no new data will be collected.

What happens if new information is learned?
You will be told of any new findings that may change your decision to continue to participate. Your consent to continue to take part in this study may be obtained again.

What information will be collected and used for this study?
If you agree to be in this study, we will collect health information that identifies you. We will collect information from your medical record including age, gender, body weight, height and general medical history etc. We will only collect information that is needed for the research. This information has been described in this consent form. If you sign this consent form, you are giving us permission to collect, use and share your health information. This permission is called authorization. If you do not want to provide authorization, then you cannot participate in this research study.

Who else will see your information?
Study records that identify you will be kept private. You will not be identified in study records or publications disclosed outside Northwell Health, except as detailed below.

Investigators will share information collected from this research study with:
- Study sponsor (Nihon Kohden Corporation) and/or its agents,
- Other researchers,
- Regulatory agencies, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS), and
- Clinical staff not involved in the study who may be involved in participant's treatment

The following reviewers may access your study and medical records to make sure that this study is being done properly:
- Representatives from the Northwell Health System Institutional Review Board (IRB - the committee that reviews research at this institution.

We will do our best to protect the privacy of your records but it is possible that once information is shared with people listed on this form, it may be released to others. If this happens, your information may no longer be protected by the federal law.

In the future, we may publish results of this study in scientific journals and may present it at scientific meetings. If we do, we will not identify you.

If the researchers learn about potential serious harm to you or someone else or other public health concerns, it will be shared with the appropriate authorities.

Will you be able to access your records?
If your research records are used for decisions related to your clinical care, then you have the right to review this information and request changes. This is limited to information about your treatment, and does not include information related to procedures or tests that are for research purposes only. You may access this information only after the study analysis is complete. You have the right to know who has and who will see your records. To request this information, please call the Human Research Protection Program at 465-1910.

How long will your health information be kept?
There is no limit on the length of time we will keep your information for this research because it may be analyzed for many years. We will keep it as long as it is useful, unless you decide you no longer want to take part or we close the study. You are allowing access to this information indefinitely.

Can you change your mind?
If you change your mind about being in the study, you may withdraw at any time. If you want us to stop collecting your health information, you need to send a letter to the researchers at the following address:

Dr. Timmy Li
North Shore University Hospital
Department of Emergency Medicine
300 Community Drive, Manhasset, NY 11030

Your letter needs to say that you have changed your mind and do not want the researchers to collect and share your health information. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

Will information about this study be available to the public?
A description of this clinical trial will be available on http://www.Clinical Trials.gov , as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this website at any time.

Does the investigator of this study receive money if you take part?
The investigators on this study receive money to conduct the study, but do not financially benefit from your participation. The money they receive is to pay them back for the costs of conducting the research study. Funding for this research study is provided by Nihon Kohden Corporation. If your doctor is an investigator for this study s/he is interested in both your healthcare and the conduct of this research. You do not have to take part in a research study conducted by your doctor.

Who can answer your questions about this study?
If you have any questions about the study, you may call Dr. Timmy Li at (516) 562-1513. If you have questions about side effects or injury caused by the research, you should call Dr. Timmy Li at (516) 562-1513. If you need emergency care, dial 911 or go to the nearest Emergency Room. If you have questions about your rights as a research participant, concerns about being in the study, or would like to offer input, you may contact the Office of the Institutional Review Board (the committee that oversees research at this institution) at (516) 465-1910.

A signed copy of this consent form will be given to you.

[Signature Page Follows]

Summation/Signature
You have read the above description of the research study. You have been told of the risks and benefits involved and all your questions have been answered to your satisfaction. A member of the research team will answer any future questions you may have. You voluntarily agree to join this study and know that you can withdraw from the study at any time without penalty. By signing this form, you have not given up any of your legal rights.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____ _____ _____
Witness's Printed Name Witness's Signature Date
(Note: A witness can be a member of the research team, but cannot be the same person signing consent as the investigator)

Impartial Witness: By signing below, I attest that I was present during the consent process for the above mentioned research study, and that a member of the research team accurately explained the study to the subject and provided ample opportunity for the subject to ask questions or express concerns. Although the subject is not able to sign the form due to a physical disability, consent was freely given by the subject to participate.

_____
Impartial Witness's Printed Name

_____
Impartial Witness's Signature Date

Investigator's Statement
In addition to advising the above participant of other forms of treatment and therapy which are appropriate, I have offered an opportunity for further explanation of the risks and discomforts which are, or may be associated with this study and to answer any further questions relating to it.

_____ _____
Investigator's signature **Date**

_____
Investigator's printed name