UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES
(v. 09.2016)

Project Title: A validation investigation of the accuracy of the Belun Ring, an innovative single-channel four-signal pulse oximetry, in patients referred to sleep lab for assessment of obstructive sleep apnea (OSA)

Brief Title: Belun Ring Validation Study for Assessment of Obstructive Sleep Apnea
NCT#: NCT03997916; **Document Date**: 7/16/2019

Principal Investigator: Ambrose Chiang MD

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because we would like to determine the accuracy of a new clip-on device called Belun Ring in assessing obstructive sleep apnea.

You are being asked to participate in this research study because you are scheduled to undergo an overnight sleep study in one of University Hospitals' sleep laboratories from which the research study is seeking information.

Things I should know about a research study

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Introduction and Purpose:

You are being asked to join in a research study to test the accuracy of a new device called Belun Ring in detecting obstructive sleep apnea (OSA). There will be 50 to 100 male and female patients with age 18 to 80 years old who will be recruited for this study. If at any time during this process you have questions, please ask the sleep technician to explain the words or information that you do not clearly understand. You will be given 2 copies of this informed consent to sign on the night of your sleep study if you are interested to join.

Belun Ring is a new device approved by Food and Drug Administration (FDA) last May 29, 2018 to work as a pulse oximeter. A pulse oximeter is a device which measures the percentage of blood containing oxygen called oxygen saturation. As a pulse oximeter, it uses a sensor which attaches to a site on the body, such as the finger for this device, in order to measure the oxygen saturation.

The purpose of this study is to check the accuracy of the Belun Ring device in detecting obstructive sleep apnea (OSA) among adults who are scheduled for a standard sleep study to be performed in

the sleep lab. As mentioned before, we will still perform on you the standard sleep study ordered by your doctor. However, we will add this new device called Belun Ring to your finger simultaneously with the standard sleep study. The Belun Ring fits like a ring you wear on your finger. It is painless but might feel a little bulky. Then, we will compare results of the Belun Ring with the results of the standard sleep study in order to check the accuracy of the Belun Ring in detecting obstructive sleep apnea (OSA).

The following device in this research study has recently been FDA-approved in May 29, 2018:

- Belun Ring Pulse Oximeter

Key Study Procedures
We expect that you will be in this research study for the whole time that you are sleeping for your sleep study.
Before and after your sleep study, questionnaires will be given to you for completion.
More detailed information about the study procedures can be found under "Detailed Study Procedures"

Key Risks
Clip-on sensor may feel bulky on your finger.
More detailed information about the risks of this study can be found under "Detailed Risks"

Participation in Study
You are being asked to participate in this study because we believe you meet the acceptance criteria. Your decision to be in this study is voluntary. To determine if you really fit in this study, you will be asked several questions to check your current state of health.

It is expected that your visit will take approximately five to ten (5-10) hours since you will be sleeping overnight in one of the Sleep Lab sites of University Hospitals during the entire study. This test requires no follow-up visit. If you decide to participate in this study and then change your mind, you can leave the study at any time.

Expected Benefits
There will be no direct benefits to your health. It is our hope that research like this will help us find out if this device can change the way we test for sleep apnea in the future

Alternatives
Because of the nature of this research, the only alternative is to not participate in this study.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Detailed Study Procedures
Once you have reviewed this information, have had all of your questions answered to your satisfaction and signed your consent, the study procedure will begin.

You will be asked to sleep during the actual test. The Belun Ring device will be applied to your finger since it fits like a ring on your finger. The goal is to have you sleep for at least 4 continuous hours. Data is collected continuously throughout the test.

You may withdraw from the study at any time. You will not be paid whether or not you complete the study. Your participation in the study will be stopped if you become very uncomfortable, or for any reason as determined by the study doctor or study staff.

At the end of the test the following morning, you will be monitored by doing the standard physiologic calibrations which you had done before the actual sleep study. After that, you will be released from the study. Also, you will receive a copy of the signed written informed consent at the end of the test.

Detailed Risks and Discomforts
Occasionally, the sensors on the Belun Ring device are warm to the touch and may cause some discomfort but not hot enough to burn the site of application. If this happens during the test, you should tell the study staff during the test and the offending device will be removed and will not be reapplied to you. However, the offending device will be later inspected for faulty conditions.

Also, the Belun Ring device is painless since it does not have any sharp edges. However, it may appear and feel bulky when you wear it.

The adhesive and gel in the electrode pads may cause irritation to the skin. Typical skin irritations include redness of skin and in some cases allergic reaction. Because the adhesive is strong on the electrode pads, it may cause pulling of the skin or hair upon removal.

There is a risk of breach of confidentiality which means that someone who is not listed in this form might view your data either by accident or from malicious actions. We are protecting against this by storing information directly linked to you on UH computers or UH-approved laptops only which are all encrypted and secured with password and firewalls.

If any new risks become known in the future, you will be informed of them.

Some of the questions may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question.

It is very important that you tell the study staff immediately about any side effects. If you are not honest about your side effects, it may not be safe for you to stay in the study.

Voluntary Participation / Withdrawal

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Your participation in this study may be stopped at any time by the study doctor or study staff without your consent because:

- Your failure to cooperate fully (as determined by the study doctor or study staff) with the required conduct of this study.
- Your development of an illness.
- A determination by a University Hospitals representative, for whatever cause, that the study should be discontinued.
- Technical issues with the equipment that prevent adequate collection of the data.

Financial Information

There is no cost to you nor to your health insurance for participation in this study. However, you and your health insurance are still responsible for the cost of the routine standard sleep study which was ordered by your doctor.
You will not be paid for your participation in this study.
You will not be reimbursed for parking or transportation.
You will not be responsible if the Belun Ring device got lost, stolen, broken, or not functioning properly.

Notice for Managed Care (Medicare Advantage Plan) Beneficiaries

Certain services provided to you as a participant in a clinical trial are allowable to be billed to, and paid by, your medical insurance. These services are referred to as "covered" clinical trial services. If you have a Medicare Advantage Plan as part of your medical insurance, the Centers for Medicare & Medicaid Services (CMS) require that traditional Medicare will be billed for those services. When this occurs, you will remain responsible for paying the coinsurance and deductibles according your Medicare Advantage Plan. Your Medicare Advantage Plan should cover any associated cost share related to Medicare. Please speak with a financial counselor to understand what the specific financial impact will be for you associated with participating in this clinical trial.

Research-Related Injury

If injury occurs as a result of your involvement in this research, medical treatment is available from University Hospitals or another medical facility but you/your medical insurance will be responsible for the cost of this treatment. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not considered a "research injury". There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury. To help avoid injury, it is very important to follow all study directions.

Clinically Relevant Research Results:

When applicable, include whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and for research involving biospecimens.

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will contact you to let you know what they have found. If the researchers return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.

Future use of Data

It is possible that some of the data collected during this research project may be helpful for other project(s) as well. If this is the case, we would like to ask your permission to use your data (basic demographic information, medical information including relevant health history, records made through observations during the study, records made through phone calls as part of this research, records about your study visit) in these project(s). Please check the box that correctly indicates your choice**.** Of note, all your data such as name and date of birth will be de-identified in this study. De-identified means a specific code will be assigned for all data related to you. This way, your personal health information is protected and secured.

- ❑ My data may be used for this project only.
- ❑ My data may be used for future research.

Contact for Future Research

Our study team may have additional research studies in the future. We would like your permission to contact you in the future if we think you could be a potential participant in one of our studies. Please check one of the boxes below that indicates your choice to be contacted for future research.

- ❑ Please contact me by _____ for future research opportunities.
- ❑ Please do not contact me for future research opportunities.

CLINICAL TRIAL INFORMATION

U.S. NATIONAL INSTITUTES OF HEALTH (NIH) CLINICAL TRIAL DATABASE: A description of this clinical trial will be available on http:///www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time to find out information about the trial and basic results.

Confidentiality

The results of your examinations will be collected in a centralized computer or data registry at University Hospitals. A specific subject identifying code will be used to maintain confidentiality.

Privacy of Protected Health Information

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and

outside of University Hospitals. This Authorization form is specifically for a research study entitled "A validation investigation of the accuracy of the Belun Ring, an innovative single-channel four-signal pulse oximetry, in patients referred to sleep lab for assessment of obstructive sleep apnea (OSA)" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, [Ambrose Chiang, MD], and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI about you: Basic demographic information, Medical information including relevant health history, Records made through observations during the study, records made through phone calls as part of this research, Records about your study visit This PHI will be used to track the accuracy of data used to determine the accuracy of using the Belun Ring. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, Governmental agencies in other countries, Salus Independent Review Board, The Sponsor or Sponsor's representatives, other staff from the Principal Investigator's medical practice group; University Hospitals, including the Center for Clinical Research and the Law Department; Government representatives or Federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to:

Ambrose Chiang, MD
UH Cleveland Medical Center
Department of Medicine-Pulmonary/Critical Care and Sleep Medicine/House Staff
11100 Euclid Ave Bolwell Building 6th floor
Cleveland, OH 44106

If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

Summary of your rights as a participant in a research study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of your study records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals

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Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact information

_____ has described to you what is going to be done, the risks, hazards, and benefits involved. The Research Coordinator, Mary Andrews can be contacted at (216)-844-2386 or email her at Mary.Andrews@UHhospitals.org. The Principal Investigator, Ambrose Chiang MD, can also be contacted at (216)983-0871. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Associate Chief Scientific Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

x	
Signature of Participant	Date
x	

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Printed Name of Participant

Study personnel (only individuals designated on the checklist may obtain consent)

x	
Signature of person obtaining informed consent	Date
x	
Printed name of person obtaining informed consent	