Title: **Effect of continuous background noise at specific frequencies on sleep quality and architecture.**

Sponsor Name: **Beth Israel Deaconess Medical Center**

PI Name: **Wellman, David** Protocol #: **2016P000982** Type: **Continuing Review 2**

Date Received: **January 26, 2018**

Study Staff

Name	Role	Degree	Organization	Citi Certified
Azarbarzin, Ali	Co-Investigator	Ph.D	BWH > Medicine > Sleep Medicine	2/9/2018
Calianese, Nicole	Intern/Student		BWH > Medicine > Sleep Medicine	1/2/2017
Gerard, Nathan	Intern/Student		BWH > Medicine > Sleep Medicine	1/3/2017
Hess, Lauren	Research Coordinator/Manager	BS	BWH > Medicine > Sleep Medicine	9/6/2016
Joseph, Callie	Research Coordinator/Manager		BWH > Other	2/3/2017
Lucey, Elizabeth	Research Assistant	BA	BWH > Other	9/13/2016
Messineo, Ludovico	Co-Investigator		BWH > Medicine > Sleep Medicine	11/17/2016
Oliveira Marques, Melania	Co-Investigator	MD	BWH > Medicine > Sleep Medicine	5/27/2015
Pomeroy, Hayley	Research Assistant		BWH > Medicine > Rheum, Allergy and Immuno	6/1/2016
Sands, Scott	Co-Investigator	Ph.D	BWH > Medicine > Sleep Medicine	6/23/2016
Taranto Montemurro, Luigi	Co-Investigator	MD	BWH > Medicine > Sleep Medicine	1/16/2018
Wellman, David	Principal Investigator	MD, Ph.D	BWH > Medicine > Sleep Medicine	11/28/2017

Signatures

PI Name: Wellman, David, A, MD,Ph.D
Authenticated: January 26, 2018

Continuing Review - Intervention / Interaction

For help with the preparation of a continuing review submission, print and read the Continuing Review Submission Instructions before continuing. For help submitting using Insight, see the Quick Reference Guide.

---

1. Sponsor / Funding Information

Is the research funded at this time?

⊙ Yes ○ No

Check all current funding sources that apply.

☑ Government (Federal / State)

PARTNERS HUMAN RESEARCH COMMITTEE
DETAILED PROTOCOL

Version: March 15, 2016

Title: Effect of continuous background noise at specific frequencies on sleep quality and architecture.
Principal Investigator: David Andrew Wellman, MD, PhD

I. BACKGROUND AND SIGNIFICANCE

It is known from many research studies that human performance declines with insufficient or disrupted sleep causing loss of cognitive and behavioral flexibility together with reduction in attention that produces errors on the work environment with consequences sometimes severe (1). Moreover it has been shown in the past years that sleep disruption may have wide-ranging effects on the cardiovascular, endocrine, immune, and nervous systems such as obesity, diabetes and impaired glucose tolerance, hypertension and other cardiovascular diseases, anxiety symptoms, depressed mood and alcohol use (2).
According to the *Sleep in America* survey from the National Sleep Foundation, two of the top five issues associated with disrupted sleep in adults are *inside* and *outside noise* (3). Indoor and outdoor noises can prevent sleep consolidation by increasing the wake-after-sleep-onset (WASO) time or increasing the number of brief *arousals* (3 to 15 seconds) from sleep.

One possible approach to improve sleep quality in the general population is to reduce the impact of indoor and outdoor noise. Stanchina and coworkers (4) recently proved in an Intensive Care Unit setting that application of mixed frequency sound noise (62 DB) in patients' room reduced the numbers of arousals from sleep by increasing the acoustic arousal threshold. These authors also showed that the change in noise level from baseline is more important than the peak noise level in determining the arousal from sleep.
Another study showed that application of constant noise (40 to 60 DB) during the night could increase stable sleep when measured with a technique called cardiopulmonary coupling. This method is designed to assess sleep stability using a measure derived from the ECG recording (5).

Although these and others studies showed a possible relationship between exposure to overnight constant noise of mixed frequency sounds and sleep quality, no study performed a complete assessment of all the sleep variables that determine sleep quality in the clinical setting.

II. SPECIFIC AIMS

To determine the effect of mixed frequency sound on subjective and objective sleep quality.
We hypothesize that the exposure to sound during sleep will improve sleep quality and will reduce sleep onset latency.

Specifically, we will test this hypothesis by assessing;
The effect of exposure to a range of frequencies from 350 to 4000Hz at a pressure level of 40dB on subjective sleep quality scores, sleep onset latency, sleep architecture (time spent in rapid eye movement (REM) and non-REM (NREM) sleep stage 1, 2, 3), number of arousals from sleep and time of wakefulness after sleep onset in a group of healthy subjects.

III. SUBJECT SELECTION

We will recruit a group of 20 healthy controls aged 21 to 65 years old. Normal controls will be recruited from the community, as well as from our existing database of control subjects, and will be completely healthy and thus without medical or sleep problems.

Exclusion criteria:

- Individual affected by insomnia or other sleep-related diseases.
- Individual taking any medication known to influence sleep/arousal state

Equal number of males and females will be recruited. We will consider all applicants regardless of sex, race, color, creed, or national origin.

IV. SUBJECT ENROLLMENT

Subjects will be recruited through email, telephone, newspaper, and or bulletin advertisements. Only subjects who have stated in the initial clinical questionnaire that they are interested in hearing about research studies will be contacted by phone. Should the subject be interested in the study, they can call the study physician or coordinator to inquire about study participation. We will also recruit from our existing database of research participants.

Subjects who respond will be given a thorough review of the risks, discomforts, potential benefits to the study and their expected involvement using a prepared script approved by our Institutional Review Board. Subjects will be given a copy of the informed consent and allowed a minimum of 24 hours to review the information and make a decision on study participation. During this time, the subject will have the opportunity to discuss the research with his/her primary care physician or clinician. The study investigators will be available to answer any questions should any arise. Informed consent will be obtained from all subjects by the principal investigator or a co-investigator prior to commencement of any study procedures. Subjects will be informed that they may withdraw from the study at any point, with no impact on their ongoing care.

Inclusion and exclusion criteria will be carefully assessed prior to enrollment. Assuming subjects meet the inclusion criteria, they will begin the protocol by scheduling their overnight studies in the clinical/physiology laboratories. Subjects will be informed that they may withdraw from the study at any point, with no impact on their ongoing care. We have not previously had difficulty enrolling participants into similar studies performed in our laboratory.

V. STUDY PROCEDURES

Protocol:
The protocol will be composed by 2 overnight sleep studies (a night with no noise and a night with background noise) to be conducted at Brigham and Women's Hospital. The 2 nights will be performed approximately one week apart in random order. Sleep will be scored by an expert sleep technologist blinded to the randomization order. Pittsburgh Sleep Quality Index questionnaire will be administered to all study participants before sleep on the first study night. Stanford Sleepiness Scale score and a subjective sleep quality score will be obtained from every subject after each study night.

Measurements and equipment:
Subjects will be instrumented with standard polysomnography (PSG) recording sensors. Sleep stage and arousals will be measured with electrodes pasted on to the scalp, face, chin and chest (EEG, EOG, EKG, chin EMG). Paste-on EMG electrodes will be placed over the anterior tibialis muscle to detect leg

movements. Respiratory effort belts will be placed around the chest and abdomen to measure breathing movements. Oxygen saturation will be measured continuously with a pulse oximetry probe placed on either the fingertip or earlobe. Snoring will be detected with a small microphone positioned over the suprasternal notch. Body position will be recorded with a sensor taped to the thoracic belt. Each of these devices is standard for diagnostic PSG and should not be uncomfortable.

The mixed frequencies noise background will be delivered by four speakers included in two wall mount modules powered by A/C and will include a range of frequencies from 350 to 4000Hz at a pressure level of 40dB (Nightingale, Cambridge Sound Management). The system will be activated at "lights off" time via computer by a co-investigator or a trained student who will monitor patients and data recordings overnight.

Data Analysis:
Sleep will be scored by an expert sleep technologist blinded to the randomization order following American Academy of Sleep Medicine rules.
If the data collected will be considered insufficient, the subject will be asked to repeat the whole study or a part of it without signing a new informed consent form.

Reimbursement
Subjects will receive $100/night for participation in each overnight study (TOTAL = $200).
Reimbursement for parking expenses will be provided.
If the subjects will repeat a part or the entire protocol because of insufficient data collection, they will be reimbursed $100 for any extra night.

VI. BIOSTATISTICAL ANALYSIS

In this protocol we want to collect pilot data to measure the possible size effect of this intervention. Variables of interest will be compared using a Student T-test with $p<0.05$ considered as statistically significant.

VII. RISKS AND DISCOMFORTS

We believe that the risks associated with participation in this study are minimal. All study procedures have been conducted in our laboratory without serious incident. Anticipated risks and discomforts are listed below:

1. The equipment used for assessing sleep (paste on electrodes) is standard and poses no risk. The electrodes may be mildly uncomfortable and could cause some sleep interruption. Thus subjects may feel somewhat tired the day following this study.

2. The background noise could cause sleep disruption and mild discomfort at wake-to-sleep transition. In case the subject will not tolerate the noise we will reduce the intensity or stop the noisy signal.

VIII. POTENTIAL BENEFITS

Although it is unlikely that there will be any direct physical benefit to the subjects from participating in this study, we will make known to each subject, if requested, some of the information we have gathered from this physiologic testing. This study provides a unique opportunity to gain insight into the specific mechanisms by which continuous background noise may improve sleep quality. The results may, in the future, lead to improved strategies for the treatment of insomnia. However, if previously unknown abnormalities of sleep are encountered, this information will be passed onto the subject. Results can be forwarded to the primary care physician or clinician at the request of the subject.

IX. MONITORING AND QUALITY ASSURANCE

As this study is a physiological investigation and not clinical trial, a formal Data and Safety Monitoring Board will not be implemented. The PI will be responsible for monitoring safety and quality assurance. Additionally, the ongoing results, problems, and limitations of the study will be presented on a regular basis to the investigators in the Division of Sleep Medicine. Any adverse events will be promptly reported to the Human Research Committee for review according to HRC guidelines.

Adequacy of Protection Against Risks

All of our laboratory personnel involved in the research of human subjects have completed the required institutional program for education in the protection of human research participants and their confidentiality. The institutional educational program consists of the review of regulatory and informational documents pertaining to human-subject research, passing a test demonstrating knowledge of the ethical principles and regulations governing human-subject research and signing a statement of commitment to the protection of human subjects.

All electronic data will be stored on secure computers under password protection with no access allowed to individuals outside of our research team. All paper data will be stored under lock and key with access only given to the study staff.

Protection Against Risks

We believe that all possible safeguards are in place to minimize the risk. However, several steps will be taken to insure patient comfort and safety. We will work with our IRB to come up with a safety monitoring plan to minimize risk and discomfort. This will include:

- Reporting any complications of our studies immediately to the IRB.
- Appoint a safety officer (David Wellman, MD) who will work with our physicians and technicians to maximize safety and comfort.

The study coordinator will meet with the safety officer and PI monthly (and as needed) to go over any complaints or problems. The safety officer will call the patients with problems directly to verify important issues. If problems are identified, the protocol will be adjusted as needed. Based on conversations with the NIH and the NHLBI policy (http://www.nhlbi.nih.gov/funding/ethics.htm), we will not require a

formal data safety monitoring board. However, we do have a thorough data safety monitoring plan whereby our safety officer will review all adverse events in order to classify them as serious adverse events, minor adverse events, and whether they are anticipated or unanticipated, and study related or unrelated as per our IRB rules and the NHLBI policy. The medical monitor will be an academic physician with considerable experience in clinical research but not involved in our research program or a co-investigator in any of our studies. The medical monitor will strictly adhere to the following definitions:

Definitions

Definitions are per January 2007 OHRP *Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events, OHRP Guidance,* http://www.hhs.gov/ohrp/policy/AdvEvntGuid.htm

Adverse Event (AE): any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

Serious adverse event (SAE): any adverse event that:

- Results in death
- Is life threatening, or places the subject at immediate risk of death from the event as it occurred
- Requires or prolongs hospitalization
- Causes persistent or significant disability or incapacity
- Results in congenital anomalies or birth defects
- Is another condition which investigators judge to represent significant hazards

Unanticipated Problem (UP): any incident, experience, or outcome that meets all of the following criteria:

- unexpected, in terms of nature, severity, or frequency, given the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and the characteristics of the subject population being studied;
- related or possibly related to participation in the research, in this guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research;
- suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Adverse Events (FDA) versus Unanticipated Problems (OHRP)

- All adverse events are not necessarily unanticipated problems
- All unanticipated problems are not necessarily adverse events
- Some events may be both

REFERENCES

1. Williamson AM, Feyer AM. Moderate sleep deprivation produces impairments in cognitive and motor performance equivalent to legally prescribed levels of alcohol intoxication. Occup Environ Med. 2000 Oct;57(10):649-55.
2. Institute of Medicine. Committee on Sleep Medicine and Research BoHSP. Extent and health consequences of chronic sleep loss and sleep disorders. Sleep disorders and sleep deprivation: and unmet public health problem Washington, D.C.: The National Academies Press; 2006. p. 55-135.
3. Buxton OM, Chang AM, Spilsbury JC, Bos T, Emsellem H, Knutson KL. Sleep in the modern family: protective family routines for child and adolescent sleep. Sleep Health. 2015 May 1;1(1):15-27.
4. Stanchina ML, Abu-Hijleh M, Chaudhry BK, Carlisle CC, Millman RP. The influence of white noise on sleep in subjects exposed to ICU noise. Sleep Med. 2005 Sep;6(5):423-8.
5. Zhou J, Liu D, Li X, Ma J, Zhang J, Fang J. Pink noise: effect on complexity synchronization of brain activity and sleep consolidation. J Theor Biol. 2012 Aug 7;306:68-72.

Partners HealthCare System
Research Consent Form

Subject Identification

General Template
Version Date: October 2014

Protocol Title: Effect of continuous background noise at specific frequencies on sleep quality and architecture.

Principal Investigator: D. Andrew Wellman, MD

Site Principal Investigator: BWH

Description of Subject Population: Healthy Adults

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Why is this research study being done?

This research study is being done to learn whether the presence of a noise produced at specific frequencies can help people sleeping better.

In this research study, you will be exposed to a continuous noise produced by four speakers positioned in the wall of the hospital bedroom for the entire night. While the ultimate goal of this project is to treat people with insomnia, we are testing in this protocol the effect of background noise in healthy subject.

Our hypothesis is that the background noise will improve the quality of your sleep, will reduce the time required to fall asleep and the awakenings during the night.
The side effects of these background noise are listed below under the Risks section.

In this study we will recruit 20 subjects at Brigham and Women's Hospital (BWH).

Dr. D. Andrew Wellman is paying for this research to be done thanks to philanthropic donations to our laboratory.

How long will I take part in this research study?

It will take you two nights to complete this research study. During this time, we will ask you to visit the Harvard Catalyst Clinical Research Center (HCCRC) at BWH.
On one night you will be exposed to the background noise and on the other night you will sleep in the same room without noise. The two overnight sleep studies will take about 12 hours each.

What will happen in this research study?

If you choose to take part in this study, we will ask you to sign this consent form before we do any study procedures.

You will have two research sleep studies, which are explained in detail below. During one study, you will sleep in a room where a noise will be generated from four speakers plugged into the wall. The noise will be similar to the one produced by a fan.

You cannot have any alcohol for at least 24 hours before this study visit, as alcohol may affect your sleep.

Research overnight sleep study:
This visit will take about 12 hours. We will ask you to arrive at the HCCRC at about 8:00 pm.

When you arrive we will:

- Ask you about your medical history
- Ask you to answer one questionnaire about our sleep quality and about your sleepiness in the previous month.
- Do a physical examination to make sure that you are healthy enough to take part in this study
- Do a urine pregnancy test, if you are a woman who is able to become pregnant. You cannot take part in this study if you are pregnant.

We will then attach several pieces of equipment to you, which you will wear while you sleep to measure your sleep and breathing. We will:

- Attach electrodes (thin wires) to your scalp, face, chin, and chest to measure your brain activity, eye movements, muscle tone (how contracted or tense your muscles are), and heartbeat. These electrodes will be attached with paste and/or tape to your body. We will also attach electrodes to your legs so we can measure how much your legs move while you are sleeping.
- Put a small probe on your fingertip or earlobe to monitor how much oxygen is in your blood. This probe does not puncture your skin and will not hurt.

Once all of this equipment is placed on you and you are comfortable, you will be asked to look in several directions, blink, wriggle your feet, and make chewing movements so that we can check that all of our equipment is working.

After that, we will turn off the light and let you go to sleep. We will record your breathing and sleep until approximately 6:00 am, when we will wake you up and remove all the study equipment, electrodes, and sensors.

The investigator will ask you some question about the quality of your sleep and about your level of vigilance. We will ask you to stay until you feel rested enough to return home. You should not drive your car, especially if you are feeling sleepy. We can help you get public transportation or a taxi if you do not have a responsible adult that can drive you home.

What are the risks and possible discomforts from being in this research study?

Risks of Sleep Study Procedure

Due to the extent of the equipment we use to monitor you when you sleep, and to the background noise, you may not sleep well and may be tired the next day.

You should not drive or take part in other potentially dangerous activities while you are feeling sleepy. If you plan to drive, you will have to stay in the laboratory until you have rested enough to drive safely.

What are the possible benefits from being in this research study?

You will not benefit from taking part in this study. Others with insomnia may benefit in the future from what we learn in this study. We hope that the results of this study will lead to improved treatments for insomnia.

Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should I do if I want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will I be paid to take part in this research study?

You will receive $100 for each overnight visit. We will also pay for parking your car at the Brigham and Women's Hospital during the overnight sleep studies.

What will I have to pay for if I take part in this research study?

You will not have to pay anything to participate in this study.

What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Andrew Wellman, MD, PhD is the person in charge of this research study. You can call him/her at 508-982-7401 Monday-Friday 9am-5pm. You can also call Luigi Taranto-Montemurro at 617-732-6541 Monday-Friday 9am-5pm or 617-407-8645 24/7 with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call Lauren Hess at 617-732-8976.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 617-424-4100.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my privacy?

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as "health information." In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

In this study, we may collect health information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable health information and why they may need to do so:

- Partners research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within Partners who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The Partners ethics board that oversees the research and the Partners research quality improvement programs.
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health information without your

permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your health information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your information for any mailing or marketing list. However, once your information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.

- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

Subject	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent	Date	Time (optional)

Consent of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language

Statement of Hospital Medical Interpreter

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Hospital Medical Interpreter	Date	Time (optional)

Statement of Other Individual (Non-Interpreter)

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Name	Date	Time (optional)

Consent Form Version: May 27, 2016