

****FOR CCI USE ONLY****

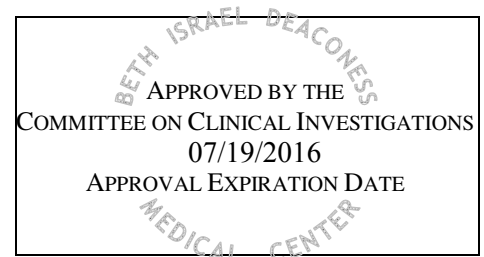
Approved by the Beth Israel Deaconess Medical Center Committee on Clinical Investigations:

Administrator: Astrid Joseph (JG)

Consent Approval Date: 8/14/15

Protocol Number: 2015P000144

Study Approval Expiration Date: 7/19/16



INFORMED CONSENT FORM TO TAKE PART IN A RESEARCH STUDY

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: Pitch perception in musicians
PRINCIPAL INVESTIGATOR: Gottfried Schlaug
CO-INVESTIGATORS: Lars Rogenmoser, Hui Li
PROTOCOL NUMBER: 2015P000144

INTRODUCTION:

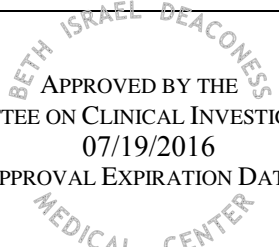
You are invited to take part in a research study assessing how musicians perceive tones or pitched information. This study involves EEG recording while you listen to tones and judge pictures (Phase 1), and optionally stimulating certain regions of your brain to test their contribution to Absolute Pitch ability (Phase 2). You are being asked to take part in this study because you are a healthy musician with or without absolute pitch. Please read this consent form carefully and ask the investigators or study staff to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study.

- This is a research study;
- Your participation is voluntary;
- A research study includes only people who choose to take part;
- You may or may not benefit from participating in the study. However, your participation may help others in the future as a result of knowledge gained from the research;
- You may leave the study at any time;
- If you choose not to take part, or if you leave the study, your decision will in no way harm your relationship with any member of the research team or any other individuals at Beth Israel Deaconess Medical Center.

Once you read this consent form and understand what your participation in this study will involve, you will be asked to sign this form if you wish to take part. You will be given a signed copy of the form to keep for your records.

DISCLOSURE OF SPECIAL INTERESTS OF BIDMC AND INVESTIGATORS

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: PITCH PERCEPTION IN MUSICIANS
PRINCIPAL INVESTIGATOR'S NAME: GOTTFRIED SCHLAUG
CO-INVESTIGATORS: LARS ROGENMOSER, HUI LI
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This study is being conducted by Dr. Gottfried Schlaug. One co-investigator (Lars Rogenmoser) is funded by a fellowship from the Swiss National Science Foundation. BIDMC or Dr. Gottfried Schlaug, Lars Rogenmoser and Hui Li have no additional financial or other interests in this research project.

WHOM TO CONTACT IF YOU HAVE QUESTIONS OR PROBLEMS

If you have any questions, concerns or complaints about this research or experience any problems, you should contact Dr. Gottfried Schlaug at [617] 632-8917.

PURPOSE

For musicians, processing tones is of great importance. From time to time, however, one may be confronted with tones played out-of-tune that can be quite disturbing. This is especially the case for musicians possessing absolute pitch. Furthermore, aged musicians increasingly tend to feel disturbed even when hearing certain in-tune tones. The goal of this study is to investigate this specific experience and its underlying brain mechanism. A set of listening tests and questionnaires will determine your eligibility for this study. If you fulfill our criteria, we will invite you to participate in an EEG session (using a technique called electroencephalography). Musicians who suffer from hearing mistuned (“sharped”) during everyday music listening or music playing are welcome to participate in the second part of our study (Phase 2) in which we will use tDCS (a technique called transcranial direct current stimulation) to test the contribution of brain regions to the absolute pitch ability. For the second part, we will arrange two appointments with you, if you qualify. Results will help us to better understand certain clinical conditions (e.g., developmental disorders) and provide a possible basis for an intervention supporting musicians in managing unpleasant feelings during music listening or music playing.

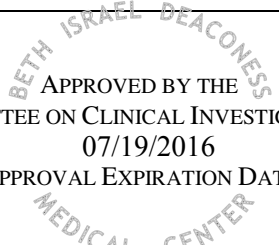
STUDY PARTICIPANTS

You have been asked to be in the study because

1. You are a musician with or without absolute pitch
2. You are either between 18 and 28 years or between 40 and 60 years of age.
3. You have normal hearing.
4. You do not have any history of neurological or psychiatric disorders/diseases
5. You are not pregnant.
6. You do not have any implants with metallic, magnetic, or electronic components.

Approximately 45 people will take part in this study at Beth Israel Deaconess Medical Center.

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DESCRIPTION OF STUDY DETAILS

Phase 1:

If you agree to be in this study, you will be asked to read and sign this consent form. After you sign the consent form, the following things will happen:

Screening Procedures: Screening procedures are tests and procedures that will be done to confirm your eligibility for this research study. For this research study, the screening procedures include: First, we will assess your hearing, pitch and rhythm discrimination ability, pitch-labelling performance and verbal and reasoning skills using several listening and performing tests. Furthermore, you will fill out several questionnaires on your musical background, your educational background, your primary language, other languages you speak and your handedness. This initial testing will take about 30 minutes.

Research Procedures: If you qualify to take part in this research study, you will undergo these research procedures: After this initial testing, we will start with the EEG session.

Electroencephalography (EEG): We are using EEG to assess the underlying brain mechanism. EEG is a non-invasive technique to record brain electrical activity using electrodes and a gel or paste applied to your scalp. The EEG device involved in this study is investigational and has been cleared by the Food and Drug Administration (FDA) for use in research.

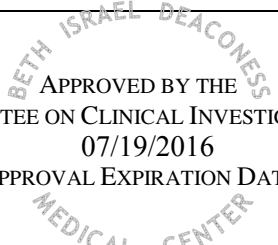
The EEG session will consist of three parts. In the first one, we will record your brain activity during rest (so-called resting state). For 5 minutes, we are going to ask you to relax, either with open or closed eyes. The second part will be the actual experiment, in which we are going to ask you to evaluate pictures as fast as possible. Some pictures will be pleasant, whereas some will be unpleasant. However, tones and notes will precede these pictures. The second part will have 3 blocks of approximately 8 minutes each and 2 breaks in between, resulting in approximately 30 minutes in total. The third part of the EEG session will be an evaluation of pictures without the preceding tones and notes in order to determine how your brain merely evaluates pictures. This will take about 10 minutes.

Altogether, the study will take about 2 hours of time.

Phase 2:

If you suffer from hearing mistuned music (“music that appears to be higher than it should be”) while listening to music you know and if you have participated in Phase 1 of our study, you might qualify for the second part (Phase 2) of this study in which we are using non-invasive brain-stimulation to test

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whether or not we can interfere with the auditory aversion experience.

Transcranial Direct Current Stimulation (tDCS): tDCS is a technology where a machine transmits a weak electrical current (2mA) through the brain via electrodes attached to the scalp. The subject usually experiences a tingling sensation on the scalp under the areas where electrodes are attached; this tingling sensation usually diminishes after several seconds. The transcranial direct current stimulation (tDCS) device involved in this study is investigational and has been cleared by the FDA as it is a form of non-invasively stimulating your brain. When the electrodes are placed on the scalp and the device is transmitting current through them, tDCS may influence the function of the underlying brain region. TDCS can be used to determine if a particular brain region plays an important role in a particular function by potentially altering the nerve signaling activity of that region. The goal of the tDCS portion of our study is to determine the roles of brain regions used to hear and to sing, by altering the function of these brain regions and measuring behavior under different conditions of stimulation.

The tDCS study will take place in two sessions separated by several days. During your first visit, you will have the experimental tasks (listening to sounds) explained to you and be given an opportunity to practice each. Before and after the stimulation session you will be asked to perform several tasks that involve listening to sounds and judging pictures as either pleasant or unpleasant by pressing one of two response buttons. Next we will measure your head and place two electrodes on your scalp, one over the brain region of interest, which will be estimated via measurements, and another on your forehead. The experiments begins with doing the pre-stimulation tasks, which is followed by the stimulation phase and the tasks are repeated after the stimulations completed. When we remove the electrodes you will find a small amount of residual gel in your hair; this generally comes out easily with water and shampoo.

Each session (including tDCS and experimental tasks) will take approximately 1 hour. Two separate sessions will be scheduled several days apart. On one day you will receive real stimulation and on the other day you will have a sham stimulation. The experimenter will schedule these sessions with you at the start of the first tDCS session.

RISKS AND DISCOMFORTS

EEG is a non-invasive and safe technique. Occasionally, a sensation of tension on the scalp may occur that is totally harmless. However, to ensure an optimal recording signal we will have to use a specific gel that will come into contact with your hair. Thus, hair washing is recommended after the EEG session. However, the gel is harmless and easy removable. We have showers, shampoos and towels available for our subjects to use.

Given that we are investigating unpleasant feelings in response to tones, some of the stimuli we are

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presenting during the experiment might possibly induce discomfort.

Transcranial Direct Current Stimulation (TDCS): TDCS is a safe and painless procedure for most people. However, it is not safe for people who have pacemakers, ear implants, shrapnel injuries, or other types of metal or electric devices in their body. Such persons will not be allowed to participate in the study. You must tell the investigator about any operations you have had and any metal you may have in your body, so it can be decided if it is safe for you to proceed with the stimulation. We will also require that all people involved in the study remove all metal from their clothing, all jewelry, and all metal objects from their pockets. TDCS may cause some, all or none of the side-effects listed below:

More Common: There is a tingling sensation under the electrode pads when the stimulation begins. This sensation is not usually considered painful, but some people may find it uncomfortable.

Less Common: TDCS has the potential to cause redness of the skin around the area of the electrode pads. Such reddening has been found to go away quickly after the stimulation ends.

Rare: No epileptic seizures have been reported in published studies, yet people with a personal history of epilepsy are not allowed to participate in tDCS studies.

Immediately after tDCS you may experience subtle changes to your singing and listening abilities. These effects have not been found to last longer than 30 minutes in research studies after 30 minutes or less of stimulation. No other cognitive changes have been reported after tDCS.

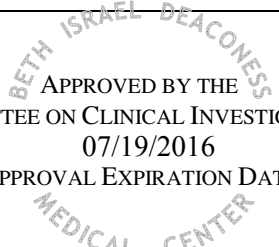
Since tDCS is fairly new, there may also be other side effects that we cannot predict because the long-term effects of stimulation have not been assessed.

Because of the effects of tDCS on the developing fetus are unknown, you may not participate in this study if you are pregnant. If you are not using adequate birth control and if you are not sure whether or not you could be pregnant, you will be required to take a urine pregnancy test to verify that you are not pregnant before receiving your first MRI and/or tDCS.

If you are a woman capable of becoming pregnant, you must agree to use adequate birth control. For the purpose of this study, use of adequate birth control includes one of the following:

1. oral hormonal contraceptives;
2. implanted hormonal contraceptives (intramuscular progesterone injections);
3. diaphragm with spermicide;
4. condoms;
5. Intra-uterine device;
6. abstinence.

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If you believe you have become pregnant while participating in this study, you must inform your study investigators immediately. They will have you take a pregnancy test. If the results demonstrate that you are pregnant, you must withdraw from the study, and the study investigators will ask to monitor your pregnancy. To monitor your pregnancy may include (but not limited to) office visits, blood work, and questionnaires.

LOSS OF CONFIDENTIALITY

There is the potential for loss of confidentiality by participating in this study. Every effort will be made to protect the confidentiality of your identifiable information.

CONFIDENTIALITY

Information derived from this study and from your medical record may be reviewed and photocopied by state and federal regulatory agencies and the Committee on Clinical Investigations of the Beth Israel Deaconess Medical Center with protection of confidentiality so far as permitted by applicable law. Information resulting from this study and from your medical record may be used for research purposes and may be published; however, you will not be identified by name in such publications. Information learned about you during this research program will be maintained confidentially by the research staff. Beth Israel Deaconess Medical Center Committee on Clinical Investigations and other persons charged with monitoring the way in which the research is conducted may have access to data bearing your identifying information, but persons having such access will provide an assurance of confidentiality to Beth Israel Deaconess Medical Center.

POSSIBLE BENEFITS

You will not benefit directly from participation in this study. However, your participation may help others in the future as a result of knowledge gained from the research.

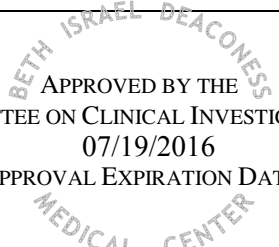
OTHER AVAILABLE OPTIONS

This study does not involve a treatment that is expected to be of benefit to you. You may choose not to participate in this study.

IF YOU DECIDE NOT TO TAKE PART IN THE STUDY

Participation in this study is voluntary. You have the right to decide not to take part in this study. If you choose to participate, you have the right to leave the study at any time. Your decision to not participate will not result in any penalties or loss of benefits to you. The investigators will tell you

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about new information that may affect your willingness to stay in this study.

If you decide not to participate in the study or decide to leave the study early, your decision will not affect your relationship with the research team or any other individual at Beth Israel Deaconess Medical Center.

INVESTIGATORS RIGHT TO STOP THE STUDY

The investigators have the right to end your participation in this study if they determine that you no longer qualify to take part, or if it would be dangerous for you to continue, or if you do not follow study procedures as directed by the investigators. Beth Israel Deaconess Medical Center may stop the study at any time.

COSTS AND/OR PAYMENTS TO YOU

COSTS COVERED BY STUDY

You will not be charged for the behavioral tests and EEG that are part of this research study.

PAYMENTS TO YOU:

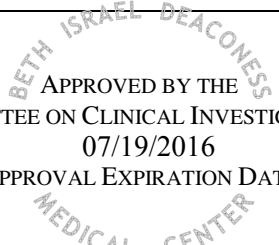
You will be paid \$25 per hour of participation in this study. Partial payments will be made if you decide to withdraw after having completed part of the study. You will not be reimbursed for travel expenses to and from our lab. Payment is made in the form of a check from Beth Israel Deaconess Medical Center (BIDMC). It may take up to 8 weeks for you to receive payment by check.

Any payments made to you may be taxable income to you. This does not include any payments you may receive to reimburse (pay you back) you for certain expenses like parking fees or travel. We are required to obtain your name and social security number for preparation and submission of Internal Revenue Service (IRS) Form 1099-Misc. You may receive an Internal Revenue Service Form 1099 from BIDMC if you receive more than \$600 or more in one calendar year for taking part in one or more research studies at BIDMC. Questions about your own tax status should be referred to your personal tax advisor.

COST OF RESEARCH RELATED INJURY:

If you are injured as a direct result of your participation in this study you should contact the Investigator at the number provided under the section "Whom to Call if You Have Questions" in this form. You will be offered the necessary care to treat your injury. You or your insurance company will be billed for medical care and/or hospitalization related to this injury. You will be responsible for all co-payments and deductibles required under your insurance. BIDMC will consider reimbursement of injury related expenses not covered by your insurance on a case-by-case basis.

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At this time there is no plan to reimburse you for items such as lost wages or lost time from work. By signing this consent form you have not given up any legal rights.

AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION

As part of this study, we will be collecting, using and sharing with others information about you. Please review this section carefully as it contains information about the federal privacy rules and the use and disclosure of your information.

PROTECTED HEALTH INFORMATION [PHI]

By signing this informed consent document, you are allowing the investigators and other authorized personnel to use [internally at BIDMC] and disclose [to people and organizations outside the BIDMC workforce identified in this consent] health information about you. This may include information about you that already exists (for example: your medical records and other sources of health information, demographic information, the results of any laboratory tests, and mental health records if applicable as well as any new information generated as part of this study. This is your Protected Health Information.

PEOPLE/GROUPS AT BIDMC WHO WILL SHARE AND USE YOUR PROTECTED HEALTH INFORMATION

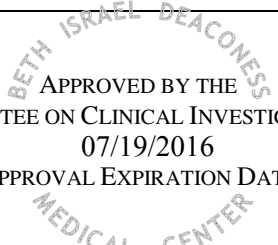
Your Protected Health Information may be shared with and used by investigators listed on this consent form as well as the supporting research team [i.e. research assistants and coordinators, statisticians, data managers, laboratory personnel, pharmacy personnel, administrative assistants], and may also be shared and used by other health care providers at BIDMC who have treated you in the past and have information relevant to the research, or who provide services to you in connection with the research. Your Protected Health Information may also be shared with the members and staff of the Committee on Clinical Investigations of Beth Israel Deaconess Medical Center, which is responsible for reviewing studies for the protection of the research subjects.

PEOPLE/GROUPS OUTSIDE OF BIDMC WITH WHOM YOUR PROTECTED HEALTH INFORMATION WILL BE SHARED

We will take care to maintain confidentiality and privacy about you and your Protected Health Information. We may share your Protected Health Information with the following groups so that they may carry out their duties related to this study:

- The funding source and/or sponsor of this study [Swiss National Science Foundation] and, where applicable, the people and companies that the funding source and/or sponsor use to oversee, administer, or conduct the research (for example, clinical research organizations are

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companies that are sometimes hired by research sponsors to help manage and run a clinical research study)

- The other hospitals and medical centers taking part in this study and research collaborators at those institutions
- Any external health care providers who provide services to you in connection with this research
- Laboratories not affiliated with BIDMC that are involved in conducting tests related to the research
- Statisticians and other data monitors not affiliated with BIDMC
- The members and staff of any other IRBs (beyond the BIDMC Committee on Clinical Investigations) that oversee the research
- Centralized data collectors
- Your health insurance company
- The Food and Drug Administration [FDA], the Department of Health and Human Services [DHHS], the National Institute of Health [NIH], the Office for Human Research Protections [OHRP], and other federal and state agencies that may have jurisdiction over the research
- Hospital and Clinical Research Accrediting Agencies
- Data and Safety Monitoring boards that oversee this study (if applicable)

Those who receive your Protected Health Information during the course of the research may not be required by the federal privacy regulations to protect it, and they may make further disclosures to others and use your information without being subject to penalties under those laws.

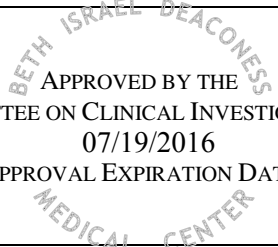
WHY WE ARE USING AND SHARING YOUR PROTECTED HEALTH INFORMATION

The main reason for using and sharing your Protected Health Information is to conduct and oversee the research as described in this Informed Consent Document. There are many other reasons beyond the research for which BIDMC may use or disclose your Protected Health Information. Not all of these reasons require your express written authorization. For example, we will use and share your Protected Health Information to ensure that the research meets legal, institutional and accreditation requirements and to conduct public health activities. The various ways in which BIDMC may use and disclose your protected health information without your authorization are explained in a document called the Notice of Privacy Practices. If you have not received a copy of BIDMC's Notice of Privacy Practices, please ask us for one and review it before signing this form. In addition to signing this document, you may also be asked to sign a BIDMC General Agreement form acknowledging that you have received the BIDMC Notice of Privacy Practices.

NO EXPIRATION DATE – RIGHT TO WITHDRAW AUTHORIZATION

Your authorization for the use and disclosure of your Protected Health Information in this Study shall never expire. However, you may withdraw your authorization for the use and disclosure of your

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Protected Health Information at any time provided you notify the Principal Investigator in writing. If you would like to take back your authorization so that your Protected Health Information can no longer be used in this study, please send a letter notifying the Principal Investigator of your withdrawal of your authorization to Dr. Gottfried Schlaug at 330 Brookline Ave., Boston, MA 02215. Please be aware that the investigators in this study will not be required to destroy or retrieve any of your Protected Health Information that has already been used or disclosed before the Principal Investigator receives your letter, and they are permitted to continue to use and disclose your previously collected information as necessary to complete the research.

REFUSAL TO SIGN

Your clinical treatment may not be conditioned upon whether you sign the Authorization for Research. However, if you choose not to sign this informed consent document and authorization for the use and disclosure of your Protected Health Information, you will not be allowed to take part in the research study.

RIGHT TO ACCESS AND COPY YOUR PHI

If you wish to review or copy your Protected Health Information as it is made part of your medical record, you may do so after the completion or termination of the study by sending a letter to the Principal Investigator requesting a copy of your Protected Health Information. You may not be allowed to inspect or copy your Protected Health Information until this study is completed or terminated.

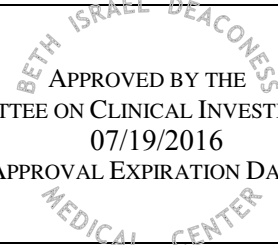
ADDITIONAL CONTACT FOR QUESTIONS OR CONCERNS

You may contact the Human Subjects Protection Office at [617] 667-0469 in the event that you would like to obtain information or to offer input about the research study. This office is independent of the investigator or investigator's research staff and can also assist with questions relating to your rights as a participant in research, which may include questions, concerns or complaints about your participation in the study.

ICF REVISION DATES:

5/4/2015: original submission date; 7/29/2015: made changes requested by CCI; 8/14/2015: made changes requested by CCI

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THE FOLLOWING PARAGRAPHS CONTAIN SOME STANDARD INFORMATION WHICH GENERALLY APPLIES TO INDIVIDUALS PARTICIPATING IN A RESEARCH STUDY.

CONSENT FORM FOR CLINICAL RESEARCH

I have read the previous page[s] of the consent form and the investigator has explained the details of the study. I understand that I am free to ask additional questions.

If I wish additional information regarding this research and my rights as a research subject, or if I believe I have been harmed by this study, I may contact the Human Subjects Protection Office (HSPO) at [617]667-0469

I am aware that this is a research project and that unforeseen side effects may occur.

I understand that the Beth Israel Deaconess Medical Center has no formal program for compensating patients for medical injuries arising from this research. Medical treatment will be provided for injuries at the usual charge to me or to my insurer unless payment is otherwise provided for in this consent form.

I understand that participation in this study is voluntary and I may refuse to participate or may discontinue participation at any time without penalty, loss of benefits, or prejudice to the quality of care which I will receive.

I acknowledge that no guarantees have been made to me regarding the results of the treatment involved in this study, and I consent to participate in the study and have been given a copy of this form.

Signature of Subject or
Legally Authorized Representative
(Parent if the subject is a minor)

Date

Relationship of Legally Authorized Representative to Subject

The subject has been given the opportunity to read this consent form and to ask questions before signing, and has been given a copy.

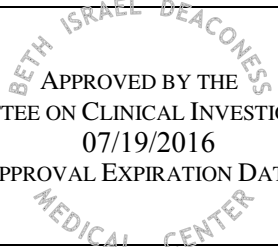
SIGNATURE OF INVESTIGATOR/Co-Investigator

DATE

PRINT INVESTIGATOR'S/Co-Investigator's

NAME

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THE FOLLOWING SECTIONS ARE NOT NEEDED FOR ALL STUDIES AND SHOULD BE UTILIZED AS INDICATED:

If the subject is able to speak and understand English but is not able to read or write

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

If the subject is able to understand English but is not physically able to read or write or see

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

If the subject is not English speaking and signed the translated Short Form in lieu of the English consent document.

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.

Signature of Interpreter: _____

Printed name of Interpreter: _____

Date: _____