

The Feinstein Institute for Medical Research
North Shore-Long Island Jewish Health System (NS-LIJHS)

TITLE OF PROTOCOL: Genetics and Epidemiology of Absolute Pitch and Related Cognitive Traits
Principal Investigator: Peter K. Gregersen, MD

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

SUBJECT'S NAME _____

Introduction You are being asked to participate in a research study to understand the genetic basis of absolute pitch and related cognitive traits. The following information is being given to you to explain the purpose of the study, what you will be asked to do as a participant, and the potential risks and benefits. You may withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled. You are encouraged to ask questions before deciding to participate, or at any time during the course of the research study. You will be informed in a timely manner of any information that may affect your willingness to continue participation in this study. All the aspects of this research study will be described to you and you will be given the opportunity to ask questions.

This consent form is written from the point of view of a research subject. If consent will be obtained from the parent or legal guardian of a minor or a legally authorized representative, the words “you” and “your” should be read as (“your child” or “the research subject”). Written informed consent will be necessary and you will receive a signed copy of this consent form. Participation in this research study is voluntary.

Purpose of the study To investigate the genetics basis of absolute pitch and related traits. You agree to participate in this research study because you have absolute pitch. Absolute pitch is the ability of individuals with some musical training to identify the pitch (frequency) of a note without reference to another pitch. Your decision to participate is based on an interest in helping further research into the genetics of absolute pitch and related traits. Participation in this research study does not include any medical care.

Study Procedures If you agree to participate in this study you will be asked to take a seven-minute pitch identification test conducted over the telephone by Elena Kowalsky, the coordinator. You also have the option of taking this test over the Internet. The pitch test was recorded on compact disk and consists of 90 randomly selected pitches (piano tones and sin waves, (sin waves are pure tones)) played one at a time. You will be asked to identify each pitch by their letter name. (For example A-flat or G-sharp etc...) The purpose of taking this test is to verify that you have absolute pitch.

You will also be asked to give a sample of your buccal (saliva) cells. The purpose of obtaining the buccal sample is to obtain cells so that we can learn the location of the gene(s) (a segment of DNA

required to contribute to a function) that contribute(s) to absolute pitch ability. The collection of buccal cells is done by spitting approximately one tablespoon of your saliva into a sterile container.

If you are eighteen years of age or older, you will be given the option to donate a sample of your blood, instead of the buccal sample. You will be asked to donate approximately 2 [two] tablespoons or 20 ccs of blood. The study coordinator at North Shore-LIJ Health System will arrange for your blood to be drawn by Examination Management Services Inc. (EMSI) and returned to The Feinstein Institute for Medical Research for processing, at no cost to you. Examination Management Services is a travelling blood drawing service. This will be a one-time blood draw at an EMSI center near your home or at your home/work at a time convenient for you. The visit should take no more than 30 minutes.

If you are a PGP (Personal Genome Project) participant, you will not be asked to donate a DNA sample.

Possible Recontact for Follow-up Study: Based on your responses to questions about your absolute pitch ability, we may ask you to fill out a follow-up questionnaire and take additional sound tests. You may ask to see these questions before deciding whether or not to participate in this study. If eligible, you will be recontacted by phone or email before any follow-up begins and the procedures will be re-explained to you. The follow-up questionnaire is conducted by mail. Sound tests are conducted by mail, Internet or on a mobile device.

Risks and Discomforts There is minimal risk involved taking part in this research study. The collection of buccal cells is a painless procedure that requires no collection of blood or blood products. If you consent to a blood draw, the sample obtained by inserting a needle into a vein, involves temporary discomfort (from the needle stick) and may result in bruising, lightheadedness, possible fainting, and very rarely, infection. Blood drawing will be performed at an EMSI center near you, at work or at your home. There are no known risks involved in the completion of questionnaires related to absolute pitch, sound tests or buccal samples.

Study Duration If you choose to participate, you will be one of approximately 1500 individuals with absolute pitch expected to take part in this research study. Participation in this study should take approximately one-two (1-2) hours of your time in total. In addition, some subjects may have additional follow-up participation in a questionnaire and sound tests regarding pitch perception or a cognitive ability related to absolute pitch. Follow-up participation should take an additional 30-60 minutes of your time. We plan to keep you updated on the results of this study by newsletter or other means.

Alternatives to Participation You may choose not to participate in this study. Your decision will not have any affect on your treatment.

Voluntary Participation Your participation in this project is voluntary. 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 the North Shore-Long Island Jewish Health System. The quality of your medical care will be the same, whether you join, refuse to join, or decide to leave the study. Your participation may be terminated by the investigator (Peter K. Gregersen, M.D.) or the IRB (the committee that oversees research at this institution) under certain

circumstances without your consent. The reasons may be participation is no longer in the best interest of the individual or inadequate cooperation or non-compliance on the part of the subject. You will be informed should the investigator or IRB terminate the study.

Collection, Research and Storage of Information and Genetic Material The purpose of this study is to investigate the genetic basis of absolute pitch and related traits. This can only be done by studying large populations of subjects with absolute pitch and their families.

Under no circumstances will any of your genetic information or material or data be released to any third party, including family members, health care providers or insurers. No one outside the immediate group of scientists working with Dr. Gregersen will have access to these samples. Your DNA/cells and data will not be used for any purpose other than research into the genetic basis of absolute pitch. Study records that identify you will be kept private. You will not be identified in study records or publications disclosed outside the North Shore-LIJ Long Island Jewish Health System, except as detailed in the confidentiality section below.

Your DNA/cell sample will remain stored indefinitely in order to allow for the studies to be completed. Your DNA/cells will be stored in locked freezers in a secured and locked building with limited access, available only to Dr. Gregersen and his immediate group of scientists. Your data will be stored in a password-protected computer in a locked office. All stored samples and data will be identified by code, defined and kept by Dr. Gregersen at the North Shore-LIJ Research Institute. By agreeing to participate in this study, you agree to the use of your DNA/cell sample and data in connection with this research study. These DNA samples will not be available for routine medical care or any future diagnostic testing.

You will be informed of the general results of this study. However, since it is currently impossible to interpret the results of such studies on any particular individual, you will not be provided any information on your own genes.

Benefits There will be no direct benefit to you in participating in this research study; knowledge may be gained that may benefit others or increase scientific knowledge of absolute pitch and related traits.

Costs/Compensation There will be no cost to you to participate in this study. All study related procedures will be provided at no cost to you. If you are having your blood drawn, there will be a fixed reimbursement of \$40 to cover any expenses related to this procedure. Payment will be made when you complete your participation. 1 out of every 100 individuals who complete participation in the study will be awarded an iPad.

Confidentiality If you agree to be in this study, we will collect health information that identifies you. We may collect the results of tests, questionnaires and interviews. We may also collect information from your medical record. 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.

Study records that identify you will be kept private. Your records may be reviewed in order to meet federal or state research regulations. Reviewers may include the NS-LIJHS Institutional Review

Board (IRB – the committee that reviews research at this institution). If this group reviews your research record, they may also need to see your entire medical record. Please be aware that once private information is disclosed, it is subject to re-disclosure by the recipient and can no longer be considered protected.

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, or for any questions related to your health information, you may contact the Research Privacy Officer at 516-562-2018.

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 researcher at the following address:

Dr. Peter K. Gregersen
The Feinstein Institute for Medical Research
Robert S. Boas Center for Genomics and Human Genetics
350 Community Drive
Manhasset, NY 11030.

Your letter needs to say that you have changed your mind and do not want the researcher 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.

The information that is collected for research will be analyzed for many years and it is not possible to know how long this analysis and follow-up will take. Therefore, you are allowing access to this information indefinitely.

Data from this study may be used in medical publications or presentations. The information will be de-identified so that individual subjects cannot be recognized and the information will no longer be considered Protected Health Information (PHI).

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.

Right to Withdraw By agreeing to participate in this study, you agree to the use of your DNA/cell sample and data in connection with this research study at North Shore University Hospital. However, you may withdraw your consent, in writing, at any time, without penalty of loss of benefits to which you are entitled and without any effect on your continuing care. Any samples and/or data you have contributed will be discarded at the point of your withdrawal. Results obtained prior to your withdrawal from the study will be maintained, and your identity will not be disclosed in any scientific publication of data.

Offer to Answer Questions If you have any questions with regard to this study or with regard to any research-related injury, you may contact Dr. Gregersen at (516) 562-1542. If you have any questions with regard to your rights as a participant in a clinical research study you may contact the Office of the

PARENT’S/LEGAL GUARDIAN’S CONSENT FOR MINOR SUBJECT

Possible Follow-up Contact

- I agree to have my child participate in a follow-up questionnaire and/or sound test(s) if she/he is eligible. The follow-up procedures have been explained to me. I have had the opportunity to ask questions. I know that I may ask further questions at any time or change my mind about my child’s participation in the follow-up study at any time.

When participant is less than 18 years old:

Subject’s Printed Name

Parent’s/Legal Guardian’s Printed Name

Parent’s/ Legal Guardian’s Signature

Date

Witness’s Printed Name

Witness’s Signature

Date

Check here if witness signature is waived due to mailed or electronic consent

STATEMENT OF THE INVESTIGATOR

In addition to advising the above subject about this research, I have offered an opportunity for further explanation of the risks and discomforts that are, or may be associated with this study and to answer any further questions relating to it.

Investigator’s Printed Name

Investigator’s Signature

Date

North Shore-Long Island Jewish Health System

Campus: Manhasset

Assent to be in a Research Study for children 17 years of age or younger

Title: Genetics and Epidemiology of Absolute Pitch and Related Cognitive Traits

My name is Elena Kowalsky. We are asking you to take part in a research study because we are trying to learn more about the musical ability called absolute pitch and other abilities related to it.

We want to tell you about some of the things that might happen to you if you are in this study. You may be asked to answer questions about your experience with music and take musical sound tests on the Internet or phone. This will not hurt. You may also be asked to spit a small amount of your saliva in a plastic tube that we will send you by mail. This will not hurt. Sometimes things that don't feel good happen in research studies. Some things that could happen may hurt you or make you feel upset. Some of the things might happen to you or they might not. Or things might happen that we don't know about yet. People may also have good things happen to them when they are in research studies. The good things may be having fun taking the sound tests and helping the researchers to understand more about absolute pitch.

Please talk to your parents about this before you decide whether or not to be in this research study. We will also ask your parents to give their permission for you to be in this study. But even if your parents say "yes," you can still decide not to be in this research study. If you don't want to be in this study, you don't have to. You may stop being in this any time. Remember, being in this study is up to you and no one will be upset if you don't want to take part in this study or even if you change your mind later and want to stop. You can ask any questions that you have about the study. If you have a question later that you didn't think of now, you can call me at 1-888-897-3098 or ask me next time. Putting your name at the bottom means that you have decided to be in this study. You and your parents will be given a copy of this form after you have signed it.

Name of Subject

Put your name here ↑

Date

Name of Investigator Obtaining Assent

Signature of Investigator Obtaining Assent

Date

Signature of Witness

Date

Check here if witness signature is waived due to mailed or electronic consent