UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	**Treating primary progressive aphasia and elucidating neurodegeneration in the language network using transcranial direct current stimulation**
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Research Study Summary for Potential Subjects

You are being invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

The research study is being conducted in order to determine whether High-Definition Transcranial Direct Current Stimulation (HD-tDCS) paired with speech therapy (mCILT) can improve language in persons with Primary Progressive Aphasia (PPA). The researchers are also interested in using fMRI data to better understand how brain damage caused by PPA influences aphasia severity and whether we can use fMRI results to predict whether tDCS will be a successful treatment for PPA.

If you agree to join the study, a screening will take place to determine if you qualify. Next, we will determine baseline language performance and brain functioning. You will then enter the first arm of treatment where you will be randomized to receive either real or sham HD-tDCS + speech therapy. Immediate, 6 week, and 12 week language follow-ups will occur after treatment is complete. At this point, you will crossover into arm 2 of the study. You will complete all sessions starting with baseline testing for a second round. However, patients who received real HD-tDCS first will now receive sham and visa-versa.

Please note, that you may be asked to discontinue any outside speech therapy you are currently receiving during the course of your participation.

Your participation will last for 6-8 months or about 39 visits.

There is no guaranteed benefit to participation; however, all participants will crossover into the real HD-tDCS group and may benefit from treatment. We note that the study is also potentially of benefit to participants as they will receive two weeks of mCILT, an accepted form of speech therapy for which there is evidence of efficacy. The most common risks of HD-tDCS are mild burning, tingling, or itching at the site of stimulation.

Should you not participate in the study you will retain other options currently available to you, including speech therapy.

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, costs, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

Why am I being asked to volunteer?

You are being invited to participate in a research study because you have Primary Progressive Aphasia (PPA; an acquired disorder of language) as a result of neurodegenerative disorders like dementia. Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the investigator and/or the research team about this form. If you decide to participate, you will be asked to sign this form. Your doctor may be an investigator in this research study. You do not have to participate in any research study offered by your doctor. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. You may also decide to discuss the study with your family, friends, or family doctor. Being in a research study is different from being a patient. As an investigator, your doctor is interested both in your clinical welfare and in the conduct of this study.

What is the purpose of this research study?

This is a study for individuals who have been diagnosed with Primary Progressive Aphasia; a disorder that leads to trouble speaking or understanding language. The study is being performed to determine if combining high-definition transcranial Direct Current Stimulation (HD-tDCS), a form of non-invasive brain stimulation, and Constraint-Induced Language Therapy (CILT) will improve your ability to speak and understand language. During HD-tDCS, small electrical currents are applied to the scalp through five electrodes. HD-tDCS is experimental; the technique has been in use for approximately 10 years around the world and for more than 5 years at Penn. HD-tDCS is not approved by the FDA and has not been proven as an effective treatment for any neurological condition.

How long will I be in the study?

The entire study is expected to last 5 years. Your participation will last about 6 – 8 months. We hope that 66 subjects will complete this study. The University of Pennsylvania is the only site at which the study is being performed.

What am I being asked to do?

The timeline of your participation in the study is depicted below:

Enrollment	Baseline MRI	Baseline	Treatment	Follow-up	Follow-up MRI	6 week Follow-up	12 week Follow-up MRI	12 week Follow-up
SCREENING	VISIT 1	VISIT 2-3	Visit 4-13	VISIT 14-15	VISIT 16	VISIT 17-18	VISIT 19	VISIT 20
- Informed Consent - Screening Forms - Demographics Form	**MRI**	**Language Assessment ***	**HD-tDCS + mCILT OR Sham HD-tDCS + mCILT**	**Language Assessment***	**MRI**	**Language Assessment***	**MRI**	**Language Assessment***
~ 1 hour	~ 2 hours	~ 2 hrs	~ 1.5 hrs	~ 2 hrs	~ 1 hour	~ 2 hrs	~ 2 hrs	~ 2 hours

Crossover Baseline	Crossover Treatment	Crossover Follow-up	Crossover Follow-up MRI	Crossover 6 week Follow-up	Crossover 12 week Follow-up	Crossover 12 week Follow-up MRI
VISIT 21*	VISIT 22-31	VISIT 32-33	VISIT 34	VISIT 35-36	VISIT 37-38	VISIT 39
Language Assessment*	**HD-tDCS + CILT OR Sham HD-tDCS + CILT**	**Language Assessment***	**MRI**	**Language Assessment***	**Language Assessment***	**MRI**
~ 2 hours	~ 1.5 hours	~ 2 hours	~ 2 hour	~ 2 hours	~ 2 hours	~ 2 hours

* An additional visits may be necessary for the language assessments depending on the participant's individual stamina

Baseline Phase:

If you qualify and are interested in participating in the study you will first undergo an MRI scan of the brain. The MRI scan will not have dye (contrast). Although the MRI is painless, it will be somewhat noisy inside the magnet due to beeping and hammering sounds, so you will be given disposable earplugs. You will be asked to lie down on a platform. Foam pads will be placed around your head to limit head movement during the study. You will then be moved into the magnet. You will be asked to lie still while several images are taken. This MRI scan will last about 2 hours.

Next you will be asked to participate in two sessions of language testing. In these sessions, you will be asked to take several tests that are commonly used to judge the language ability of persons with aphasia. These tests will include assessments of speech production, comprehension, reading & writing.
The language testing will occur over 2 sessions. Each session will last about 2 hours. If more time is required to finish the language testing, then an additional baseline visit will be scheduled.

These in-person baseline sessions of language testing may be substituted with testing conducted on a computer or tablet through video conference software. We will send testing materials through the mail that will be completed during the language testing session. If a computer or tablet is not available to you, we will provide a tablet for use for the testing.

During the baseline visits, we may ask you to provide a DNA sample for genotyping. This will involve you spitting into a bottle so that we can collect a saliva sample. You are completely free to refuse to give us your DNA sample (the saliva), which will not affect your participation. If you want to give us the sample, we will use it to test the DNA at the University of Pennsylvania. The samples will not have your name on them and won't be connected to your name. If you agree to give us your DNA sample, you will check the box at the end of the form.

Treatment phase:
The treatment phase of the study includes 10 sessions (Monday-Friday for 2 consecutive weeks) which will last about 90 minutes. During each session you will receive 20 minutes of real or sham HD-tDCS while participating in 60-90 minutes of speech therapy.

You will be assigned by chance to receive either real or sham HD-TDCS with speech therapy. Fifty percent of our participants will get real HD-tDCS first, followed by sham HD-tDCS at crossover; the other fifty percent will get sham HD-tDCS first, followed by real HD-tDCS at crossover. All participants will receive the same speech therapy called Constraint Induced Language Therapy (CILT). CILT is a commonly used type of speech therapy that have been proven beneficial. You will be asked to produce words or sentences in response to commands from the researcher. CILT requires that you speak without using any other forms of communication, like gestures.

HD-tDCS is a type of non-invasive brain stimulation in which small electrical currents are applied to the scalp for 20 minutes via 5 electrodes. The current, 1.5 mA, is approximately of the same intensity as the current provided by a 9-volt battery. To deliver the current, electrodes that are placed in gel will be attached to the left side of your head; they will be held in place with an elastic cap. For both real and sham stimulation the electrodes will be placed on the scalp. During the sham HD-tDCS a current will be delivered for a short amount of time and then turn off. Most people cannot tell the difference between real and sham stimulation. Study personnel who are trained in the use of tDCS will administer the stimulation and will be present during the entire session.

Follow-up Phase:
Several days after the end of the treatment phase you will be asked to complete immediate follow-up testing. This will include all of the language assessments you completed at the baseline sessions. You will also be asked to complete another 2 hour MRI scan.

Six weeks after the end of the treatment phase you will be asked to complete 6 week follow-up testing. You will complete the same set of language tests you did during the baseline sessions.

Finally, 12 weeks after the end of the treatment phase you will be asked to complete 12 week follow-up testing. You will complete the same set of language tests you did during the baseline sessions. You will also be asked to complete another 2 hour MRI scan.

Follow-up visits may be conducted virtually, on the computer, in the same manner as the baseline testing visits.

Crossover Phase:
This is a crossover study which means that all participants will receive both real and sham HD-tDCS. One the first phase of the study is complete, you will be asked to return and repeat all visits beginning at baseline. If you received real HD-tDCS the first time, you will now receive sham HD-tDCS and visa-versa. Both you and the researcher will be blind to which type of stimulation you received. We will not be able to tell you which stimulation order you received until the study is complete.

Optional Remote Testing for Cross-Validation:
We are asking that subjects participate in an additional follow-up session that will allow us to validate our remote testing measures with your performance on in-person tests. You will be asked to complete these remote testing visits from home; however, if you are unable to do so, you may be able to complete these tests in a private testing room at Penn but separated from our researcher. The testing will be done virtually, over computer. Testing is expected to take 6 hours and be completed over 2-3 days.

Please initial inside the box if you would like to participate.

What are the possible risks or discomforts?

Behavioral Testing Risk
Risks from the language testing and CILT are considered to be modest; it is possible you might become frustrated, irritated or even bored by the tasks. Should this occur, you will be permitted to rest and relax.

MRI Risk
The known risks associated with MRI are minimal.
Implanted medical devices, metallic objects, and metallic foreign fragments inside your body may pose a risk if you were to enter the MRI magnet room. Therefore, questions regarding medical and work history will be asked prior to your exam. All subjects undergoing MRI scanning must complete a screening evaluation risk in advance of the study for the presence of medical implants or other foreign bodies that could pose an injury. Every effort will be made to insure that disclosed implants or foreign bodies do not pose a risk to subjects. In cases where there is insufficient information to evaluate the risks associated with an implant or foreign body, the MRI study will not be allowed to

proceed.The greatest risk is a magnetic object flying through the air toward the magnet and hitting you. To reduce this risk we require that all people involved with the study remove all magnetic metal from their clothing and all magnetic metal objects from their pockets. No magnetic metal objects are allowed to be brought into the magnet room at any time except by approved personnel. In addition, once you are in the magnet, the door to the room will be closed so that no one inadvertently walks into the room. There is no known health risk associated with exposure to magnetic fields during an MRI. There are minimal risks from the loud noise associated with the MRI scanner and from the discomfort of lying on a hard surface. We shall provide you with protective earplugs as necessary and make every attempt to ensure your comfort with blankets, etc. during your time in the scanner. Although there are no known risks related to MRI on pregnant women or a fetus, there is a possibility of yet undiscovered pregnancy related risks. Since there is no possible benefit from participating in this protocol for a pregnant woman, we will exclude pregnant women. Some of the pulse sequences and/or RF coils are not FDA approved but are considered to pose no more than minimal risk.

This MRI is not a clinical scan. It is possible that during the course of the research study, the research staff may notice an unexpected finding(s). Should this occur, the finding(s) will be considered by the appropriate personnel and the PI will inform you if necessary. These possible finding(s) may or may not be significant and may lead to anxiety about your condition and to further work-up by your physician.

tDCS Risk

HD-tDCS has been used around the world for approximately 10 years; we have been using it at Penn for approximately 5 years.

There are no known major risks from HD-tDCS. There are, however, a number of common side effects about which you should be aware. The most common side effects are tingling, itching or burning at the location of the electrode; itching and/or tingling occurs in most people but is usually not painful. Approximately 10% of people report mild pain from the stimulation. Approximately 10% of people also report a mild headache that usually goes away without treatment. Since sham stimulation does include approximately 30 seconds of stimulation, these side effects can also sometimes be experienced during sham stimulation.

Reproductive Risk

Because of the effects of this drug/device, there could be serious harm to unborn children or children who are breast-feeding. These effects could also harm the mother. It is also possible that harmful side effects that are not yet known could happen to both the mother and unborn or breast-feeding child. If you are currently pregnant, it is important that you inform the investigator because you will not be able participate in the study. If you are able to become pregnant, you will be given a urine pregnancy test prior to your first HD-tDCS sessions. You should not become pregnant while you are taking this drug/device. If you do become pregnant, you must tell the investigator and consult an obstetrician or maternal-fetal specialist.

What if new information becomes available about the study?
During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?
We hope that HD-tDCS used with CILT will improve your language abilities. However, HD-tDCS treatment is experimental and you may not get any benefit from being in this research study.

What other choices do I have if I do not participate?
Should you choose to not participate in the study you will retain other options currently available to you, including participation in other studies.

Will I be paid for being in this study?
You will be paid $20 per hour for the time spent in testing and treatment; approximately $750 over the course of the study. We will also reimburse you up to $50 per visit for your transportation cost. All payments will be completed via the GreenPhire clincard system. The GreenPhire card is a reloadable debit card that can be loaded at the completion of each session.

Please note: In order to be compensated for your participation in this study, you must provide your Social Security Number. Additionally, please note that the University of Pennsylvania is required to report to the IRS any cumulative payments for participation in research studies that exceed a total of $600 in a calendar year.

Will I have to pay for anything?
Language testing, brain imaging, HD-tDCS and speech therapy will be provided by the study. There is no direct cost from participating in the study.

You are still responsible for any deductibles or applicable co-pays for routine office visits, scans and blood work. Please talk to your doctor and study team about putting you in touch with a financial counselor to determine exactly what the deductible and co-pay will be for you; this is highly variable depending on your type of insurance.

Will I receive the results of research testing?
Most tests done in research studies are only for research and have no clear meaning for health care. Results from your MRI brain imaging may be placed in your electronic medical record at Penn. Research results related to your response to the treatment will be made available to you at your request once the study is complete. These results will not be placed in your medical records and no clinical follow-up will occur.

What happens if I am injured from being in the study?
We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate,

for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. You do not give up your legal rights by signing this form.

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

When is the Study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time by your physician, the study Sponsor, or the Food and Drug Administration (FDA) without your consent because:

- The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The Sponsor, the study Principal Investigator, or the Food and Drug Administration (FDA) has decided to stop the study.
- Change of PPA diagnosis

If you decide not to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future care in any way. We ask that you notify study investigators promptly should you decide to withdraw from the study. A study investigator may contact you by phone or via mail to obtain this information. Note that data collected prior to your withdrawal will be included in the study; data or observations made after withdrawal (with the exception of survival data) will be excluded from the investigation.

How will my personal information be protected during the study?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records. If this study is being overseen by the Food and Drug Administration (FDA), they may review your research records.

Your confidentiality will be maintained by keeping records in a secure location. Most of the information will take the form of computer files; these will be de-identified. Subject names, ages and ethnicity will be recorded only in a secure, password-protected

computer location. In addition, the following precautions will be exercised in protection of your confidentiality.

- Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study.
- Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords.
- Whenever feasible, identifiers will be removed from study-related information.

During language tasks, you will be digitally audio & video recorded for later analysis. These files will be de-identified and stored on password-protected computers & severs.

Certain research data may be stored with the online file-sharing service Penn+Box. Data stored online may include computer scripts, experimental stimuli, and de-identified behavioral data from testing sessions. Online records will not include Protected Health Information (PHI) as defined by the HIPAA Privacy Rules.

Future Use of Data

Your identifiable information will be stored for future research purposes. Future researchers may receive information that could identify you. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information only applies to the information collected on this study.
The following identifiers will be retained with your information: study ID number.

Your information may be stored and used for future research purposes for an indefinite amount of time.

There are no plans to tell you about any specific research that will be done. Possible future research may include difference in tDCS response in individuals.

We may share your identifiable information with other researchers at Penn or other research, academic, or medical institutions.

We will not follow up with you to tell you about the specific research that will be done. We will not give you any results from these studies. It is possible that you may have chosen not to participate in these future research studies, had you been approached for participation.

Research results of any future testing of specimens will not be returned to you because they would not be relevant to your healthcare.

There is a risk of breach of confidentiality (unintentional release of your information). We will do our best to make sure that this doesn't happen. However, we cannot guarantee total privacy. We will protect your confidentiality during storage and sharing by using electronically secure means of sharing. Also, by using your subject ID, there is a low chance that the data could be traced back to you.

You will likely not directly benefit from future research with your information. Research with your identifiable information may help others by improving our understanding of

health and disease, improving health care and making safer or more effective medical therapies, and developing new scientific knowledge.

If you have questions about the storage of your information, or have changed your mind, you can contact the Laboratory for Cognition and Neural Stimulation at 215-572-4336.

If you change your mind, please note that data storage and analysis is ongoing so your data may have already been included in research analysis.

Will information about this study be available to the public?

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you.

What may happen to my information and samples collected on this study?

Collection of Identifiable Specimens

Your samples will not be used to create products. They will be destroyed after genetic testing.

Whole genome sequencing will not be conducted on your samples. Whole genome sequencing involves analyzing your entire personal genetic code.

Future Use of Data and Specimens

If you have agreed to give a saliva sample, this sample will not be stored or shared for future research purposes.

Your identifiable information will be stored for future research purposes. Future researchers may receive information that could identify you. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information only applies to the information collected on this study. The following identifiers will be kept with your information: your voice and appearance from audio/video recordings. Your information may be stored and used for future research purposes for an indefinite amount of time. There are no plans to tell you about any of the specific research that will be done. Possible future research may include other studies about aphasia.

We may share your identifiable information with researchers at other research, academic, and medical institutions. We will not follow up with you to tell you about the specific research that will be done. We will not give you any results from these studies. It is possible that you may have chosen not to participate in these future research studies, had you been approached for participation. There is a risk of breach of confidentiality (unintentional release of your

information). We will do our best to make sure that this doesn't happen. However, we cannot guarantee total privacy. We will protect your confidentiality during storage and sharing by keeping your information on password protected computers and servers and by sharing data using secure file exchange.

You will likely not directly benefit from future research with your information. Research with your identifiable information may help others by improving our understanding of health and disease, improving health care and making safer or more effective medical therapies, and developing scientific knowledge.

If you have questions about the storage of your information, or have changed your mind, you can contact the Laboratory for Cognition and Neural Stimulation at 215-573-4336.

Electronic Medical Records and Research Results

What is an Electronic Medical Record and/or a Clinical Trial Management System?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

A clinical trial management system (CTMS) is used to register your information as a participant in a study and to allow for your research data to be entered/stored for the purposes of data analysis and any other required activity for the purpose of the conduct of the research.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, information related to your participation in the research (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS. Information related to your participation in clinical research will also be contained in the CTMS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any information produced from your participation in this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Information related to your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.

Once placed in your EMR or in the CTMS, your information may be accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by

UPHS to be appropriate to have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

What information about me may be collected, used or shared with others?

The following personal health information will be collected, used for research and may be disclosed or released during your involvement with this research study:

- Name
- Address
- Age
- Social Security number (to arrange payment)
- Contact information (e.g., telephone number)
- Past medical history as it relates to PPA
- Demographic information, including date of birth, age, gender, handedness, occupation, education, primary and secondary language, ethnic and racial group.
- Results of neuroimaging studies and dates, including MRI a

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done right
- to evaluate and manage research functions.

Who may use and share information about me?

The following individuals may use or share your information for this research study:

- The investigator for the study and the study team
- Other authorized personnel at Penn, including offices that support research operations
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Who, outside of the School of Medicine, might receive my information?

As part of the study the Principle Investigator, study team and others listed above, may disclose your personal health information, including the results of the research study tests and procedures to the following:

- Office of Regulatory Affairs at the University of Pennsylvania
- The Institutional Review Board of the University of Pennsylvania
- The U. S. Office of Human Research Protections (OHRP)
- Government agency and/or their representative: National Institutes of Health (NIH). The NIH may require this information to confirm the accuracy of the results submitted to the government using government funds
- The Food and Drug Administration (FDA)

- Dr. Lynn Maher at the University of Houston. Dr. Maher is an expert in constraint induced language therapy (CILT) and will help analysis language data collected during this research.

Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may the School of Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document, you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than

those working on the study, you may contact the IRB at the number on page one of this form.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

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

- No, I do not want to provide a saliva sample for DNA testing
- Yes, I do want to provide a saliva sample for DNA testing

_____	_____	
Name of Subject (Please Print)	Signature of Subject	Date

_____	_____	
Name of Person Obtaining Consent (Please Print)	Signature	Date

For subjects unable to give authorization, the authorization is given by the following authorized subject representative:

_____	_____	
Authorized subject representative **[print]**	Authorized subject representative Signature	Date

Provide a brief description of above person authority to serve as the subject's authorized representative.

_____