Institutional Review Board
3600 Civic Center Blvd., 9th Floor
Philadelphia, PA 19104
Phone: 215-573-2540
(Federalwide Assurance # 00004028)

DATE:	05-Nov-2020
TO:	Thomas Tropea
CC:	Paul, Rachel
	Han, Noah
	Bardakjian, Tanya
RE:	
IRB PROTOCOL#:	843748
PROTOCOL TITLE:	GEnetic counseling Through VIRTUAL visits in Parkinsons Disease
SPONSOR:	NO SPONSOR NUMBER
REVIEW BOARD:	IRB #6

IRB AMENDMENT: NOTICE OF APPROVAL

Dear Dr. Tropea,

The documents noted below, for the above-referenced protocol, were reviewed by the Institutional Review Board using the expedited procedure set forth in 45 CFR 46.110 and approved on 04-Nov-2020.

Consistent with the regulations set forth in 45 CFR 46.109(f), continuing review of this research is not required. IRB approval of this protocol will not expire and continuing review applications should not be submitted. However, you are still required to submit modifications and reportable events to the IRB for review.

The documents included with the application noted below are approved:
HSERA Modification, confirmation code: dcfigdeg, submitted 10/27/2020
ONGOING REQUIREMENTS:

- You must obtain IRB review and approval under 45 CFR 46 if you make any changes to the protocol, consent form, or any other study documents subject to IRB review requirements. Implementation of any changes cannot occur until IRB approval has been given.
- Reportable event, such as serious adverse events, deviations, potential unanticipated problems, and reports of non-compliance must be reported to the IRB in accordance with Penn IRB SOP RR 404.
- When enrolling subjects at a site covered by the University of Pennsylvania's IRB, a copy of the IRB approved informed consent form with the IRB approved from/to stamp must be used unless a waiver of written documentation of consent has been granted.

COMMITTEE APPROVALS: You are responsible for assuring and maintaining other relevant committee approvals. This human subjects research protocol should not commence until all relevant committee approvals have been obtained.

If your study is funded by an external agency, please retain this letter as documentation of the IRB's determination regarding your proposal.

If you have any questions about the information in this letter, please contact the IRB administrative staff. A full listing of staff members and contact information can be found on our website: http://www.irb.upenn.edu

***This letter constitutes official University of Pennsylvania IRB correspondence. ***

UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	Genetic Counseling Through Virtual Visits in Parkinson's Disease (GET VIRTUAL-PD)
Principal Investigator:	Thomas F Tropea and Alice Chen-Plotkin 330 South 9th St, Philadelphia, PA 19107 215-829-6500
Emergency Contact:	Thomas F Tropea 215-829-6500

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 to compare methods of genetic counseling for people with Parkinson's disease.

If you agree to join the study, you will be asked to complete the following research procedures: Provide a saliva sample to genetic testing, provide medical and family history, participate in genetic counseling via web-based method, virtual or telephone visits, and complete clinical questionnaires before and after counseling, and again at 3 and 6 months after genetic counseling. All visits will be completed remotely without any need for in-person research visits.

Your participation will last for about 6 months.

During this study you will receive free genetic counseling and limited genetic testing. The most common risks of participation are the risk of a negative emotional response to learning your own genetic information.

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 participated in the MIND research recruitment study indicating your interest in being contacted about future studies, and you have Parkinson's disease or a family history of Parkinson's disease.

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.

If you decide to participate, you will be asked to sign this form. You will receive an email with a copy of the signed form.

What is the purpose of this research study?

The purpose of this study is to evaluate different methods of genetic counseling in people with PD. Genetic counseling typically involves meeting with a counselor before genetic testing to explain the process with you, to discuss the potential risks and benefits, and to determine what tests are appropriate. After genetic testing is performed, genetic counselors would again meet with you to discuss the results. In this study, we are comparing a novel form of pre-test genetic counseling via the IMAGINE-PD website that we developed to a virtual or telemedicine visit with a genetic counselor. We are additionally comparing virtual or telemedicine visits to telephone genetics results disclosure. We are comparing your responses on questionnaires of genetics knowledge, satisfaction with counseling, and distress.

How long will I be in the study?

The study will last for three years; however, we expect your participation should be completed around six months after enrolling. We expect to enroll 320 participants in this study at the University of Pennsylvania.

What am I being asked to do?

During this study we ask that you complete questionnaires before and after two sessions of different types of genetic counseling. We also ask that you provide a new saliva sample for genetic testing. This will be used to confirm the research-based genetic testing that was previously completed as part of the MIND study. Prior to genetic counseling we will assign you into one of four groups. Two groups will complete counseling prior to genetic testing using a website that we developed specifically for PD participants, while the others will have virtual or telemedicine visits with a genetic counselor. You will then have the choice to provide a sample for the genetic testing. After genetic testing is performed, half of the participants will have their genetic testing results disclosure visit by a virtual or telemedicine visit, and the remainder via telephone. Three and six months after genetic results disclosure, we again ask that you complete a series of questionnaires. This means there are a total of four study visits. The first visit will last about two hours, while each subsequent visit will last about 30-45 minutes. The questionnaires that we will ask you to complete are to collect information

about your genetics knowledge, your experience with different forms of genetic counseling, distress related to genetic counseling, and questionnaires about your mood and quality of life. All visits and questionnaires will be completed at home without the need to come to the office. This means we will also ask you to have technology appropriate for these visits. This may include a telephone, or a computer, smart-phone or tablet computer with audio and video capabilities.

What are the possible risks or discomforts?

Risks of Genetic Testing

This research includes genetic testing. Even without your name or other identifiers, your genetic information is unique to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information.

There can be a risk in knowing genetic information. New health information about inherited traits that might affect you and your blood relatives could be found during a research study. Even though your genes are unique, you share some of the same genes with your blood relatives. Although we are not able to know all of the risks from taking part in research on inherited traits, we believe that the risks to your family are very low, because we are only performing genetic testing for the participants that are personally involved in the study. The genetic results will be returned to you if you participate in this study. These results will not be returned to your doctor, but you will be able to provide them to your doctor if you choose. Your family members will not be receiving their own genetic testing as part of your involvement in this study.

Very rarely health or genetic information could be misused by employers, insurance companies, and others. For example, it could make it harder for you to get or keep a job or insurance, or life insurance companies may charge a higher rate based on this information. We believe the chance these things will happen is very small, but we cannot make guarantees.

A federal law (Genetic Information Non-Discrimination Act, GINA) helps reduce the risk from health insurance or employment discrimination. The law does not include other types of misuse by life insurance or long-term care insurance. If you want to learn more about GINA, you can find information about it on the internet or ask the study staff.

Risks of Completing Questionnaires

Some questionnaires will ask personal questions. You may feel uncomfortable answering these questions. If you do not feel comfortable and would prefer not to answer these questions you may omit responses and let the research staff know.

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?
You may not get any benefit from being in this research study. However, you will receive genetic counseling and limited genetic testing as part of the study

What other choices do I have if I do not participate?
If you prefer not to participate in this research, you may still have genetic counseling and testing as part of your regular medical care. If you would prefer to pursue genetic counseling and testing, but not participate in this research study, you can discuss this with your physician, the genetic counselor, or the research staff.

Will I be paid for being in this study?
You will not be paid to participate in this research study.

Will I have to pay for anything?
You will not be asked to pay anything to participate in this research study.

Will I receive the results of research testing?
Part of this study involved research-based genetic testing. Participants will have previously enrolled in MIND, and had research-based genetic testing conducted. Participants who do not carry a *LRRK2* or *GBA* gene variant will have a repeat, research-based genetic screening test. This test will not be conducted in a clinical lab. This result will be returned to you as a negative test.

For participants who have a *LRRK2* or *GBA* gene variant found in the initial MIND testing, a confirmation test will be conducted at Fulgent Genetics (a clinical lab) as part of this study. This clinical result from Fulgent Genetics will be disclosed to you during genetic counseling. Neither result will be automatically entered into your medical record. However, you may choose to provide your neurologist or other medical professional with these results.

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 study Principal Investigator, or the Food and Drug Administration (FDA) has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Withdrawal will not interfere with your future care.

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.

All data collected during this study will be stored on the secure REDCap platform. All data collection will be directly recorded into the database, and no paper records will be generated. Participants will have been assigned a unique identifier in the Integrated Neurodegenerative Disease (INDD) database as part of the MIND study. As part of this study, subjects will be assigned a Global Unique Identifier (GUID), which is an ID that is assigned to you that allows your information to be shared between different studies that you participate in, but without sharing your identifiable information. Data from REDCap will be backed up on the INDD database. Only researchers involved in this study will have access to this data.

For the participants that have genetic testing at Fulgent Genetics during this study, your personal information including your name and date of birth will be shared with Fulgent Genetics in order to identify your sample. This information ensures that the testing is secure in the lab. Fulgent Genetics is a CLIA-certified clinical lab that follows good clinical practice and HIPAA guidelines. The result report will include your name, date of birth, and genetics result. Your identified genetic result will be stored in the database for this study, and will reside in Fulgent's internal database as is standard for clinical genetic testing. Fulgent Genetics follows HIPAA guidelines and your information including your results will not be released or shared without your express written consent, as indicated by law and HIPAA guidelines.

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

Collection of Identifiable Specimens
Information collected during this study will be used for the stated purposes of this research. However, future research may examine your data to answer new research questions. Saliva samples collected during this study will be used to isolate your DNA, which may be stored and used for future research. Samples collected through the mail will be labeled with a unique study identifier when shipped between your home and the University of Pennsylvania researchers. Samples that are then sent to Fulgent Genetics will have the participant's name and date of birth added as identifiers for the clinical genetic testing. The study team will add this information before sending the sample to Fulgent.

Your samples may be used to create products, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

Whole genome sequencing may be conducted on your samples. Whole genome sequencing involves analyzing your entire personal genetic code.

Future Use of Data and/or Specimens
Your identifiable information and samples 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 and samples only applies to the information and samples collected in this study.

The following identifiers will be retained with your information and samples: name, address, date of birth, telephone number, and email address. Your information and samples 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. We may share your identifiable information and samples with: other research, academic, and medical institutions, other researchers, drug and device companies, biotechnology companies and others. 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 limiting access to samples and data to those involved in this and aligned research studies only. Information is stored on a secure database.

You will likely not directly benefit from future research with your information and samples. Research with your identifiable information and samples 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 and samples, or have changed your mind, you can contact Thomas F Tropea at 215-829-6500. If you change your mind, you may ask for us to destroy your sample. Any data generated prior to that point will not be able to altered or deleted.

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?

We will collect information from your medical record, and included in this research. This information includes:

- Name, address, telephone number, date of birth
- Personal and family medical history

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information may be sent to Fulgent Genetics in order to complete the clinical genetic testing that is part of this 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
- Authorized personnel at Fulgent Genetics laboratory, the approved clinical laboratory for the clinical genetic testing in this study

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

If you receive clinical genetic testing, Fulgent Genetics will receive your information (name and date of birth) and saliva sample. They will perform the genetic testing and have access to your genetic results. The lab is CLIA certified and follows good clinical practice and HIPAA guidelines. Your name, date of birth, and genetic information will be stored in their internal database as is standard-of-care in clinical testing. Fulgent Genetics may not release information collected in this study unless you or your physician have given written authorization, or as permitted by law.

Fulgent Genetics will not perform additional analyses of the data without the express written consent of the participant and/or their physician. Fulgent Genetics may perform additional studies on the specimen collected for medical research and/or education, after it is anonymized, unless the participant contacts the lab directly to refuse and withdraw this consent.

Your samples and information may be shared with researchers with whom the members of the research team are collaborating. In the event of such a collaboration, no personally identifying information will be shared. In addition, the PDMDC Genetics

Biobank will continue to use established procedures in use by the Center for Neurodegenerative Research (CNDR) for identifying projects of scientific and clinical merit. In brief, potential collaborators who may want to access your information or samples apply with a description of the proposed project. This application is then evaluated by a Biospecimen Review Access Committee (BRAC) consisting of 3-5 Perelman School of Medicine professors and doctors, who are overseen by the Principal Investigator. Only projects deemed to have scientific or clinical merit by this BRAC will be considered eligible to receive your samples or information, from which personally identifying information will be removed prior to sharing. Collaborators could include for-profit companies, and you will not benefit financially from any products created as a result of shared information or samples.

Oversight organizations

- The U. S. Office of Human Research Protections (OHRP)

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.

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