Subject Name: _____Last 4 SSN:_____ Date: _____

Title of Study: Immediate and Cumulative Effects of rTMS on Brain Activation in Chronic Aphasia

Principal Investigator: M. Gravier, Ph.D., CCC-SLP, S. Forman, M.D., Ph.D. VAMC: Pittsburgh (646)

LAY TITLE: The Effect of Brain Stimulation on Picture Naming in Aphasia

KEY ELEMENTS:
This is a research study to 1) find out which of two different non-invasive brain stimulation approaches is more effective at improving picture naming in individuals with chronic aphasia, and 2) see where there are changes in brain activity during picture-naming that are related to better outcomes from either brain stimulation approach. Your participation in this study is voluntary.

Depending on the group to which you are randomly assigned, you will either receive low-frequency stimulation to a brain area in the right hemisphere of your brain, or low-frequency stimulation preceded by priming stimulation. In either case, you will receive 10 sessions of this non-invasive brain stimulation via repetitive transcranial magnetic stimulation (rTMS). During the rTMS, a coil will be placed on your head and brief magnetic pulses will be generated that will activate the brain underneath the coil. You will also have brain imaging sessions throughout the study during which you will be asked to view pictures of everyday objects and name them aloud while you are in an MRI scanner. During each of these testing sessions, you will also complete some language assessments. Each clinic visit will last approximately 1 hour, and assessment/brain imaging sessions will last approximately 3-4 hours. There is an optional sub-study associated with this study. If you agree to participate in the sub-study you will be asked to provide saliva samples and to complete additional brief assessments that may add 15-30 minutes to the length of the assessment sessions.

There are risks to this study that are described in this document. Some risks include: headache, hearing damage, and radiation risks from x-ray scans if needed to confirm eligibility for MRI. Rare events include seizure, facial pain/numbness, mild blurred vision, or temporary cognitive/neuropsychological changes. All precautions possible will be taken to minimize risk (e.g. you will be asked to wear hearing protection, and answer questions that help us determine whether it is safe for you to have an MRI scan). You may directly benefit from participating in this study. Direct benefits may include: improvement in your naming abilities. You may also receive indirect benefit given that you are contributing to medical science or helping to advance understanding of the use of brain stimulation to treat naming deficits following stroke.

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If you do not participate in this study, alternate treatments for aphasia include: speech-language therapy. There may also be other research studies for which you qualify or other treatment options in your community.

If you are interested in learning more about this study, please continue reading below.

STUDY CONTACT INFORMATION:
If you have a general question about this research study, or if you have any concerns or complaints related to this research study, you may call Michelle Gravier, Research Speech Pathologist at 412-360-6486 or any of the investigators listed below.

If you experience any illness, injury or other medical problem that you feel may be related to this study, please call Steven Forman, M.D., Ph.D. at 412-360-2295 or Steven Graham, M.D. at 412-360-2914 and after-hours or on weekends call 1-866-785-9015 and tell the operator that you are a research subject from the Pittsburgh VA in "The Effect of Brain Stimulation on Picture Naming in Aphasia" study and need to speak with Dr. Steven Forman or Dr. Steven Graham. Then give the operator a phone number where you can be reached. The operator will get in touch with Dr. Forman, Dr. Graham or another person listed below who will call you back. In the case of a medical emergency contact your local emergency medical service or go to your local emergency room.

Principal Investigators:

Michelle Gravier, Ph.D., Research Speech Pathologist
VA Pittsburgh Healthcare System
Building 29, Room 2M201
412-360-6486

Steven Forman, M.D., Ph.D, Psychiatrist
VA Pittsburgh Healthcare System
Building 30, GA-125
412-360-2295

Co-Investigators:

William Hula, Ph.D., Research Speech Pathologist
VA Pittsburgh Healthcare System
Building 29, Room 2M235
412-360-6439

Michael Dickey, Ph.D., Research Associate
VA Pittsburgh Healthcare System
Building 29, Room 2M235
412-360-6467

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Patrick Doyle, Ph.D., A. D. for Research, GRECC
VA Pittsburgh Healthcare System
Building 29, Room 2M255
412-360-6427

Steven Graham, M.D., Ph.D., ACOS R&D
VA Pittsburgh Healthcare System
Building 30, 1A-140
412-360-2914

STUDY SPONSOR:
Veterans' Affairs Rehabilitation, Research, and Development Service, VA VISN4 Geriatric Research, Education, and Clinical Center (GRECC), and the Veteran's Research Foundation of Pittsburgh. Additional information regarding the study sponsor can be provided upon request.

PURPOSE OF THE RESEARCH STUDY: The purpose of this research study is to compare the effect of two different sequences of magnetic pulses on improvement of picture naming in aphasia. The magnetic pulses are produced by a procedure called TMS, or Transcranial Magnetic Stimulation. Previous studies have shown that a magnetic pulse (TMS) applied to the outside of someone's head can, for a short period of time, improve picture naming. We want to see if one sequence of pulses improves naming more than the other, and whether the improvements accrue (increase) and last over time. We also want to see whether naming improvement is related to changes in activity in particular areas of the brain resulting from the stimulation. TMS does not currently have FDA approval as a means to improve naming or other language skills in aphasia.

You are being asked to participate in this research study because you have aphasia caused by a stroke to the left side of your brain and have been deemed a good candidate for TMS and MRI. Aphasia means difficulty talking, understanding, reading, and writing caused by damage or injury to the brain. Our goal is that 20 participants will complete the entire study; however, some potential participants will not qualify, or will choose not to complete the entire study. For these reasons we are prepared to enroll up to 30 subjects.
If you are enrolled in the VAPHS Audiology and Speech-Language Pathology Research Registry (ASPRR), the data collected for this study, including language assessment results, may be shared with the repository. Future research may use this data to ask, for example, whether how much you benefitted from one treatment you received was related to how much you benefitted from another.

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A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Web site at any time.

DESCRIPTION OF THE RESEARCH STUDY:
STUDY PROCEDURES:

Before Treatment Begins (Visit 1): Although you may have provided some information during your initial telephone contact and pre-screening of medical records, we need to collect further information from you to see if you meet criteria to participate in the entire study. However, before we can proceed with any additional procedures, including determining eligibility, we must tell you about the entire study and you will be given the opportunity to voluntarily consent to participate by signing this consent form. Even after signing consent you may still stop participating in the research at any time.

Following your consent, your screening assessment will take about 2-4 hours. This visit includes an interview and completion of a series of speech, and language tests. These tests may involve tasks such as naming pictures, and following brief instructions. These tests are similar to tests that you might receive if you were to have your speech and language skills assessed outside of the context of this research study. If you are unable to complete the tests in one session, you may be asked to schedule an additional session. If you attend the screening session but are found to be ineligible, or decide to withdraw from the study at that time, you will be reimbursed $25 for your time and local transportation costs associated with your participation. You will be paid via check by mail.

fMRI Scanning Baseline (Visit 2): If you indicate during screening that you may have metal in your body, including your eye or head, but are unsure, you will be given the option to have an x-ray to rule out the presence of metal. This x-ray would be considered non-standard of care. If the x-ray finds that you do have metal in your body aside from shunts or metal implants for which you have medical documentation confirming MR compatibility, you will not be eligible for this study. For non-standard of care x-rays administered, the imaging location will be dependent on where the potential foreign body is located in the subject's body (e.g. hand, foot, skull, etc.). Because the foreign body location may vary from subject-to-subject, so will the location of any imaging used.

The total number of non-standard of care x-rays may vary by subject depending on the number and location of foreign bodies that require imaging. If you qualify for further participation at this time you will be scheduled for your first fMRI (function magnetic resonance imaging) session, which will take place at the VA at University Drive. This is considered a research study procedure for the purposes of this study only. During this procedure, first you will be asked to lie still on a table while an image of your brain is captured on a computer using the MRI scanning machine. The study investigators will use this brain image to see exactly where the brain damage from your stroke is. Next, you will be asked to view pictures of everyday objects and name them aloud while you are in the scanner. The purpose of this scan is to see which areas of your brain are active while you are naming pictures. Before you enter the MRI scanner, the staff at the scanning facility at the University Drive division of VAPHS will ask you a series of screening questions to make sure that you are eligible for an MRI scan and that the MRI scan will pose no risk to your health. If you are a woman of childbearing potential and are not certain that you are not pregnant, you will be asked to take a pregnancy test prior to MRI. If you are pregnant, you will not be eligible for the MRI. The MRI scan appointment may take up to 90 minutes, including 30-60 minutes for the MRI scan itself. After your first fMRI scan, you will be scheduled for your TMS sessions.

TMS (Visits 3-12): Transcranial magnetic stimulation (TMS) is a brain stimulation technique. It involves generating a brief magnetic pulse in a coil that is placed on the scalp. The magnetic pulse passes through the skull and briefly activates the brain underneath the coil. To adjust the strength of the stimulation you will get, you will first be stimulated in the region of your brain that makes the thumb move. The strength of stimulation that barely produces a movement in your fingers is called the motor threshold. After measuring your motor threshold, you will receive TMS at the target location at 90% of motor threshold, but this will not cause any finger movement. We will also place some sensors on your head so that we can monitor the location of the coil in relation to your brain. This allows us to stimulate the target location more precisely and consistently. There will be 10 TMS sessions total, scheduled daily across 2 weeks with the exception of weekends. The TMS will last about 20 -30 minutes. During the TMS we will ask you to relax and remain still. After receiving your first session of TMS, you will return to the scanner for your second fMRI. The procedure for the second fMRI (as well as all subsequent MRIs) will be identical to the first fMRI.

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fMRI Scanning Follow-Up (Visits 13 & 14): Following your last TMS session, you will be asked to schedule two additional fMRI sessions. One session will be scheduled soon after the last TMS session, and another will be scheduled approximately 8 weeks after your last TMS session. In addition to the fMRI, during these sessions you will also be asked to complete the same speech and language tests that you were given during your initial screening visit. We will be using your performance on these tests to see whether the TMS improved your naming and other language skills.

The study team will monitor you during these tests, describe the risks of the tests to you, and let you know right away if there is a problem associated with the tests (such as a newly-discovered risk).

Please be aware that the data we collect at the VA MRI scanner at University Drive (which includes brain images and standard fMRI safety screening results (e.g., pregnancy test) may be transferred to a VA-protected server as well as an approved VA storage device in the lab. Hard copies of forms administered during the research (including any that might be able to identify you, such as this consent form) will be kept in a locked filing cabinet in a locked office at the VA University Drive.

OPTIONAL SUB-STUDY: We are interested in learning how levels of a stress-related hormone, cortisol, may relate to your response to TMS (i.e. whether and how much your language improves) and the brain activity changes that may result from TMS. If you would like to participate in this sub-study, you may be asked to complete additional testing either before or at the beginning of your treatment and at or after the end of your treatment which may take up to 30 minutes. You may also be asked to provide up to 6 saliva samples at intervals throughout your treatment. If you choose not to participate in this sub-study, this will not affect your eligibility for the primary research study.

DURATION OF STUDY PARTICIPATION: If you complete all study procedures, your participation in the study will last approximately 11-14 weeks depending upon the scheduling of your appointments. The study will require approximately 15-20 hours of your time (excluding travel) depending on the duration of your testing and MRI appointments.

UNEXPECTED CLINICAL FINDINGS: It is possible, though unlikely, that the MRI scan completed for this study may reveal new information that should be shared with your primary care physician or other healthcare provider. If that happens, we will contact you within a week of the test to let you know and the

medical staff at VAPHS will send the results to your primary care physician or other healthcare provider that you identify. Please note that we are not specifically looking for any medical problems, so it is very unlikely that we will find any underlying issues. This test is not the same as regular medical care and should not be considered a substitute for regular medical care.

AFTER STUDY PARTICIPATION: After you have completed the final TMS session, a staff member will contact you 1 and 8 days after the last session to see if you have experienced any side effects or if you have any further questions about the study. At the end of study participation, your treatment and test results, including MRI scan results, will be kept on file in a locked area and/or on a password protected electronic database at the VA Pittsburgh Healthcare System. Continuing TMS will not be an option after the conclusion of the study.

AUDIO AND VIDEO RECORDING:
We will record your voice while you are responding to some of the speech and language tests as well as while you are in the MRI scanner in order to make sure that the tests and naming are accurately scored. We will video record the TMS sessions to be able to analyze in detail the characteristics of an adverse event (the occurrence of any anticipated or unanticipated side effect). Audio will be directly recorded onto an encrypted, password-protected VA laptop. Video will be recorded onto a VA approved video recording device. Both audio and video recordings will be transferred to the secure VA network following your research session and deleted from the local recording device. These recordings will not be de-identified. Only research staff will have access to these recordings, and they will be retained along with your other research records associated with this study. Audio/video recorded information will not be disclosed outside of the VA, in accordance with Handbook 1200.05.

RISKS AND BENEFITS:
Because there may be other risks associated with participating in multiple research studies, you must tell the research staff about any other studies you are currently participating in, both within and outside of the VA. We also ask that you refrain from participating in any additional speech-language treatment for the duration of the study and follow-up. This will allow us to attribute any changes in language ability that you might experience to the experimental TMS treatment.

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MRI Scanning Procedure:

1. The MRI scanning procedure presents a common physical risk of ear discomfort due to the noise associated with the scanner. To minimize this risk, you will be provided with ear plugs during the scan.
2. The MRI scan also presents an infrequent physical risk that metal or magnetic material that is inside your body may be attracted to the scanner magnet. To minimize this risk, the resonance imaging staff will ask you a series of screening questions to determine whether you are eligible to have an MRI scan. If you have iron-containing metal in your body, you should not participate in this study.
3. The MRI scan presents an infrequent psychological risk of claustrophobia, or fear of small, enclosed spaces. If you have severe claustrophobia, you should not participate in this study. If you have mild claustrophobia and would like to participate in the study, the resonance imaging staff at the University Drive campus of VAPHS will try to minimize this risk by talking to you during the scanning procedure to give support and encouragement.
4. The long-term risks to fetal safety associated with undergoing an MRI during pregnancy have not been definitely established. Therefore, if you are pregnant, you should not participate in this study.
5. Participation in this study may involve receiving an x-ray that would be considered non-standard of care. The amount of ionizing radiation you receive from this x-ray will be dependent on what area(s) of your body are imaged. Although the dose from this x-ray will most likely be low, there is no known minimum level of radiation exposure that is recognized as being totally free from the risk of causing genetic defects (cellular abnormalities) or cancer. Because the investigators assume that this study represents the only research exposure to radiation that you will be exposed to, it is important that you inform the investigators of your participation in any other research studies or situations involving x-ray, nuclear medicine scans, or workplace exposure to radiation during the past year.

Transcranial Magnetic Stimulation (TMS): TMS has been used with many people for more than 15 years, and all safety precautions that are available will be used in this study. While we have provided information about the general risks of TMS below, you must be informed that both the TMS stimulator and the stimulator coil we are using have not been officially approved by the FDA for treatment of acquired language disorders.

You must understand that although unlikely, some of the following can happen:

1. The TMS device produces a loud clicking sound. To minimize the possibility that this clicking sound will affect your hearing, you will be given protective earplugs. Should an earplug loosen, become detached, or fall out, there is a risk of transient hearing loss. You should therefore report any loosening or detachment of an earplug during TMS immediately. The investigator will immediately stop TMS if he or she observes that an earplug has loosened or fallen out, or if you report that an earplug has loosened or fallen out.
2. You may have a headache or neck pain following the experiment. This is because the muscles on the top of your head may twitch from the magnetic pulses. If this happens, you will be offered your choice of an over-the-counter pain medicine (such as aspirin, acetaminophen, or ibuprofen). Such treatment stopped the headache and neck pain in all the people studied. The risk of headache or neck pain is estimated to be between 10%- 30%.
3. Rarely other side effects including temporary dental or facial pain/numbness, mild blurred vision, temporary cognitive/neuropsychological changes, and other biological effects including transient hormonal changes have been reported following TMS. Given the very small number of events, we cannot provide precise estimates of the risk of such occurrences but consider them rare events.
4. Although very unlikely, it is possible that you may have a seizure produced by the TMS. A seizure happens when your brain starts acting strangely and you may feel dizzy and start shaking. In over 20 studies of the effect of TMS on language in aphasia, there have been no reports of seizures. Additionally, in well over 10,000 reported sessions of TMS, there has been only one report of a healthy adult (without a history of seizures) experiencing a possible seizure from the type of TMS we will be using when safety guidelines were adhered to. It is uncertain, although possible, that having had a stroke may increase the likelihood of having a seizure. If a seizure occurs, it will occur during the TMS session itself, not after.
   We will take all the precautions possible to be sure that a seizure will not occur. If one were to happen, the investigators are trained to manage the situation safely, and there will always be an MD or nurse trained in seizure management available during each treatment. If you have a seizure induced by TMS, it doesn't mean that you will have other seizures afterwards, or that you will need to take medication to prevent seizures from happening again. The people who had seizures induced by TMS in the past have not had any health problems following this event that were related to the seizure.

If you were to have a seizure, you should contact your primary care physician for follow-up evaluation. We will give you a letter that describes your seizure and explains that your seizure occurred as a result of the study procedures, as well as any currently available information on what it may mean for your health. The purpose of this letter is to provide you with a document that you can present to anybody that would want to know about the seizure, like your employer, your medical insurance, or the department of motor vehicles. If a seizure occurs we are not required to report it to the department of motor vehicles. The letter will explain that you are not at risk to have another seizure because you had one induced by TMS.

5. Finally, there could be some unexpected complications. Although there are no known long-term negative effects of TMS, we cannot completely rule out such at this time.

Biological Specimens: Providing saliva samples presents no risks except to your privacy and confidentiality as discussed below. Samples will not be used for genetic studies nor will they be stored for future research.

Speech and Language Testing: There is a risk of frustration or fatigue associated with the several tests that are administered for the research study. These risks will be minimized by encouraging you to take breaks and to work at a pace that is appropriate for you. There are also risks to your privacy and confidentiality as discussed below:

Confidentiality: Every effort will be made to make sure that the information about you obtained from this study will be kept strictly confidential. As private information is collected about you as part of this study, there is a risk to your privacy and confidentiality. The research staff will take every precaution to protect your identity and the confidentiality of the information collected about you. Any electronic or hard/paper copies of the information collected about you will be stored in a secured location. Only those individuals who are authorized to review your information will have access to it.

If you have been recruited into this study from the VA Pittsburgh Healthcare System Audiology & Speech-Language Pathology Research Data Repository, any information obtained for this study (e.g. test scores, brain scans, health information) may be shared with that repository for updating your profile. In accordance with the guidelines for the Audiology & Speech-Language Pathology Research Data

Repository which were set forth in its IRB-approved protocol, these data may potentially be used in the future by other studies which have applied for and been granted access to the repository.

In addition, Federal agencies, including but not limited to, the Food and Drug Administration (FDA), Office of Human Research Protections (OHRP), VA's Office of Research Oversight (ORO) and the VA Office of the Inspector General (OIG) may have access to your research records. The Food and Drug Administration (FDA) may also choose to inspect research records, which may include your individual medical records, if this research is FDA-regulated. Research records, just like hospital medical records, may be released or disclosed pursuant to applicable federal and state law as well as to federal and state agencies that are responsible for oversight of medical research. Additionally, any medical information may be shared with your healthcare provider(s) with your consent, and possibly without your consent if permissible under federal laws and regulations. Finally, you consent to the publication of the study results so long as the information about you is anonymous and/or disguised so that your identity will not be disclosed.

You may benefit from participating in this study. Direct benefits may include: improvement in your naming abilities. Your participation may help medical research determine whether one of the two TMS pulse sequences being tested in this study is more effective. Your participation may also help us learn how improvement in naming is related to changes in brain activity. This may ultimately help us develop better treatment approaches for aphasia in the future. Participation in the optional sub-study may help us determine whether cortisol testing can contribute to predicting who may benefit more from TMS.

ALTERNATIVES TO PARTICIPATION:
There may be other studies that you qualify for. Talk to your provider about such options. There also may be other treatment opportunities within your community. If you decide to undergo speech-language therapy, you will need to withdraw from the study.

NEW FINDINGS: You will be informed of any significant new findings during the course of the study, which may affect your willingness to continue to participate. If requested, you may be provided with a summary of your clinical results, including individual testing results after the completion of the study via postal mail.

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INVESTIGATOR INITIATED WITHDRAWAL: The investigator(s) may stop your participation in this study without your consent for reasons such as: it will be in your best interest; you do not follow the study plan; or you experience a study-related injury.

VOLUNTARY PARTICIPATION/RIGHT TO WITHDRAW: Your participation in this study is voluntary. You do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled.

Your Speech-Language Pathologist may also be involved in this research study. As both your clinician and a member of the research team, s/he is interested both in your medical care and the conduct of this research study. You are under no obligation to participate in this or any other research study offered by your clinician. Before you agree to participate in this research study, or at any time during your participation in this study, you may discuss your care with another clinician who is not associated with this research study.

MEDICAL TREATMENT: In the event that you sustain injury or illness as a result of your participation in this VA approved research study, conducted under the supervision of one or more VA employees, all medical treatment (emergent as well as medical treatment beyond necessary emergent care) will be provided by the VA. Except in limited circumstances, the necessary medical care must be provided in VA medical facilities.

However, if such injury or illness occurred as a result of your failure to follow the instructions for this study, you may not be eligible for free care unless you have independent eligibility for such care under Federal Law.

FINANCIAL COMPENSATION: If you sustain an injury or illness as a result of participating in this research study, you may be eligible to receive monetary compensation for your damages pursuant to applicable federal law. If you believe that you are injured as a result of participation in this study, please contact the Principal Investigator. If compensation is available the Principal Investigator will provide you with an explanation as to what that compensation consists of, or where you can obtain further information regarding it.

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COST AND PAYMENTS: You or your insurance will not be charged for any costs related to the research. However, if you are receiving medical care and services from the VA that are not part of this study, and you are a veteran described in federal regulations as a "category 7" veteran, you may be required to make co-payments for the care and services that are not required as part of this research study. You may receive a payment of up to $275 to reimburse you for your time and to cover any local transportation costs associated with your participation. If you attend the screening session but are found to be ineligible, or decide to withdraw from the study at that time, you will be reimbursed $25. If you are found to be eligible and decide to participate in the study, you will be reimbursed $25 for each speech and language testing session (including the screening visit), $25 for each fMRI, and $100 for completion of the TMS series. If you participate in the optional sub-study you will receive an additional $20 for each saliva sample that you provide. If you are unable to complete all study procedures for any reason, or choose to withdraw from the study prior to completing all procedures, you will be still be reimbursed for the procedures that you did complete, according to the payment schedule outlined above.
You may be reimbursed for out-of-pocket actual expenses incurred related to participation in the research study including paid community transportation (for example, public bus or taxi service), and/or housing, up to a total of $1500.

Except in limited circumstances, payments issued through VA are generated by Electronic Funds Transfer (EFT). Therefore, in order to receive payment associated with your participation in this study, you must be willing to receive EFT and to provide banking information to VA, if that information has not already been provided. If you are not able to receive payment through EFT, the Direct Express Debit MasterCard may be issued. The Direct Express Debit MasterCard is a prepaid debit card. Please refer to the flyer that study personnel has provided for more information about which services may require a fee if using your Direct Express Debit MasterCard. In addition, due to limitations in the Financial Management System, payments made to you will generate Internal Revenue Service (IRS) Form 1099 regardless of amount. Payments will be reported to the IRS as income and your social security number will be used for this purpose. If you are a Veteran eligible for Beneficiary Travel, please speak with the research team to understand how research visits may impact your ability to receive Beneficiary Travel.

RECORD RETENTION: Your research records will be retained in accordance with the Veterans Health Administration (VHA) Records Control Schedule, or longer, if required by other Federal regulations.

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RESEARCH SUBJECTS' RIGHTS: You have read or have had read to you all of the above Dr. Michelle Gravier, Dr. Steven Forman or his/her authorized representative has explained the study to you and answered all of your questions. The risks, discomforts, and possible benefits of this research study, as well as alternative treatment choices, have been explained to you.

A description of the study has been provided to you, including an explanation of what this study is about, why it is being done, and the procedures involved. You have the right to ask questions related to this study or your participation in this study at any time. You should be giving your consent only under conditions in which you (or the person representing you) have sufficient opportunity to carefully consider whether or not to participate in this study. Your consent should not be given under conditions that pressure you or try to influence your decision in any way.

Your rights as a research subject have been explained to you, and you voluntarily consent to participate in this research study. You understand that these Research Subjects' Rights also apply to any optional study components to which you have agreed to participate. You will receive a copy of this signed consent form.

If you have any questions about your rights as a participant in this study, or wish to speak more about the study with someone not associated with the research study, you can call the Associate Chief of Staff for Research and Development at (412) 360-2394.

As long as the study is renewed as required by the IRB, your signature on this document is valid for the duration of the entire research study. Should any changes occur during the course of the study that may affect your willingness to participate, you will be notified.

By signing this form, you agree to participate in this research study.

_____ _____ _____
Subject's Signature Date Time

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_____	_____	_____
Investigator/Person Obtaining Consent	Researcher (Print)	Date

By signing below, you agree to participate in the optional saliva collection sub-study.

_____	_____	_____
Subject's Signature	Date	Time

_____	_____	_____
Investigator/Person Obtaining Consent	Researcher (Print)	Date

Version Date 12/10/18