If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: **AVERT_Acute Video-oculography for Vertigo in Emergency Rooms for Rapid Triage**

Application No.: **IRB00044228**

Sponsor: **National Institutes of Health (NIH); National Institute on Deafness and Other Communication Disorders (NIDCD)**

Principal Investigator: **David E. Newman-Toker, MD PhD**
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1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in it. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.
- 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 Web site will include a summary of the results. You can search this Web site at any time.
- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

- During this study, you will not have access to certain medical information and test results collected for study purposes. If an emergency occurs while you are in the study, medical information needed for your treatment can be made available to your study physician and other physicians who treat you. When the study is completed, all the information in your medical record will be available to you.

2. Why is this research being done?

This research is being done to learn more about the diagnosis of stroke in Emergency Room (ER) patients who are experiencing new dizziness or other balance problems.

Sometimes doctors are not able to figure out whether the dizziness or balance problem is coming from a problem with the ear or a problem with the brain (like a stroke). We are trying to make sure doctors in the ER don't miss the chance to recognize and treat strokes early, since strokes that cause dizziness are easy to miss. Specialists can diagnose strokes by looking at tiny movements of the eyes in people with recent dizziness. We are using a non-invasive device that is similar to a pair of swimming goggles that fits over a person's head and takes a video picture of their eyes to study these tiny eye movements. These goggles are already routinely being used to care for patients with vertigo, dizziness and balance problems in specialty clinics and in some ERs.

We want to see if using the information from the goggles helps give better treatment to people with dizziness or balance symptoms. To do this, we need to compare people whose treatment was guided by the information from the goggles to people who receive standard ER care. This study is a "randomized trial." Everyone will be tested with the goggles, but not everyone's doctor will be told the results. The choice of whose doctor gets the goggles test results will be random (by chance, like the flip of a coin). For some participants, the study goggles test results will guide the care they receive and become part of their medical record. For other participants, the results will not be given to their ER doctor, and they will get the same care in the ER that they would have gotten if they did not join the study.

The video goggles in this research study are approved by the United States Food and Drug Administration (the FDA) for measuring balance function. The use of the video googles in this study is investigational. The word "investigational" means that they are not approved by the FDA for diagnosing stroke. The FDA has reviewed its use in this study and determined that it presents a non-significant risk to you and other participants.

Adults, 18 years and older, who are not pregnant, coming to the ER with dizziness, vertigo, or other related balance problems may join this study.

How many people will be in this study?

Roughly 2000 people are expected to take part in the screening part of this study, but only about 226 will complete the randomized trial, including about 75 at Johns Hopkins.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

NOW, AT THE ER VISIT: After signing this consent form, you will answer some basic questions about your health, including how much your dizziness is affecting you now. Put on a pair of study goggles (like swimming goggles) that measure eye movements and a brief clinical exam will be performed. The goggles have a small camera built into the frame to record a video of your eye movements during the exam. This video technology finds more abnormalities than visual observation alone. It is important to do a portion of the exam in complete darkness and your eyes will be covered

temporarily using sticky patches that block light or a drape that covers your face. This should take about 20 minutes. We believe this will help doctors get the right diagnosis and treatment for your dizziness. During the exam, we will ask you to look from side to side, move your head around, and lie down on the bed. We will test your hearing, your balance when standing or walking, and some other routine clinical tests of brain function. We will record a video of these tests using a room camera. These video recordings are an essential part of the research study. Without agreeing to them, you cannot join the study. You may request that the video recording be stopped at any time, but this will end your participation in the trial.

By allowing doctors and researchers to view these video recordings of your examination doctors can use the information to learn and perform the tests in a more consistent manner. We want to use the video recordings of the clinical examination performed today and at the follow-up visit to educate other doctors so they can provide the best possible care for other patients like you. This includes teaching during lectures and eye movement training courses, some of which may be posted to the internet so that physicians anywhere in the world can learn. Most of the videos and other images recorded in the study will not be identifiable (for example, a close-up video picture of your eye). Signing this consent to participate in this trial means you agree to have these unidentifiable images used for the purposes of training, teaching, and scientific publication.

Some images for the research study will include a picture of your face that might be recognized. In order for us to use these identifiable recordings to help educate other doctors around the world, we are asking for your permission below. You do not have to allow us to use these recordings to take part in the study. You may still take part in this study no matter what your decision. These videos will be used for the purposes of training, teaching and scientific publications. These materials will not be used for any other purposes, such as marketing.

☐ Yes, I agree for my identifiable images in the video recordings to be used for training, teaching, and scientific publications.

- ☐ Yes, I understand that I can request that the video recording be stopped at any time and that by doing so, this will end my participation in the trial.
- ☐ Yes, I understand that I have the right to withdraw my consent before the video recordings or my images are shared with the public.

☐ No, my identifiable images in the video recordings may not be used for training, teaching, or scientific publications. I understand that my identifiable images in the video recordings will still be seen and analyzed as part of the research study.

At the end of the initial testing, the results of the eye exam with the goggles and other tests will determine if you are eligible for the trial. Even if you are not eligible for the trial, you are still eligible for the part of the follow-up study.

If you are eligible for the trial, you will be randomly assigned to one of two groups. It is like tossing a coin. If you are assigned to the first group, your care in the ER will be guided by diagnostic information from the study goggles. If you are assigned to the second group, you will receive standard care in the ER.

GROUP #1 (STUDY GOGGLES CARE)

a) The study goggles will determine your care. In some cases, your goggles results may be double-checked by a specialist doctor who is an expert in dizziness. If the specialist doctor disagrees with the goggles result, the specialist doctor's opinion will be used to guide your care. The study coordinator doing the goggles testing will tell you whether the specialist will be reviewing your goggles and other test results

b) If the study goggles (or specialist doctor's review) suggest your dizziness or vertigo probably indicates a stroke, you will be admitted to the hospital to confirm the diagnosis and be treated. This will include a brain scan (magnetic resonance imaging [MRI]) and other standard tests. The length of your hospital stay (usually about 2-3 days) will depend on test results and treatments you need. If tests confirm you have a stroke or other brain problem, you will be given standard treatments for that problem. If tests confirm an inner ear problem, you will be given standard treatments, and sent home. If you ER doctors believe you do *not* need hospital care and the hospital stay confirms this, then the research study will pay for the hospital care. If your ER doctors believe you should be admitted to the hospital or if you are found to have a problem that would typically require you to stay in the hospital, the study will not pay for your care.

c) If the study goggles (or specialist doctor's review) suggest your dizziness or vertigo is from an inner ear problem, you will be treated in the ER and sent home. You will be given standard treatments for your inner ear problem such as medications to reduce dizziness or nausea. As an added precaution before you leave, we will obtain an MRI brain scan (*details below*) to make sure you do not have a stroke.

GROUP #2 (STANDARD CARE)

You will have the study goggles test, but the results will not be given to you or your doctors. The care you receive in the ER will be the same as you would if you were not part of the study.

AFTER TODAY'S ER VISIT: If you are eligible for the trial, there will be one more in-person follow-up visit and two follow-up phone calls: (1) Week 1 (in person); (2) one month (phone); and, in most cases, (3) six month (phone). If you are not eligible for the trial, there will only be two phone calls. Each appointment is described below.

WEEK 1 IN-PERSON VISIT (TRIAL PARTICIPANTS ONLY): We will ask you to return for an in-person follow-up visit to Johns Hopkins Outpatient Clinic on the downtown campus.. You will be paid $200 for the completion of the Week-1 follow-up testing that includes a visit with dizziness specialist and an MRI brain scan. This visit will take about 6-8 hours and may take place in two half days or one full day, depending on scheduling. Free parking and transportation assistance may be offered to participants who need it. For those participants scheduled for their follow-up visit in one day, meal vouchers may be available.

A dizziness specialist will examine you and perform standard clinical tests related to dizziness and balance function. The study goggles test will be performed again. As before, we will take a video recording of your eye movement and use a room camera to record the clinical exam. Standard balance tests, including a caloric test (water in the ear test) and a complete hearing test will be performed. A repeat the MRI brain scan (*see below*) will be performed to confirm your diagnosis, since early MRI can sometimes be wrong. Unless these tests were recommended as clinically necessary by doctors at the ER visit (including any specialists, if involved), the tests will be paid for by the research study.

ONE-MONTH AND SIX-MONTH FOLLOW-UP (ALL PARTICIPANTS): You will be called by a member of the research team about one month (and, in most cases, again about six months) after your ER visit to ask some questions and see how you are doing. Each call will take about 20 minutes. We will also check to see if you were back in the ER or the hospital since your last in-person visit with a similar problem. To do this, we will look at specific parts of your medical record that relate to dizziness or strokes, like whether you saw an ear doctor (otolaryngologist) or a brain doctor (neurologist).

DETAILS ABOUT MAGNETIC RESONANCE IMAGING (MRI) BRAIN SCANS:
As part of your participation in this research study, you will have an MRI brain scan to look for stroke or other brain disease that might be the cause of your dizziness or vertigo. If you have known reasons why you cannot have an MRI brain scan you cannot take part in the trial, but you may still take part in the phone follow-up study. . If you agree to join the study, we will ask you questions to make sure you are able to have an MRI. If you are accepted into the trial, before your MRI exam, the MRI staff will ask you to complete a standard questionnaire that asks similar, but more detailed questions. The purpose of this questionnaire is to be totally sure that you are able to safely enter the MRI area.

After you are cleared as safe and ready to begin, the full MRI exam will take about 90 minutes to complete. To start your MRI test, you will lie on a padded table. A head/neck "coil" frame will be placed around your head, face, and neck (close to your face, but not touching you directly). The coil frame is necessary to help the MRI machine take pictures. The table on which you are lying will be moved to the center of an MRI magnet, which looks like a long narrow tube. Even though the tube is open, some people feel confined in small places. If this bothers you, please notify the MRI staff. You may end your participation in this study at any time by telling the MRI staff. When MRI pictures are taken, radio-signals and magnetic fields are used. When this happens, it is normal for the MRI machine to make loud, banging, and clicking noises. You will be asked to wear earplugs or headphones for your comfort during the exam, and to protect your hearing.

During the exam, the MRI staff can see and hear you. You will be able to hear the MRI staff. The MRI staff will be talking to you during your MRI exam and may give simple instructions to hold your breath, maintain your position, etc. You will generally be requested to lie perfectly still throughout the exam. Again, you may ask the MRI staff to stop at any time. If your MRI is with contrast, at some point during your MRI exam the MRI staff will interrupt the scanning procedure in order to give a "contrast agent" (sometimes called a "contrast dye"). Giving contrast allows us to take more accurate pictures of the balance organs and blood vessels. The agent is given through a needle placed (an IV) in your arm. The IV will be placed using standard hospital techniques. The research study requires an MRI at the 1-week follow-up visit; if you do not wish to receive an MRI, you cannot participate in the trial, but you may still participate in the phone follow-up study.

Incidental Findings
The MRI you are having as part of this research study will be reviewed by a qualified physician just as when having the MRI as part of your routine medical care. There is a possibility that while reviewing your MRI we may see an abnormality that we did not expect to see in this study. This is what is called an "incidental finding." We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by mail or by phone. In the case of a potential serious emergency, someone may go to your home. A qualified person (usually a member of the research team) will talk to you if there is an incidental finding. You do not have an option to decline information about an incidental finding. If you want, we will give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

- An incidental finding may cause you to feel anxious.
- Since an incidental finding will be part of your medical record, it may affect your current or future life or health insurance coverage. This risk will vary depending on the type of insurance plan involved.

The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility.

How long will you be in the study?
The entire study will last for about 5 years. You will be in this study for about six months.

4. What are the risks or discomforts of the study?

- You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

- You might experience some increased dizziness or feel sick to your stomach during the examination, although most of our patients and research participants do not.

- The sticky patches on your eyes, if used, may cause some brief discomfort when removing.

- There is a rare risk of neck pain or slowed heart rate during the examination.

- There is a rare risk of discomfort from the audiology tones during the examination.

- The risks of the MRI are the same as in routine brain scans for dizziness/vertigo.

MRI Brain Scan: The effects of magnetic fields in an MRI scanner have been extensively studied, and there are no known significant risks with an MRI exam. You may, however, be bothered by feelings of confinement (claustrophobia), or by the noise made by the magnet during the procedure. You will be asked to wear earplugs or earphones while in the magnet. You may not participate in this study if you have a pacemaker, an implanted defibrillator or certain other implanted electronic or metallic devices. It is important for you to advise the MRI staff if you have had brain surgery for a cerebral aneurysm, or if you have implanted medical or metallic devices, shrapnel, or other metal, including metal in your eye.

The contrast agent you will receive is FDA-approved and used routinely for MRI exams. It contains a material called gadolinium. The injection of contrast may cause discomfort, tingling or warmth in the lips, metallic taste in the mouth, tingling in the arm, nausea, or headache. These symptoms occur in less than 1% (less than 1 in 100) of people and go away quickly. Insertion of the needle and intravenous catheter (small plastic tube often referred to as an “IV”) to give you gadolinium may cause minor pain, bruising and/or infection at the injection site. There is a small risk of an allergic reaction to gadolinium; however, a severe allergic reaction occurs in less than one in 300,000 people.

People must have normal kidney function to receive gadolinium during the research MRI in this study. People with severe kidney failure who receive gadolinium are at risk of developing Nephrogenic Systemic Fibrosis/Nephrogenic Fibrosing Dermopathy (NSF/NFD). This (NSF/NFD) is a serious progressive disease and can result in death. There are no confirmed cases of this complication (NSF/NFD) occurring in individuals with normal kidney function (GFR above 30 mL/min).

All subjects will undergo the standard, institutionally required clinical prescreening tests, including MRI questionnaire and blood or urine test for kidney disease or pregnancy, per policy. Please notify a doctor, nurse or technologist if you are allergic to gadolinium, if you have any kidney problems, or if you experience any of these or other side effects.

A physician will be available during the procedure to administer any necessary care if side effects do occur, and to determine when or if the injection of the gadolinium should be stopped.

Unexpected Diagnosis or Future Diagnostic Tests: In this study you will get special diagnostic tests that you would not normally get. These tests could identify brain diseases that you have but did not know about (such as stroke or multiple sclerosis). Finding this out could make you upset. It could also lead to other tests or treatments outside the study that might have side effects, risks, or costs to you. These tests could also be wrong, which might lead to unnecessary tests or treatments.

Confidentiality: There is always a risk that information about you may become known to people outside this study. We will do everything we can to make sure that everyone who needs to see your information uses it only for the study and keeps it confidential.

Randomization (Coin Flip): The study goggles results (or specialist doctor's opinion after reviewing them) might lead your ER visit doctor(s) to choose tests or treatments that they might not have chosen. We believe those choices will benefit you, but we cannot be sure. For example, a common situation is that the study goggles results might require a brain scan that your ER doctor wouldn't have ordered. The tests could show an important medical condition, like stroke, but it might also turn out that these other tests don't reveal anything, making them unnecessary. We believe the goggles lead to tests that are medically necessary and decrease unnecessary tests, but we cannot be sure this will happen for you.

5. Are there risks related to pregnancy?

Pregnant women may not take part in this study because of unknown MRI/gadolinium risks for an embryo or fetus. Women of childbearing potential will have a urine pregnancy test, per institutional policy, to confirm they are not pregnant.

6. Are there benefits to being in the study?

You may or may not benefit from being in this study. The information learned from this study may help others in the future.

If you are assigned (by chance) to receive care guided by the study goggles device (that might include input from a dizziness/vertigo specialist), the results may help you get better care in the ER, hospital, and afterwards. The study goggles device has been shown in a small study to accurately diagnose inner ear versus brain causes of dizziness. We believe the study goggles will help your doctor get the correct diagnosis for the cause of your dizziness symptoms. If you are found to have an inner ear balance problem, we believe you may receive treatments that help you to get better faster, with fewer unnecessary tests. If you are found to have a stroke causing your dizziness, you will get the best possible treatments, and these could reduce your chances of a second stroke or even be life-saving. You may benefit from being examined by the dizziness/vertigo/balance specialist one week after the ER visit. You may benefit from the MRI scan or other tests obtained as part of the study. These tests may help you receive a correct diagnosis and correct treatments for dizziness.

If you are assigned (by chance) to receive standard care, there is no direct benefit to you from the study goggles testing during the ER visit. You may benefit from being examined by the dizziness/vertigo/balance specialist one week after the ER visit. You may benefit from the MRI scan or other tests obtained as part of the study. These tests may help you receive a correct diagnosis and correct treatments for dizziness, even if these problems were not diagnosed at the first ER visit.

7. What are your options if you do not want to be in the study?

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

8. Will it cost you anything to be in this study?

You will receive a separate Insurance and Research Participant Financial Responsibility Information Sheet (Sheet). This Sheet will give you the following information:

- The procedures, tests, drugs or devices that are part of this research will be paid for by the study (no cost to you).
- The procedures, tests, drugs or devices that will be billed to you and/or your health insurer. If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

9. Will you be paid if you join this study?

You will be paid $200 if you are eligible for the trial and complete the Week-1 follow-up visit. It is expected that the follow-up visit will take up to 8 hours. You will also receive free parking for the follow-up visit. Transportation assistance may be offered. For participants scheduled for their follow-up visit overlapping a mealtime, meal vouchers may be available. If you complete part of the follow-up visit, you will receive partial payment based on tests you completed. You will receive payment by check about 6-8 weeks after completing the study follow-up. There is no additional payment for the phone follow-up regardless of whether you are eligible for the trial or only the phone follow-up study. Your social security number may also be used at the 6-month follow-up to make sure you're still alive if we cannot reach you. Although your name and birthdate can be used to check government records, your social security number is the only reliable way for us to make sure we know it's you.

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

10. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

11. Why might we take you out of the study early?

You may be taken out of the study if:

- You fail to follow instructions.
- You become pregnant prior to your one-week follow-up visit.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

12. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records This could include information about sensitive health conditions (such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment) if they might be linked to your dizziness.

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins may also see or give out your information, particularly your doctors, who may need this information for your clinical care. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration or National Institutes of Health), safety monitors, other sites in the study and companies that sponsor the study. We will not give out your information unless it is necessary for the study or required by specific rules or regulations.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

13. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other health care providers. You may be asked to give us a list of other health care providers that you see.

14. What if there is a Certificate of Confidentiality for this study?

The National Institutes of Health has given us a Certificate of Confidentiality for this study. This Certificate provides some additional protection for research information that identifies you. The Certificate allows us, in some circumstances, to refuse to give out information that could identify you as a research subject without your consent, when such information is sought in a federal, state, or local court or public agency action. Still, we may disclose identifying information about you if, for example, you need medical help.

We may also disclose identifiable information about you as described in Section 12 of this form or in other cases. For example, the government may see your information if it audits us, and the research team will voluntarily comply with reporting requirements to the appropriate local or state authorities:

- if they suspect abuse, neglect or abandonment of a child or vulnerable or dependent adult;
- if certain diseases are present; and
- if the team learns that you plan to harm someone. In this case, the team also may warn the person who is at risk.

Even with this Certificate in place, you and your family members must continue to protect your own privacy. If you voluntarily give your written consent for an insurer, employer, or lawyer to receive information about your participation in the research, then we may not use the Certificate to withhold this information.

This Certificate does not mean the government approves or disapproves of this research project.

15. What does a conflict of interest mean to you as a participant in this study?

A researcher and Johns Hopkins have a financial or other interest in this study.

In some situations, the results of this study may lead to a financial gain for the researcher and/or Johns Hopkins. This financial interest has been reviewed in keeping with Johns Hopkins' policies. It has been approved with certain conditions, which are intended to guard against bias and to protect participants.

If you have any questions about this financial interest, please talk to David Zee (240-476-8804). This person is a member of the study team, but does not have a financial interest related to the study. You may also call the Office of Policy Coordination (410-361-8667) for more information. The Office of Policy Coordination reviews financial interests of investigators and/or Johns Hopkins.

16. What treatment costs will be paid if you are injured in this study?

Johns Hopkins and the federal government do not have programs to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

- If you have health insurance: The costs for any treatment or hospital care you receive as the result of a study-related injury will be billed to your health insurer. Any costs that are not paid for by your health insurer will be billed to you.

- If you do not have health insurance: You will be billed for the costs of any treatment or hospital care you receive as the result of a study-related injury.

By signing this form you will not give up any rights you have to seek compensation for injury.

17. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Newman-Toker at (410) 614-6996. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What should you do if you are injured or ill as a result of being in this study?

If you think you are injured or ill because of this study, call Dr. Newman-Toker at (410) 614-6996 during regular office hours.

If you have an urgent medical problem related to your taking part in this study, call Dr. Newman-Toker at (410) 614-6996 during regular office hours and at 443-801-1203 after hours and on weekends.

d. What happens to Data that are collected in the study?

Johns Hopkins and our research partners work to understand and cure diseases. The data you provide are important to this effort.

If you join this study, you should understand that you will not own your data, and should researchers use them to create a new product or idea, you will not benefit financially.

With appropriate protections for privacy (Institution name) may share your information with our research sponsors and partners.

18. What does your signature on this consent form mean?

Your signature on this form means that:

- you understand the information given to you in this form
- you accept the provisions in the form
- you agree to join the study

You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time

Signature of Person Obtaining Consent	(Print Name)	Date/Time

I have received the separate Insurance and Research Participant Financial Responsibility Information Sheet.

Signature of Participant	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.