

Official Title: Targeting a Genetic Mutation in Glycine Metabolism With D-cycloserine (DCS)

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Partners HealthCare System Research Consent Form

Subject Identification

General Template
Version Date: October 2014

Protocol Title: Targeting a Genetic Mutation in Glycine Metabolism with D-cycloserine

Principal Investigator: Deborah L. Levy, Ph.D.

Site Principal Investigator: Deborah L. Levy, Ph.D.

Description of Subject Population: Two carriers of a mutation affecting glycine metabolism

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called “subjects.” This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as “Partners.”

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

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.

Why is this research study being done?

We are doing this research to investigate the effects of a specific genetic mutation on brain structure and metabolism and to determine whether a specific medication (d-cycloserine, or DCS) is helpful in reducing psychotic and mood symptoms and in improving cognition.

DCS (seromycin) is an antibiotic. It is approved by the U.S. Food and Drug Administration (FDA) to treat tuberculosis. It is not approved by the FDA to treat psychotic conditions, but it has been used in several studies to enhance the effects of standard treatment in individuals with a diagnosis of schizophrenia.

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We are asking you to take part in this research study because you have a genetic mutation that affects the metabolism of glycine and you previously participated in a study involving glycine. DCS may help to normalize the functioning of the glycine receptor in the brain. During this study you will receive DCS and at other times you will receive a placebo (a capsule that does not contain medicine). You will also receive one tablet of vitamin B complex daily throughout the study.

Two people will take part in this research study.

The National Institute of Mental Health is paying for this research to be done.

How long will I take part in this research study?

It will take about 50 weeks to complete this study. During this time, we will ask you to make one visit to the University of Minnesota and McLean Hospital. Details about the specific procedures and the length of each procedure are included in the next section.

What will happen in this research study?

Study Visits and Design

Part I. If you are still taking a glycine supplement of your current psychiatric medications, you will stop taking glycine. You will receive a standard battery of clinical interviews every two weeks to assess the severity of any psychotic and mood symptoms. Each interview lasts about an hour. The interviews will be done over a “skype-like” connection with which you are already familiar. Partners Collaborative Media, which is affiliated with McLean Hospital, will create generic credentials for you and will ensure that your computers and web cameras are secure. You will be provided with any additional hardware and software that are needed at no cost to you. If your symptoms get worse after stopping the glycine, you may receive the same clinical interview every week for a few weeks. Within approximately 6 weeks or less of discontinuing to take glycine, you will start taking a low dose of DCS (50 mg/d). DCS comes in the form of a capsule that you will take once a day for 8 weeks. You will be evaluated on the same clinical measures mentioned above every two weeks. In addition, you will be in weekly phone contact with Dr. Levy.

Immediately prior to beginning to take DCS, you will have a physical examination and EKG from your own doctor. You will also have a blood test in which either 61 or 66 cc (approximately two ounces) of blood will be drawn. The same amount of blood will be drawn at the time of each subsequent blood test. For this and all blood tests, it is important that you have nothing to eat or drink and do not take any medications until after the blood test is over. You will also have a movement disorder exam using the same “skype-like” connection as in the interviews. The movement disorder exam takes about 5 minutes.

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During the 8 weeks of DCS treatment, you will have your blood drawn and get weighed once a month. You will receive the same clinical interviews every two weeks to assess the severity of any psychotic and mood symptoms. You will also be in weekly phone contact with Dr. Levy. Although we do not anticipate that DCS will cause any symptoms to worsen, this possibility cannot be ruled out in advance. If your symptoms do show a substantial worsening, you will stop taking DCS and your participation in the study will be over. In such a case, it will be your option to begin taking glycine again as part of a separate research study so that your symptoms can be stabilized.

If you develop significant side effects (such as worsening of mood or psychotic symptoms), you may be called by a study physician (Dr. Bodkin or Dr. Ongur) to follow up on your conversation with Dr. Levy if it seems medically necessary.

Part II. In the 7th week of DCS treatment, you will be flown to Minneapolis for tests of retinal function and to Boston for brain imaging procedures. In addition, the movement disorder examination, the neurocognitive battery you have had before (the MATRICS), the EEG you have had before, and a physical exam and EKG will be repeated. The procedures in Minneapolis and Boston will take about one week.

The brain imaging procedures allow Dr. Levy and colleagues at McLean Hospital to study the effects of a specific genetic mutation on brain structure and metabolism. Three magnetic resonance imaging techniques will be used.

1) Diagnostic Magnetic Resonance Imaging, 2) Diffusion Tensor Imaging at 3T (3T MRI & DTI) and 3) Magnetic Resonance Spectroscopy at 4T (4T MRS) are brain imaging techniques that use magnetic fields and radio waves to give detailed anatomical and chemical pictures of the brain, but involve no radiation. These techniques allow us to measure the levels of chemicals in the brain that help brain cells communicate with each other. Some of these chemicals are glutamate, GABA, glycine, and glutamine. The purpose of this study is to examine the effects of a specific genetic mutation in glycine metabolism on brain levels of these chemicals. Magnetic resonance imaging and spectroscopy will also be used to measure brain glycine levels before and for 2 hours after your take your usual dose of DCS. This procedure will measure how your brain absorbs DCS.

The imaging procedures at McLean will take place on several days. On one day, you will have a health screen involving a physical exam, urine toxicology screen, an EKG, a movement disorder examination, and blood tests. These procedures will take about 2 hours.

On another day there will be a structural MRI (at 3.0 T), which takes 15 minutes, and a DTI scan, which takes about an hour.

On a separate day, spectroscopy MRI at 4.0 T, which takes one hour, will be done.

On a different day, there will be spectroscopy scans using a 4T scanner. The pre-DCS scan takes one hour. After you take your DCS dose, the scan will last 2 hours.

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The neuropsychological tests (MATRICS) assess things like memory, attention, and planning and take 1 hour.

The EEG involves having electrodes pasted to your scalp and recording brain waves while you listen to auditory stimuli. It takes about 1 hour.

The retinal function tests in Minneapolis consist of two parts: a routine eye exam, including dilation of your pupils, and a more detailed exam of your retinas (the part of the eye that receives visual images and transmits them to the brain). Eye drops will be used during part of the detailed eye exam, which will numb your eyes to make you comfortable during the procedures. You should feel minimal or no discomfort. During the exam, recordings will be made from your retina, using a contact lens. There will also be a small flexible fiber placed just inside your lower eyelid, so it is in contact with your tears. This fiber relays information about the test. The fiber will be held in place by 2 sticky pads applied to your skin. There will be four additional small fibers placed on your skin near the outer corner of your eye(s), earlobe(s), forehead or on your forearm/hand. Photographs will be taken of your eyes. The exam will take about 3 hours; breaks are included.

Part III. If you complete the 8-week DCS trial, you will be randomized to receive DCS-placebo-DCS-placebo-DCS or to receive placebo-DCS-placebo-DCS-placebo, each for 6 weeks in a double-blind design. The McLean Hospital research pharmacist will determine the randomization and will know whether you are receiving drug or placebo, but you and all other study staff will not know. In case of an emergency, the study doctor can find out if you are taking DCS or placebo. There will be a total of five 6-week trials with DCS or placebo. In between each 6-week period, there will be one week of neither DCS nor placebo. The length of each double-blind arm is limited to six weeks to minimize the length of any symptom worsening you may experience when you are receiving placebo. After these five 6-week periods, you will receive DCS for 6 weeks.

Throughout this time, you will have your blood drawn and get weighed once a month. You will also receive the same clinical interviews every two weeks to assess the severity of any psychotic and mood symptoms. You will also be in weekly phone contact with Dr. Levy.

The total amount of blood that will be drawn over the course of the study will be 854 ml (about 58 tablespoons) or 896 ml (about 61 tablespoons). Both amounts are well within safe guidelines. You are asked not to donate blood during the course of the study.

At the end of all of these six 6-week periods, the following procedures will be repeated in your city of residence: the movement disorder examination (by Dr. Levy), the neurocognitive battery (the MATRICS, by Dr. Levy), and a physical exam and EKG (by your doctor).

Partners Alert System. Partners has an electronic system that lets your study doctors know if you are admitted to a Partners Hospital, or if you visit a Partners Hospital

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Emergency Department. We want to make sure the study doctors know about any possible problems or side effects you experience while you are taking part in the study.

Reasons for and procedures for early withdrawal from the study. Although we do not anticipate that DCS will cause any symptoms to worsen substantially, this possibility cannot be ruled out in advance. If your symptoms do show a substantial worsening, you will stop taking DCS and be withdrawn from the study. You may also be withdrawn if there are significant changes in your kidney or liver function. If you are withdrawn from the study you should contact your treating psychiatrist to discuss treatment options. You also have the option to begin taking glycine again as part of a separate research.

Should you become suicidal during the study, you must immediately notify Dr. Levy (617-855-2854), Dr. Bodkin (617-855-3186) and your psychiatrist, and call 911 if the situation is an emergency. If you are suicidal, we will recommend a course of action. This will include notifying your psychiatrist and internist, notifying a member of your family, and possibly calling the local EMTs to take you to a hospital if needed. You will be given a separate release form in which you will provide written consent for Dr. Levy and/or her designees to contact your psychiatrist, internist, and a designated family member.

Sending data/specimens to research collaborators outside Partners. Some of the blood samples will be processed either in a clinical lab in the city in which you live or by the clinical lab affiliated with McLean Hospital. Other blood samples will be sent to the Nathan Kline Institute (NKI) in Orangeburg, NY, where they will be analyzed for various amino acid levels (for example, glycine, serine). By signing this consent form, you give permission for Dr. Raymond Sukow and the Nathan Kline Institute permission to provide Dr. Levy and her colleagues with the results of any blood samples that are analyzed at NKI.

Storing Samples and Health Information at McLean Hospital and NKI for Future Use. We would like to store some of your samples and health information for future research related to psychiatric illnesses. We will label your samples and health information with a code instead of your name. The key to the code connects your name to your samples and health information. Dr. Levy will keep the key to the code in a password-protected computer.

Do you agree to let us store your samples and health information for future research related to psychiatric illnesses?

Yes No Initials _____

If later you change your mind and want your samples destroyed, contact Dr. Levy.

Study Information Included in Your Electronic Medical Record. A notation that you are taking part in this research study may be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example, list of allergies, results of standard blood tests done at the hospital labs).

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Please ask Dr. Levy if you have any questions about what information will be included in your electronic medical record.

Voluntary Participation. Participation in each part of this study is completely voluntary. You may refuse to participate or withdraw at any time without jeopardy to the medical care you will receive at this institution. Should you choose to withdraw, you will notify Dr. Levy or the research staff. Dr. Levy and her colleagues can remove you from the study at any time if it is determined that this is in your best interest or the best interest of the study.

What are the risks and possible discomforts from being in this research study?

Confidentiality

One potential risk is a breach of your confidentiality. This could lead your employer, insurance company, or others to find out that you participated in a research study.

Steps we take to prevent this are as follows:

Appropriate precautions will be taken to preserve confidentiality and your privacy. Your private health information is maintained in a secure manner and your identity is never associated with research records, which are assigned an alpha-numeric code that is kept in a password-protected file. However, there is some risk that identifying personal information could be shared or intercepted. Risks also include compromising identifying personal information on computers and compromising study documents with identifying information. These risks will be minimized by storing your data and personal information on a password protected computer or in a locked filing cabinet in a locked office that will be accessible only to study staff.

MRI/MRS

MRI/MRS technology does not use ionizing radiation. Instead, it uses strong magnetic fields and radio waves to collect the images and data.

There are no known hazards or risks associated with MR techniques. Significant risks may exist for people with:

- Cardiac pacemakers
- Metal clips on blood vessels (also called stents)
- Artificial heart valves
- Artificial arms, hands, legs, etc.
- Brain stimulator devices
- Implanted drug pumps
- Ear implants
- Eye implants or known metal fragments in eyes
- Exposure to shrapnel or metal filings (wounded in military combat, sheetmetal workers, welders, and others)
- Other metallic surgical hardware in vital areas
- Certain tattoos with metallic ink (please tell us if you have a tattoo)

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Certain transdermal (skin) patches such as NicoDerm (nicotine for tobacco dependence), Transderm Scop (scopolamine for motion sickness), or Ortho Evra (birth control)
Metal containing IUDs

If you are unsure whether you have any of these items in your body, you should know that most would have been implanted as part of a surgical procedure. So, trying to remember any past operations may help you remember. You will be asked whether you have any implanted devices or history of exposure to shrapnel or metal filings, and if so, you will not be able to participate in this study.

Significant risks also can arise if certain materials (many types of metal objects) are brought into the scanning area, as they can be pulled into the magnet at great speed. Such items can cause serious injury if they hit you. Therefore, these types of items are not permitted in the scanning area. You will not be allowed to bring anything with you into the scanning room. The MR exams are painless, and except for pulsating sounds, you will not be aware that scanning is taking place.

3T scanners are approved by the FDA for routine clinical studies in children or adults. Although there are no known risks from these scans, there could be adverse effects that are delayed or very mild, such that they have not yet been recognized. Most people experience no ill effects from these scans, but some people do report claustrophobia (fear of being in enclosed small spaces), dizziness, mild nausea, headaches, a metallic taste in their mouth, double vision, or sensation of flashing lights. These symptoms, if present, disappear shortly after leaving the scanner.

Unlike a standard clinical MRI scanner (1.5 or 3 Tesla), one scan of the present study will be conducted in a high field (4T) MRI Scanner. This scanner is not used for routine clinical studies in children or adults, but the FDA has determined (July 14, 2003) that scanners with a magnetic field strength of less than 8 Tesla (double that of this scanner) or less do not represent a significant risk to adults, children, or infants aged more than 1 month. There could be adverse side effects that are delayed or very mild, such that they have not been recognized. Most people experience no ill effects from 4T scans, but some people do report claustrophobia (fear of being in enclosed small places), dizziness, and the other symptoms described in the previous paragraphs. These symptoms, if present, disappear shortly after leaving the scanner. No serious effects have been reported to date at any site operating at 4T strength.

We are doing the 4T MRI scan in this study to answer research questions, not to give you medical care. The information created by this study will not usually become part of your hospital record. This 4T MRI scan is not the same as one that your own doctor would order. It may or may not show problems that would be found on a standard clinical radiological test. If we do see something that looks like a medical problem, we will ask a radiologist (a doctor who specializes in x-rays / scans / test results of this sort) to review the results. If the radiologist thinks there might be a problem, we will tell you and help you get follow-up care. If the radiologist thinks that you might have a medical problem, but it turns out that you don't, we may have caused you to worry needlessly about your health.

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In rare cases, a very slight, uncomfortable tingling of the back is induced in some people undergoing certain types of scans. If you experience this sensation, you are asked to report this immediately so the scan can be stopped. Although these precautions will avoid all known risks associated with MRI, this procedure may involve risks to you that are currently unforeseeable. The sounds that you hear inside the scanner are the normal operating sounds the scanner makes while it takes pictures of your brain. While they may be annoying, their intensity is not harmful to your hearing. However, you will be given a pair of earplugs to wear to muffle the sounds. You also may be asked to wear a set of headphones, which further reduces the noise level and permits the technician to speak to you.

Women of childbearing age: Not applicable.

Blood tests

You may receive a bruise at the site of the needle insertion. There is also the risk of infection at the site of blood withdrawal, but standard aseptic techniques will be used, making this an unlikely event (<1% of subjects).

DCS-Placebo Treatment

During the open label-DCS treatment period and the DCS-placebo treatment periods: When you are taking DCS, you may experience a modest and time-limited worsening of “negative” symptoms (withdrawal, lack of motivation), but this is unlikely. When you are taking placebo, you may experience a worsening of psychotic, negative, and mood symptoms that had improved on DCS. If you experience these or any other any side effects, you must report them to Dr. Levy immediately (617-855-2854 or page through the McLean Hospital operator at 617-855-2000). If you are unable to reach Dr. Levy, you may also contact Dr. Alexander Bodkin at 617-855-3186 M-F 9-5 (can also be paged through 617-855-2000) or Dr. Dost Ongur at 617-855-3922 M-F 9-5 (can also be paged through 617-855-2000).

DCS at high doses can cause B12 and folate deficiency. You will be taking a low dose of DCS, so these side effects are unlikely. To make sure that you do not develop either deficiency, you will be given vitamin B complex tablets to take daily (1/day) throughout the study.

You will have periodic blood tests to monitor your kidney and liver function to make sure that you can safely continue to take DCS.

Neuropsychological Test Procedures

No adverse effects of the neuropsychological procedures are expected, but the testing may be tiring.

EEG

The paste that is used to stick the electrodes to your scalp is a clear gel. It may make your hair feel greasy and can be washed out.

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Eye Exams

Eye drops will be used during part of the detailed eye exam, which will numb your eyes to make you comfortable during the procedures. You should feel minimal or no discomfort. Your eyes will be dilated for each part of the exam, so it will take a few hours before you can read easily and you will need to wear sunglasses outside during the day.

You will be told of any significant new findings that develop during the course of this study that may relate to your willingness to continue to participate.

You may end any of these procedures at any time without penalty to current or future treatment.

There may be risks that are currently unknown from taking DCS or undergoing the various research procedures.

What are the possible benefits from being in this research study?

There are no direct benefits to participating in this research. The information obtained in this study may help to explain the effects of a mutation in glycine metabolism on brain structure, function, and metabolism. One potential benefit of participating in this research is that structural scans obtained for this research will be analyzed by a radiologist and significant findings will be reported to you. An additional potential benefit is that DCS may reduce your psychotic and mood symptoms and improve your cognitive abilities.

What other treatments or procedures are available for my condition?

You may choose not to participate in any of these procedures and continue to receive standard psychiatric care. The treatment provided in this study, DCS, may be available to you through prescription and preparation by a compounding pharmacy without taking part in this study.

Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

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What should I do if I want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will I be paid to take part in this research study?

You can receive up to \$2,200 if you complete all study visits. You will be paid \$1,000 by check for participating in the open-label DCS study and the procedures during weeks 7-8. You will be paid an extra \$200 for the retinal function tests in Minneapolis. You will be paid an additional \$1,000 by check for the six 6-week periods during the randomized DCS-placebo part of the study. If you do not complete all of the procedures, you will be paid a pro-rated amount based on the proportion of the study that was completed. For example, if you complete 80% of the procedures during the open-label DCS study, you will be paid \$800. If you incur transportation-related expenses related to your participation, such as gas or taxis, you will be reimbursed up to \$500 in the first year of the study and up to \$300 in the second year of the study, based on submitted receipts.

If you do not complete the study, we will pay you a pro-rated portion for the part of the study that you did complete.

What will I have to pay for if I take part in this research study?

Study funds will pay for the cost of all of the research procedures, including your travel, lodging, food, and local transportation expenses while you are participating. If you incur expenses, such as parking or gas costs, you will be reimbursed.

What happens if I am injured as a result of taking part in this research study?

If you are injured as a direct result of taking part in this research study, we will assist you in obtaining the medical care needed to treat the injury. This means arranging for (but not paying for) transportation to an acute care center for treatment of the injury. McLean Hospital is a psychiatric care facility and does not provide general health care services.

The care provider may bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

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For the blood draws at Bozeman-Deaconess Hospital, McLean Hospital will not be involved in mitigation of any injuries that may occur.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

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

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Dr. Deborah Levy, Ph.D., is the person in charge of this research study. You can call her at 617-855-2854 M-F 9-5 or at 617-455-8007 24/7. You can also call Dr. Alec Bodkin at 617-855-3186 M-F 9-5 or page him through the McLean Hospital operator at 617-855-2000 24/7 with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call Dr. Levy at 617-855-2854 or 617-455-8007.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 617-424-4100.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my privacy?

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as “health information.” In general, under

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federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

In this study, we may collect health information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable health information and why they may need to do so:

- Partners research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within Partners who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The Partners ethics board that oversees the research and the Partners research quality improvement programs.
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your health information only when we must, and we ask anyone who receives it from us to take measures to protect your

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privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your information for any mailing or marketing list. However, once your information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

