Consent Cover Sheet
Glutamate reducing interventions in schizophrenia

Below is a summary of the study you are being asked to participate in. This outline is meant as a guide for you to use while considering the study and reading the consent form. It is not meant to replace the consent form which you will need to sign if you decide to participate in the study. The consent form contains detailed information about the study and the risks you will need to consider in making your decision.

Overview:
• This study has not been designed for your benefit.
• You are being asked to participate in a research study that is designed to evaluate the effect of a drug called LY2140023 (Pomaglumetad or "POMA" for short) on a naturally occurring chemical called glutamate in the brain. You will be randomly assigned to take one of four doses of POMA twice a day for 14 days by mouth.
• You will have two magnetic resonance imaging (MRI) brain scans during which you will receive an injection of gadolinium as a contrast agent, each scan takes about one hour to complete. One scan is done before starting the study drug and one at the end of the study drug. You will also take some pen and paper tests and an interview to see how you are feeling and thinking.
Some of your visits may be conducted remotely using the telephone or HIPAA-compliant video teleconferencing.
There are risks associated with participating in this study. These are discussed in detail in the consent form.

Risks:
• POMA is an experimental drug being developed by Denovo, for treatment of psychiatric illnesses, including psychosis. The most common side effects of POMA are inability to sleep, an increase in one type of white blood cells (eosinophils), feeling anxious, feeling sick to your stomach (nauseous), feeling restless or upset, an infection of the upper breathing system, vomiting, rashes, headaches, dizziness, increases in muscle enzymes in the blood, high blood pressure, stomach pain, constipation, and feeling sleepy. Seizures are a rare but possible risk. Doses as high or higher than the highest dose that you could receive in this study (160 mg twice a day) has been taken by 24 healthy people without psychiatric illness for 11 days in a previous study without significant side effects. No one has ever taken POMA at these higher doses for as long as you may be taking them. Please see the Risks section of the consent form for detail regarding rare side effects.
• The contrast agent used in the MRI, gadolinium, may have side effects, including nausea and a skin reaction. People with kidney disease should not receive gadolinium. The details of the common and rare side effects are listed in the consent form and you can discuss these with the study doctor.
• You are not expected to notice any improvement in your thinking or symptoms during this study. Even if you do, this is not expected to last after you finish the study.
• You don't need to participate in this study to receive help for your symptoms. There may be treatments available to help you, and your doctor can discuss these options.
• Like all research, your decision is up to you – taking part is voluntary. Also, you cannot participate if you have kidney disease.

Glutamate reducing interventions in schizophrenia

Patient Consent Form

Overview/Study Purpose

We are asking you to take part in a research study. You are being asked to participate because you show one or more symptoms that sometimes lead to developing psychosis. This does not mean that you will develop psychosis. Other people who show these symptoms do not always develop psychosis. All participants in this study will receive one of four different doses of POMA. In addition, some participants may not receive active medication during the course of the research. To join the study is voluntary.

This study is funded by the National Institute of Mental Health (NIMH). In this study we will be testing a drug to see if its helps treat brain problems that we think happen in people who have a chance that they will develop a disorder such as schizophrenia. The purpose of the study is to learn about the effects of the drug LY2140023's (Pomaglumetad or "POMA" for short) effects on brain function. Researchers think that treating a brain region (the hippocampus) with POMA may reduce the risk of developing schizophrenia. POMA is an experimental medication being developed by a company called Denovo for conditions such as psychosis. Its use in this study is experimental. As part of this study, you may be exposed to a high dose of POMA for two weeks. Only a small number of other people have taken doses in this higher range in previous studies. No people have previously taken such doses for as long as 2 weeks. It is important that you understand that this study was not designed for your benefit. By participating, you will help researchers answer the goals of the study. There are risks associated with participation; these are described in the Study Risks section. Dr. Scott Small is the principal investigator and the person in charge of the study at New York State Psychiatric Institute (NYSPI). Study procedures will be conducted at NYSPI as well as the Neurological Institute of New York at Columbia University. The study will enroll 50 people at Columbia University and NYSPI.

Voluntary participation

Participation in this project is voluntary, and you may refuse to participate or discontinue participation at any time without loss of benefits to which you are otherwise entitled. A decision not to participate in this study, or to withdraw at any time, will not affect your present or future medical care or employment at either the Columbia University Medical Center or the NYS Psychiatric Institute or COPE. On the other hand, we might terminate the study without regard to your consent under circumstances where continuing the study would not be safe, such as a pregnancy, or a worsening of your symptoms, or a severe medical problem, such as seizures. We will disclose to you during the study any significant findings from the research that may affect your willingness to continue participation.

Also, please note that there would be added risk if you were to participate in a trial in addition to this trial at the same time. If you are planning to participate in another trial at the same time as this one, you will not be allowed to participate in this trial.

Alternative Treatments/Alternatives to participation The information being collected is for research purposes only and is to learn more about brain function and psychosis risk, not about you. It is not necessary to participate in this research study to have an MRI, and the MRI done as part of this study is not the same as one done for medical purposes. The goal is not to provide treatment to you. There are treatments that may help improve symptoms you may have that are common in patients in the COPE or Lieber clinics, including treatments that do not involve taking medication. Your doctor can discuss these options with you at any point, whether you decide to participate in this study or not.

Study Procedures

<u>General Information:</u>

This study will last about 4 weeks. During the study, there will be up to 5 visits to the clinic for study procedures as detailed below. There is a screening period that lasts up to 14 days with tests and procedures to find out if you are eligible to be in the study. During screening, the study doctor

will ask you about symptoms you may have that might indicate an increased risk for psychosis. You will have a physical exam and blood and urine tests, as well as an EKG to measure the electrical activity of your heart. A small portion of the blood drawn will be used for DNA analysis to see how your genetic makeup may affect how POMA affects you. You will be asked not to eat after midnight the day before this visit so that fasting blood tests can be done in the morning. About 2 tablespoons of blood will be taken for standard tests. Urine will be tested for drugs. If you are a woman, you will have a blood pregnancy test. If you are eligible when screening is complete then you will enter a 2-week treatment phase. You will be randomly assigned (by chance, like the flip of a coin) to receive one of four doses of POMA. Neither you nor the study doctor will know which dose of POMA you are taking, but they can find out in an emergency.

Outline of Procedures:

• You will always take study medication 2 times a day: morning and at bedtime. Your study doctor will monitor you for side effects on study visits. In addition, research staff will observe take each of your doses via hipaa compliant video.

• During the study you will be asked about your psychiatric symptoms and have tests of your cognitive function (such as memory and concentration). At every visit, you will also be reminded to take your study drug first thing in the morning and at bedtime. If you forget to take a dose of study medication, --simply skip that dose, and take the next scheduled dose. The study drug will be given to you during your study visits. You will be reminded to bring back all bottles of study drug every visit even if you took all study drug. On days 7 and 14 after starting the investigational drug, we will evaluate how you are feeling on the study drug and whether you have any side effects. We will take blood and urine samples, ask questions about your symptoms, and test your cognition (like your attention and memory). We will also draw blood samples to look at blood levels of POMA on days 7 and 14. These visits will take 2-3 hours.

• MRI (Magnetic Resonance Imaging). You will receive an MRI before you begin taking POMA, and on Day 14 of being on POMA. The MRI uses strong magnetic fields and radio waves to take pictures of your brain. The MRI scanner to be used in this study works with a 3T magnet. This magnet is stronger than the magnets used routinely in scans done for clinical purposes. MRI involves lying on a table that slides into a large magnet shaped like a cylinder. Before beginning the imaging procedure, we will make sure that you do not have a pacemaker or any metallic implants (other than tooth fillings, or braces), and you will be asked to remove any metal or magnetized

objects (such as keys, chins, hairpins, or credit cards). You will be asked to lie flat on your back in the MRI scanner for 45-60 minutes. You will be asked to remain as still as possible. You will not feel anything, but will hear a knocking noise. This is a normal sound produced by the MRI scanner and does not indicate that anything is wrong. On the day of the scan, you will be asked to take some pen and paper tests and to answer some questions about how you are thinking and feeling. This testing will take a total of 2.5 hours. You will receive a contrast agent gadolinium. Gadolinium is given to you by an I.V. An I.V. uses a small needle to place a small plastic tube into your vein. The small tube is connected to a source of water and the contrast solution, and during the MRI scan, the contrast and water are pushed into your vein. Most people do not notice the injection part of the study, but a cool sensation in your arm is a common and normal response to have. If at any time during the injection of the contrast agent you feel uncomfortable or are sick to your stomach, you can notify the imaging staff immediately by pressing a button that they give you at the beginning of the scan. Nausea may occur due to the POMA, or the gadolinium, and vomiting in the scanner could be dangerous. Therefore, it is important to alert staff immediately if you feel nauseated or like you need to vomit so you can be removed from the scanner. The scan will then be stopped and the study doctor will evaluate you.

- Study participants who withdraw from the study early for any reason are eligible to receive payment for procedures completed to the time of study withdrawal.
- Upon study completion, you will not know what dose of POMA you received. POMA will not be available to you even if it helped because it is an experimental medication.
- To participate in the study, you must be willing to come to all study visits and to follow all study procedures and instructions.
- Some of your visits may be conducted remotely using the telephone or HIPAA-compliant video teleconferencing.

<u>End of Study Clinical Treatment</u>

You will be eligible for treatment in NYSPI's outpatient clinic (COPE clinic) for two years as part of COPE or you may continue with your current treatment provider. The treatment in NYSPI is free except for the cost of medications.

<u>Early Termination of the Study</u>

At any point during this study you may decide to stop participating. The study doctor (Dr. Girgis) may also decide to stop your participation in the study if your condition worsens or if you develop side effects or complications. At that time we will ask you to complete some end of study tests. Completing that final testing is also voluntary. Even if you do not finish taking part in this research study, you will be eligible to receive clinical treatment, as described in the section "End of Study Clinical Treatment."

Standby

Additionally, you may be asked to come in as a standby subject. If you agree to be a standby subject, you will be asked to come in on a day when a brain scan is scheduled for another participant. If for some reason the original participant does not complete the imaging procedures, you will be asked to participate in the imaging procedures in place of that person. If the original participant does complete the imaging procedures, you will be paid for your time and sent home. We expect that you will have to wait between 1-3 hours as a standby participant. You can choose to be a standby subject by checking one of the boxes found at the end of this consent form. Please be aware that you may be asked to be a standby subject multiple times. We estimate that you may be asked to be a standby 1-3 times before you are scheduled for your own imaging scan.

Study Risks

Risks and Discomforts Associated with POMA

As further described in this section, the most serious side effects associated with POMA and similar medications in previous trials have been seizures and rashes. Nausea is also experienced by people who take POMA. In clinical studies to date, POMA has been given to 582 healthy people and approximately 2,877 patients with schizophrenia or schizoaffective disorder. Most of these people received doses in the lower range of what is possible in the present study. Doses of POMA as high or higher than the highest dose that you could receive in this study (160 mg twice a day) have been taken by 24 healthy people without psychiatric illness for 10 days in a previous study without significant side effects. 44 patients with schizophrenia completed a multiple dose escalation study over a dose range of 160 to 480 mg BID for 7 days. Therefore, you might get a dose that relatively few people have been exposed to so far. No one has ever taken POMA at these higher doses for as long as you may be taking them.

In less than 1% of patients with schizophrenia who were treated with POMA, events of sudden, uncontrollable, and rapid shaking or seizures have been reported. These periods of rapid and uncontrollable shaking or seizures appear to have been associated with POMA. Your doctor may ask you additional questions to make sure you are not at risk for this event. Because of these experiences, events of sudden, uncontrollable, and rapid shaking or seizures will be monitored. Be sure to tell your study doctor immediately if you experience sudden, uncontrollable, and rapid shaking or seizures. There have also been reports of muscle spasms and skin rashes.

The most common adverse events (10% or more) in studies conducted in healthy people were: nausea, headache, vomiting, and dizziness. The following serious adverse events have been reported in healthy subjects (1 person each): infected sebaceous cyst (skin infection), deep vein thrombosis (clot in vein), pulmonary embolism, and syncope due to vasovagal event (Fainting). You should let the study doctor know immediately if you become nauseous during the MRI scan.

Risks and Discomforts in 1555 Patients with Schizophrenia Taking POMA

Frequency	Risks and Discomforts
Common **At least 1% to 9.9%**	• Inability to sleep • Increase in one type of white blood cells (called eosinophils) • Worsening of schizophrenia • Feeling anxious or apprehensive • Headache • Feeling sick to the stomach (nausea) • Feeling restless and upset • Vomiting • Skin reactions or rashes • Increase of muscle enzymes in the blood • High blood pressure • Stomach pain • Constipation • Feeling sleepy • Indigestion • Weight loss • Shakiness or trembling, muscle movements without purpose • Bronchitis • Feeling sad, hopeless, worthless, or pessimistic • An unpleasant or uncomfortable emotion such as sadness, feeling restless and upset, and feeling irritable. • Fast heart rate • Weakness or loss of strength • Restlessness or inability to sit still • Soft or watery stools • Muscle and joint stiffness • Muscle stiffness and shaking • Abnormal sleep patterns • Toothache • Dizziness

Some patients died during prior trials from suicide, some on active medication and some on placebo. So, we do not know if the POMA medication increases risk of suicide. But if you begin to have thoughts of suicide or are feeling more down or worse in other ways, you should alert study staff immediately

An increased level of POMA in blood has been observed in subjects who have problems with their kidneys compared with subjects who have normal kidney function. No problems appeared to be associated with the increased levels of drug in the blood, after a single dose; however, multiple doses have not been administered in subjects with kidney problems and it is not known whether there will be problems associated with this increased exposure.

If you are taking an antidepressant that works on a brain chemical called serotonin, there is a theoretical risk that you will develop a condition called serotonin syndrome when you take POMA in addition to the antidepressant. We do not know how often this could happen. Serotonin syndrome includes high body temperature, agitation, increased reflexes, tremor, sweating, dilated pupils, and diarrhea. In its most severe forms it can also cause seizures and an increase in a muscle enzyme called creatine phosphokinase in the blood. If you have any symptoms such as the above, we would ask you to contact the study doctor as soon as possible as this could be an emergency.

Gadolinium risks: Gadolinium compounds do have side effects. There are different forms of compounds; we use Dotarem.

Common side effects of gadolinium: Nausea and vomiting is observed in less than 2% of people injected with gadolinium. If you feel nauseous, please alert staff immediately. Dry mouth (less than 2%), dizziness (less than 3.6%), and headache (less than 5%) are also possible side effects. An additional side effect is hives, observed in less than 1% of people injected with gadolinium. All of these side effects resolve within 20 minutes to several hours. People with active asthma, allergies, or known sensitivities to contrast agents are at increased risk for more serious side effects (less than 1 in 10,000 injections), such as severe allergic reaction that may result in sudden difficulty in breathing. Therefore, they will not be injected with Gadolinium. Gadolinium can be harmful to someone with kidney disease; so you should not participate in this study if you have kidney problems. You will be screened for renal impairment through medical history interview and laboratory blood tests.

The Food and Drug Administration (FDA) has issued an announcement stating they are investigating a possible risk of adverse health effects from repeated use of gadolinium for MRI. Though the FDA has not reached a conclusion at this time, you should not participate in this study if you have previously had more than 1 MRI scan with gadolinium.

The experimental medication you will be taking during the study, POMA, can cause nausea and vomiting. The medication administered during the MRI scan, gadolinium, can also cause nausea and vomiting. Vomiting inside the MRI scanner could be dangerous because

of a risk of choking. Therefore, if you feel nauseated or have been vomiting before beginning the MRI scan, you should let study staff know and should not have the scan done at that time. While you are in the scanner if you begin to feel nauseated, alert the staff right away, so that you can be removed from the scanner.

MRI risks: The main risk of MRI is the risk of nausea and vomiting while in the MRI machine, due to either the gadolinium or POMA. Vomiting inside the MRI scanner could be dangerous because of a risk of choking. Therefore, if you feel nauseated or have been vomiting before beginning the MRI scan, you should let study staff know and should not have the scan done at that time. While you are in the scanner if you begin to feel nauseated, alert the staff right away, so that you can be removed from the scanner.

While there have been no reports of any harmful long-term effects caused by 3T magnets or magnets of even higher strength, the long-term effects of being placed in a magnet of this strength are unknown. Also, although there are no known risks associated with pregnancy, we will not scan someone who is pregnant. If you are a female in your childbearing years, you will be asked to take a pregnancy test to ensure that you are not pregnant. Some people have reported sensations during MRI scans with the 3T magnet, such as "tingling" or "twitching" (or, very rarely, a painful sensation), which are caused by changes in the magnetic field that can stimulate nerves in your body. With any MRI scan, on occasion, some people experience nervousness or discomfort due to the scanner's small space and the need to lie still. Except for pacemakers, some types of metallic implants, and medication patches, we are not aware of any other potentially dangerous interactions or hazards associated with the MRI scan. The MRI scanner also produces a loud noise; earplugs will be provided to reduce this discomfort. If you experience any discomfort and wish to stop the scan, you can push a button to tell the MRI technologist, and he or she will stop the scan immediately.

Blood draw/IV risks: The needle stick of the blood draw and brain imaging I.V. may cause mild pain, bleeding at the site, bruising, dizziness, and, in rare cases, infection. The total amount of blood drawn in the study will be approximately 3 tablespoons.

Pregnancy risks: The procedures of this study including MRI, gadolinium, and taking POMA, are not considered safe during pregnancy or breast-feeding, because there is concern about causing permanent damage to a developing fetus or young infant (for example, birth defects, or problems

that emerge during infancy or childhood), such as abnormal bone development. Therefore, you should not participate in this research if you are pregnant, or breast feeding a baby, or if you plan to become pregnant during the time you are in the study.

COVID-19 risks: Going out in public and traveling involves some risk of infection with COVID-19. There is risk of COVID-19 infection during in-office visits and during travel for research purposes. This risk can be reduced by taking recommended precautions. These include always wearing a mask in public and while traveling, practicing hand hygiene, and staying at least 6 feet away from others. If you do not feel comfortable traveling to the medical center for an appointment, for example if the subway or bus you would normally take is crowded, you can reschedule, or we may be able to arrange alternative transportation. We have also minimized in-office visits to lessen this risk.

We will keep you informed about current public health recommendations, such as federal and local government guidelines and directives.

To determine your eligibility for this study, a pregnancy test will be conducted before you enter the study. If the test is positive, you will not be able to participate in the study. Pregnancy tests will be repeated before every MRI during the study as well as on the first visit before you receive POMA and on Day 7. It is important to understand that even if a pregnancy test is negative, you could still be pregnant, because these tests cannot detect very early pregnancies (that is, within the first few days). If you are sexually active, it is very important that you use an effective form of birth control before and throughout your study participation. Methods of birth control considered to be effective include: double barrier methods (condom plus spermicide, or diaphragm plus spermicide), IUDs or intrauterine devices, birth control pills, injectable hormones, or if your partner has a vasectomy. It is important to understand that even if you use an effective birth control method, there is still a chance you could become pregnant. Also, if you do not use the birth control method consistently (for example if you don't use condom/spermicide some of the time) you may become pregnant. If you think you might be pregnant, it is important to let the study team know right away. The study team will conduct a pregnancy test and help you decide what to do next.

For males: Because the risks of POMA on male reproductive safety are not known, you must use an effective form of birth control during this study. Methods of birth control considered to be effective for males are condoms, condoms with spermicide, and vasectomies. If you are sexually active, it is very important that you use an effective form of birth control before and throughout your study participation.

Research Interview risks: The research interviews and testing are time consuming and deal with personal matters. If at any time you feel upset, tired or anxious, you can choose not to answer specific questions. You can also ask to have the interview stopped at any time.

Benefits

This study was not designed for your benefit. We do not expect that you will notice any changes during the study. If you do feel better during the study, we don't expect it will last after you finish the study. Your participation will provide important information about the safety and action of POMA on brain regions and people may benefit from the information learned from the results of this study.

Results of your MRI

While MRI scans are sometimes done for clinical purposes, the kind of MRI scan you will have as part of this study is for research purposes only. This means that the scans are not designed to provide clinical information that might be helpful to you or your doctor and they may not show problems that would normally be found in an MRI ordered to evaluate a specific medical problem. It is likely that the MRI scan will not have the quality of those done for clinical purposes. However, within 7 days of the MRI, the scan will be read by a neuroradiologist for evidence of any obvious irregularities requiring your follow-up. You, or a physician whom you may designate, will be informed only when significant abnormalities are detected. If you wish, we can also inform you if there were no obvious findings. Given the nature of the scan, the absence of a finding does not mean that one is not present.

Compensation

If you participate in the study, you will receive $50 per study visit, which is up to three study visits for screening, as well as the Day 7 and Day 14 study visits (5 total). You will also receive $150 for each of the brain imaging sessions (up to 2 total). You may receive compensation reasonable for local travel expenses

Therefore, the total estimated compensation if you participate in the study is $550. If you agree to come in as a standby subject, you will receive a check for $50. If you come in as a standby subject and are asked to participate in the scanning procedures, you will be paid according to the protocol. If you come in as a standby subject multiple times, you will be paid $50 for each visit.

You will be paid by cash or check. If you are paid by check, you will receive a check in 4-6 weeks from that study visit.

We are required by law to report your earnings to the IRS. Therefore, your Social Security Number and amount earned will be reported and you will receive the appropriate IRS form at the end of the year in which you have been paid. No information about which study you have participated in or anything else about this study will be provided to the IRS. Please note that payment for this study may affect entitlements/benefits that you receive, such as Medicaid, Social Security, and other city and state support services.

Confidentiality All written information acquired in this study will be stored in locked files, accessible only the researchers directly involved in this study. All computer-stored information (such as the MRI images) will be "coded"—labeled only with a code. These code numbers will not use a name or any other identifying feature, and will be randomly assigned to the MRI images. The brain imaging data contains only the coded number, and does not contain the person's name, initials, date of birth, sex, or other personally-identifying information. The link between a person's identity and the code number will be stored in locked files, accessible only to the researchers directly involved in this study. When the results of this study are published or presented, no information which could identify you will be used. The results of your MRI scan will be maintained in an electronically secure database at NYSPI or CUMC and be accessible only to the members of the research team. The coded brain imaging data will be shared amongst investigators at NYSPI and CUMC for purposes of brain imaging data analysis.

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 for the whole study. You can search this web site at any time.

In addition to the confidentiality protections described in this consent form, a federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance or by adoption agencies. GINA also does not protect you against discrimination based on an already diagnosed genetic condition or disease. If you would like to know more about it you can discuss this with the principal investigator of this study

or you can go to the following website www.genome.gov/10002328. This study will not include whole genome sequencing.

Additionally, the Food and Drug Administration (FDA) may inspect the records for this study.

This research is covered by a Certificate of Confidentiality issued by the Department of Health and Human Services (DHHS). The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse, intent to harm self or others, or communicable diseases, but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

This Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the organization which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). Records will be available to research staff, and Federal, State and Institutional regulatory personnel (who may review records as part of the routine audits).

Any information obtained as part of this study, including biospecimens, may be used in future research studies or distributed to another investigator for future research studies, but will not include any information that can identify you.

When conducting remote visits, we will use telephone or HIPAA compliant video conferencing.

Data Sharing

A data repository has been created by the National Institute of Mental Health (the funding agency for this study) that allows sharing of research data and scientific collaboration. The data repository is accessible only to qualified investigators. All subject data will be de-identified (your name will not be used) and each subject will have a separate identifier called a Global Unique Identifier (GUID) to remove any possibility that the data can be linked directly to you. The GUID is a universal subject ID that allows researchers to share data specific to a study participant without exposing personally identifiable information (PII). All subjects in this study will be assigned a GUID. The following information will be collected and entered into the study database to generate a GUID: First name, Last name, Middle name (if applicable), Month of birth, Day of birth, Year of birth, Physical sex at

birth, and Name of city/municipality of birth. Once the GUID is generated, all personal information will be deleted from the study database.

During and after the study, the researchers will send deidentified information about your health and behavior and in some cases, your genetic information, to NDCT (National Database for Clinical Trials), which is a national database for information from clinical trials that are sponsored by the government/NIMH. Other researchers nationwide can then file an application with the NIMH to obtain access to your deidentified study data for research purposes. Experts at the NIMH who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You will not benefit directly from allowing your information to be shared with NDCT. However, the information provided to NDCT may help researchers around the world treat future children and adults with mental illnesses so that they have better outcomes. NIMH will also report to Congress and on its web site about the different studies that researchers are conducting using NDCT data. However, you will not be contacted directly about the data you contributed to NDCT.

You may decide now or later that you do not want to share your information using NDCT. If so, contact the researchers who conducted this study, and they will tell NDCT, which can stop sharing the research information. However, NDCT cannot take back information that was shared before you changed your mind. If you would like more information about NDCT, this is available online at http://ndct.nimh.gov.

The data from this study may also be shared with the company that makes POMA (DeNovo). Any data that will be shared with them will be deidentified, meaning it will have no information that would be able to identify you. The company may use these data for commercial profit that you would not share in.

We will tell you about any clinically relevant research results, including individuals research results, such as results of blood laboratory values or MRI results. We can also share this information with a physician of your choice.

Risks to Privacy: As in any research study, it is possible that personal information about you could become known to other people. The investigators will take precautions to prevent this from happening. Your name will not appear on any questionnaires or test that you complete during the study. Instead, all questionnaires and tests you complete will be coded with a study code number.

Questions

The investigators will answer to the best of their ability any questions that you may have about the procedures or your response to them. You can contact the Principal Investigator, Dr. Scott Small at

(646) 774-5553 if you have any questions about the study now or in the future. If you have any questions about the rights of research participants or complaints, you may call the NYSPI IRB Main Office at (646) 774-7155 during business hours. An IRB is a committee that protects the rights of human subjects in research studies.

Compensation for Research Related Injuries

Federal regulations require that research participants be informed about our institutions' policies with regard to the provision of treatment and compensation for research related injuries. If you believe you have sustained an injury as a result of participating in this research study, you should contact the Dr.

Girgis, at (646) 774-5553, or the NYSPI IRB Main Office at (646) 774-7155 so that you can review the matter and identify medical resources that may be available to you.

Please be aware that:

a. New York State Psychiatric Institute, New York Presbyterian Hospital, and the Columbia University Medical Center will each furnish that emergency medical care and assistance in arranging follow up care determined to be necessary by its medical staff.

b. You will be responsible for the cost of such care, either personally or through your medical insurance or other form of medical coverage.

c. No monetary compensation for wages lost as a result of injury will be paid to you by New York State Psychiatric Institute, New York Presbyterian Hospital, Research Foundation for Mental Hygiene, or by Columbia University Medical Center.

d. By signing this form, you are not waiving any of your legal rights to seek compensation through the courts.

_____ I am planning on having a gadolinium MRI scan within the 2 weeks before the study, during the study, or within 2 weeks after the study.

_____ I am not planning on having a gadolinium MRI scan within the 2 weeks before the study, during the study, or within 2 weeks after the study.

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_____ I agree to being considered as a Stand by subject.

_____ I do not want to be considered to be a Stand by subject.

You will be given a copy of this consent form to keep.

Documentation of Consent

I voluntarily agree to participate in the research study described above.

Name of Participant

Signature of Participant Date

Statement of the Investigator (Must be M.D.)

I have discussed the proposed research with this patient, and, in my opinion, the patient understands the benefits, risks and alternatives (including non-participation) and is capable of freely consenting to participate in this research.

Printed Name

Signature Date

Independent Assessment of Capacity

I have examined on for the purpose of determining whether he/she is capable of understanding the purpose, nature, risks, benefits and alternatives (including non-participation) of the research, making a decisions about participation, and understanding that the decision about participation in the research will involve no penalty or loss of benefits to which the patient is otherwise entitled, for Dr. Scott Small's research project "Glutamate reducing interventions in schizophrenia".

On the basis of this examination I have arrived at the conclusion that:

___ A. This patient has this capacity at this time.

___B. There is a question about this patient's capacity at this time.

___C. This patient clearly lacks this capacity

Printed Name

Date

Signature

(Member of treatment team; MD or PHD; Not a member of the research staff)