The University of New Mexico Health Sciences Center
Consent and Authorization to Participate in a Research Study
Key Information for:
The relationship between the efficacy of lumateperone and central glutamate and dopaminergic metabolism: A comparison with risperidone in first episode psychosis

You are being invited to take part in a research study about the effects on brain chemicals (glutamate and dopamine) between different two medicines (lumateperone and risperidone) that are available to treat psychotic disorders (like schizophrenia and bipolar I disorders). Psychotic disorders are illnesses that affect the brain and can present with psychotic symptoms like hearing things that others cannot hear ("voices"), having unusual scary thoughts, or having difficulty organizing your thoughts.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THE STUDY?

By doing this study, we hope to learn the effects of lumateperone in brain glutamate and dopamine and whether these effects are related to the benefits and the side-effects of the medicine. Half of the participants will be treated with lumateperone and half with risperidone, another standard medicine helpful for psychotic symptoms, for 6 weeks. Both medications are FDA approved for schizophrenia. Risperidone is FDA approved for bipolar-I mania however lumateperone is not. Still both medications are widely used for psychotic disorders following doctor's best clinical practice standards. You will not know which of the two medicines you will be taking.

During the course of the study, we will ask you questions about yourself, past and current mood symptoms, medical history, medication history, and smoking habits. You will also get two brain scans (one at the start and one at the end of the study), you will do some tasks to see how quickly you process information and test your memory, and have some blood drawn. You will get breaks to rest as needed. Your participation in this research will last about 23 hours over the course of 12 weeks.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

If you participate in this study you will get an MRI of your brain with a report from a neuroradiologist. Also, after completing the initial 6 weeks of the study, you will be offered lumateperone for treatment of psychotic symptoms at no cost to you for up to 6 months. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE THE KEY REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You may feel anxious when doing the two MRIs that are part of the study. Your psychotic symptoms may not get better when taking either of the drugs that are part of the study (lumateperone or risperidone). For a complete description of the risks, refer to the Detailed Consent/Appendix

If you chose not to participate, your Dr. may still offer treatment with lumateperone, risperidone, or any other antipsychotic drugs approved for the treatment of psychotic symptoms. For a complete description of alternate treatment/procedures, refer to the Detailed Consent/Appendix.

DO YOU HAVE TO TAKE PART IN THE STUDY?
If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?
The person in charge of this study is Dr. Juan Bustillo of the University of New Mexico Health Sciences Center, Department of Psychiatry. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, his contact information is 505-272-9552.

If you have any questions or concerns about your rights as a volunteer in this research, contact staff in the University of New Mexico Health Sciences (UNMHSC) Human Research Review Committee (HRRC) between the business hours of 8AM and 5PM, Mountain Standard Time (MST), Monday-Friday at 505-272-1129.

DETAILED CONSENT
Version: March 16, 2023

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?
You could be excluded from participating in the study if: you are under 18 or over 40 years of age; you are using illegal substances like cocaine or heroin; you are pregnant; you are very fearful of enclosed spaces or of having your blood drawn; you do not want to take any medicines for psychotic symptoms; you have been taking antipsychotic medicines daily at standard dosages for longer than one week.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?
The research procedures will be conducted at Center for Psychiatry Research and the Mind Research Network. You will need to come 12 times during the study. Each of those visits will take about 30 min to up to 6 hours. The total amount of time you will be asked to volunteer for this study is about 23 hours over the next 12 weeks. We plan to recruit up to 60 people for this study.

WHAT WILL YOU BE ASKED TO DO?
The study will have three parts: Screening, Study-Medication and Follow-up.

1. **Screening** (2 visits): You will be interviewed at the Center for Psychiatric Research (CPR) and asked for certain information, such as your age, education level, phone number and how you feel about being in an MRI scanner. The research doctor and staff will ask you questions about your symptoms and about which medications you are currently taking and about medications you have taken in the past. During the interview, you may refuse to answer any question at any time. The clinical assessments take approximately 2 hours to complete. Also, the staff will ask a relative, close friend or clinician you agree for us to contact, some questions about how you have been doing (like how well are you cleaning your home). During this visit, you will also have a physical exam (e.g: listen to your heart and lungs) and be examined to see if you have any muscle stiffness, abnormal body movements, or side effects from medication(s) you may be taking. A blood sample will be drawn from a vein in your arm to make sure different parts of your body are working properly. You should not eat or drink anything in the morning before this blood sample is drawn and the blood will be drawn at the UNM Hospital Tricore laboratory. A urine drug screen will be performed (at the CPR) which may result in exclusion from the study if the result is positive for some substances (like cocaine or heroin). All women will also have a urine pregnancy test (if she is pregnant she may not participate in the study). The physical exam and blood and urine tests take approximately 30 minutes. You will also complete a Magnetic Resonance Imaging (MRI) scan, at the Mind Research Center (MRN) which is connected to the CPR. The MRI will take pictures of your brain. You will lie back on a table and will then be placed into a long donut-shaped magnet; the scan will take approximately 60 minutes. During scanning, you will hear loud rapping and knocking noises coming from the

magnet. You will be provided with headphones and/or ear plugs to block out the noise. If you feel nervous to do the scan, the doctor may offer you lorazepam, a medicine for anxiety that you can take 1-2 hours before the scan. Finally, the research staff will give you a bottle of study medicine for you to take during the next part of the study.

2. **Study-Medication** (6 visits): You will start taking the study medicine (lumateperone or risperidone) 1 capsule each evening. You will be assigned by chance (like flipping a coin) to take either medicine for the next 6 weeks and neither you nor the research staff (including your doctor), will know which medicine you are taking. This is the usual way most drug studies are done. If you were taking another medicine for a psychotic disorder, it will be gradually discontinued over the first week of this part of the study.

   The day before your visit, the research staff and/or your study doctor will call you on the phone to remind you of your appointment and to check how you are doing. You will see the study doctor and staff each week at the CPR for alternating short (about 1 hour) or longer (about 2 hours) visits. Each visit you will be asked different questions about any symptoms and side-effects. You must always bring the bottle for you study medicines. Any leftover study medicines will be counted by the research staff. During the longer visits you will also be examined for muscle stiffness and asked additional questions. Also, each visit your doctor will adjust you study medication to a higher or lower dose (although you will always take only 1 tablet) depending on how you are feeling. Every week, you will leave the research office with a new bottle of study medicine. The doctor may prescribe additional medication to help you with difficulty sleeping or with muscle stiffness or restlessness. This additional medication you would pick up at your pharmacy as it will not be provided through the study (you or your insurance would be responsible for the cost). If you are not doing well with the study medicine you were initially assigned to, your doctor may recommend to switch you to the other study medicine (either lumateperone or risperidone). Still neither you nor your doctor will know which of the two medicines you will be taking. If your study medication is switched, the final assessments (described below) may be moved to be done as close as possible to the day the medication switch was made.

   After 6 weeks of taking the study medicine you will have a final visit. This visit will be the longest of all (about 6 hours) and will include a blood (at the UNM Hospital Tricore laboratory) and urine tests (at the CPR), questions about your symptoms, questions to a relative, close friend or clinician about how you have been doing, an exam for stiffness, a second MRI (at MRN) and a cognitive test (at the CPR). The cognitive test involves things like connecting a series of dots and letters or listing words in a specific category. You will be given breaks and can stop at any time. These tests are designed to measure how quickly you process information and how your memory works. They take approximately 90 minutes to complete.

3. **Follow up (4 visits):** Finally, the study medication will be discontinued and you will be given a prescription for lumateperone or for any other medication for psychotic disorder that you and your doctor agree would be most helpful to you. You will come to see your research psychiatrist every week for about 30 minutes to see how you are doing with the change in medication. During this Follow-up part of the study, no research data will be collected and you will not be paid. The company that pays for this study (Intra-Cellular Therapies) has agreed to provide the lumateperone free of cost to you for up to 6 months. If you chose to take another medication, you and your insurance company will be responsible for its cost.
4. **Notes in UNM Hospital record:** During each of the Study-Medication and Follow-up visits, your research doctor will add a note in your UNM hospital medical record briefly describing how you are responding to the research treatment, for your physicians in the hospital to be aware of.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Risk of study medications: Both lumateperone and risperidone are widely available antipsychotic medications (they are not experimental drugs) and have similar side-effects which include:

1. Involuntary movements are occasional (shaking, stiffness, restlessness, muscle spasms)
2. Metabolic risks are occasional (weight-gain, increases in cholesterol and other blood fats, and increases in blood sugar and prolactin, a hormone that can cause leaking from the nipples)
3. General risks are occasional (sleepiness, dry-mouth, dizziness and nausea; see attachment for full side-effect profiles).

A limited amount of information available suggests that the movement and metabolic side-effects may be less frequent with lumateperone than with risperidone. A very serious, life-threatening but rare complication of treatment with all antipsychotics is neuroleptic-malignant syndrome. Likewise, all antipsychotic agents can cause tardive dyskinesia, a serious long-lasting movement disorder that may occur usually after months or years of treatment (this would be rare after 6 weeks). Your doctor will meet with you weekly and will examine you for any possible side-effects. If necessary, he/she will recommend medically accepted treatments (like lowering the dose, switching medicines, or adding a drug to counter the side-effects).

Risk of psychotic symptoms worsening: If you were taking a medicine that was helpful and it is changed to the study medicine, it is possible the study medicine (lumateperone or risperidone) will not work as well for you (this risk will be rare). If so, your doctor will address this by increasing the dose, switching medicines, or discontinuing the study.

Clinical and cognitive assessments: There is always the possibility of a loss of privacy when participating in research. Your privacy will be maintained as much as possible. You may feel uncomfortable with some of the questions asked during interviews (occasional). However, you may refuse to answer any of the questions at any time. There is also a possibility of fatigue when

participating in research. You may take breaks at any time throughout the course of the interview or testing. To help ensure your privacy, information collected as part of this project will be labeled with your unique identifier and will be entered into password protected computers, and stored securely in restricted and protected databases. Only relevant research staff will have access to this protected database located at the research clinic.

MRI Scan: The MRI machine is a large magnet. MRI scans are non-invasive and considered minimal risk. However, there are unforeseeable risks associated with MRI scans (rare). Loose metal objects, like pocket knives or key chains, are not allowed in the MRI room. If you have a piece of metal in your body, such as a pacemaker, nerve stimulator, or certain metal surgical implants, you will not be allowed into the MRI room and cannot have an MRI. You will complete an MRI safety screening form prior to being scanned. Having an MRI may mean some added discomfort to you. In particular, you may be bothered by feelings of claustrophobia (fear of closed spaces; occasional) and by the loud banging noise during the study. Ear plugs will be provided for your safety and comfort. Lorazepam may be prescribed by your doctor for claustrophobia. You can stop the brain scan at any time.

No long-term harmful effects from MRI are known. However, since the effect of MRI on early development of the fetus is unknown, subjects who are pregnant should not go in the MRI. If you are a woman 18 years of age or older and there is a possibility that you may be pregnant, you will be asked to take a urine pregnancy test before being allowed to participate in the study. You are the only person who will get the results; we will not report the results of the pregnancy test to anyone else. Rarely, large or recent tattoos can heat up during an MRI scan and cause skin irritation like a sunburn (rare), so the MRI technologist will want to see any tattoos you have prior to the scan.

Due to the very high sensitivity of MRI in detecting abnormalities, there is a risk of false-positive findings, identifying something on imaging studies that may or may not be important. This may result in anxiety and additional testing, possibly including a recommendation for clinical scans at your cost. The radiology report or other study data will not be put into your medical record unless you provide it to your physician. If the radiology report becomes part of your personal medical record, it may or may not have an effect on getting health insurance or life insurance in the future.

General risks (uncommon): There are risks of stress, emotional distress, inconvenience and possible loss of privacy and confidentiality associated with participating in a research study (rare).

Blood sample: Soreness and bruising (occasional); and infection, fainting and bleeding (rare). The results of most of your blood (eg. cell blood count, liver function, blood sugar, etc.) and urine tests will be posted in your UNM hospital medical record for your physician to see. The results of the urine drug screens, urine pregnancy tests (if applicable), and the blood samples genetic testing will not be posted to your medical record.

Risk of exposure to COVID-19: Due to the current global pandemic, there is an increased risk of exposure to the coronavirus (occasional). This is part of a "new normal" when going to any public setting. Study staff will follow State and Federal guidelines regarding social distancing, touch surface disinfecting, screening for symptoms of COVID-19, and wearing face masks. Despite these best efforts for risk mitigation, there is always a chance of getting coronavirus whenever there is contact with people.

There is always a chance that any medical treatment can harm you. The research treatments/procedures in this study are no different. In addition to risks described in this consent, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

Your participation in the study may help gain information and overall understanding of mental health conditions and treatment of future patients with conditions like yours. The potential benefits for this study are minimal. Participants will likely improve in their psychotic symptoms with blinded treatment, since improvement in first episode psychosis is over 90% with antipsychotic therapy. However, this should not be thought of as specific to the study since both drugs (lumateperone and risperidone) are available for prescription by any physician as part of the standard of care.

Also, if you participate in this study you will get an MRI of your brain with a report from a neuroradiologist. After completing the initial 6 weeks of the study, you will be offered lumateperone for treatment of psychotic symptoms at no cost to you for up to 6 months. However, without participating in the study, your regular Dr. can order an MRI and order lumateperone but you or your insurance would be responsible for the costs.

WHAT WILL IT COST YOU TO PARTICIPATE?

You will not be charged for any study procedures. The costs of the MRIs, blood and urine tests, study medications, and research clinic visits required by the research will be covered by the study. If you need assistance with transportations to and from your study appointment, the staff will make arrangements for a ride at no cost to you. You or your medical insurance will be responsible for the costs for any antipsychotic medication not provided by the study and for additional medications for side-effects, difficulty sleeping, or anxiety in the MR scanner.
You and/or your insurance company, Medicare, or Medicaid will be responsible for the costs of all care and treatment that you would normally receive for any conditions you may have. These are costs that are considered medically necessary and will be part of the care you receive even if you do not take part in this study.

If incidental findings from the study result in the need for further evaluation/treatment, then you or your insurance company will be responsible for any clinical evaluation/treatment that may be needed.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information for all participants. We will keep your name and other identifying information private. We will make every effort to prevent anyone who is not on the research team from knowing that you gave information, or what the information is.

Information collected as part of this study will be labeled with your unique identifiers and will be entered into a computer database that is password protected. Data linking your MRI scan to your identity will be maintained at the Mind Research Network indefinitely. This is because the neuroradiologist is required to compare future scans with previous ones.

You should know there are some circumstances in which we may have to show your information to other people. For example, the law may require us to share your information with the following agencies and for the following reasons:

- The law requires us to share your information with authorities if you report information about a child being abused
- If you pose a danger to yourself or someone else.
- A court or agencies, if you have a reportable disease or condition.
- Authorities, if you report information about a child being abused, if you pose a danger to yourself or someone else.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study. If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. The study medication will no longer be provided to you but will be available for purchase by your insurance company. This may occur for a number of reasons. You may be removed from the study if you are not able to follow the directions from study staff, they find that your participation in the study is more risk than benefit to you, or the agency paying for the study chooses to stop the study early for a number of scientific reasons.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEACH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may not take part in this study if you are currently involved in another research study. It is important to let the investigator and your doctor know if you are in another research study. You should discuss this with the investigator and your doctor before you agree to participate in another research study while you are in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call your research psychiatrist (Dr Bustillo, Dr Lenroot or Dr Tohen) at 505-272-9552 or the UNMH Psychiatric Emergency Service a 505-272-2920 and ask for the Research Psychiatrist on call immediately. Your research psychiatrist will determine what type of treatment, if any, is best for you at that time.

It is important for you to understand that the University of New Mexico does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of New Mexico will not pay for any wages you may lose if you are harmed by this study.

WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

You will receive up to $310 in merchandise cards for taking part in this study. In return for your inconvenience for participating in this study you will be paid $50.00 for each MRI scan, $10.00 for each blood test, $25.00 for the initial clinical assessments, $25.00 for the cognitive test and $20 for each of the weekly visits during the Study-Medication part of the study. If you withdraw from the study early, you will be paid for the portion of the study that you completed. If you earn $600 or more by participating in research, it is potentially reportable for tax purposes.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

You will be informed if the investigators learn new information that could change your mind about staying in the study. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

Dr. Mauricio Tohen, a co-PI on this study serves as a paid consultant for pharmaceutical companies that manufacture PH/PAH therapies, including Intra-Cellular Therapies, the sponsor of this study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESARCH TESTS?

Generally, tests done for research purposes are not meant to provide clinical information information/diagnoses and cannot be used to make decisions about standard medical care. All research MRI scans will be read by a neuroradiologist (a doctor with experience reading MRI scans) unless you have been scanned at MRN in the previous six months. When your scan is read, you will receive an e-mail letting you know you can download your MRI report from the Participant Portal Homepage. If we find an abnormality that requires follow-up, we may also mail a copy of the report to you, or contact you and your doctor (with your permission) by phone to help answer question. The MRN Medical Director or the research team is always available to answer any questions you may have about your scan.

There is a slight possibility that during a research project, an investigator could discover something that could affect the health of you or your family. If this occurs, the finding will be reviewed by the Research Psychiatrist treating you.

If so, the Research Psychiatrist will contact you using the information you provided. He/She will present possible risks or benefits of receiving the information. At that time, you can choose to receive or refuse the result or finding. If you would like more information about this, call the research staff Crystal Garcia at 505-272-9552.

You may also withdraw your consent to be contacted with information about research results or incidental findings by sending a written request to Crystal Garcia by email at crabaca@salud.unm.edu or by mail at MSC 11 6035, UNM Center for Psychiatric Research, 1101 Yale Blvd NE, Albuquerque, NM 87106.

Intracellular Therapies is providing financial support and/or material for this study.

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

WHAT ELSE DO YOU NEED TO KNOW?
If you volunteer to take part in this study, you will be one of about 60 people to do so at the University of New Mexico.

FUTURE USE OF YOUR PROTECTED HEALTH INFORMATION OR SPECIMEN(S).
Identifiable information such as your name, medical record number, or date of birth may be removed from the information or samples collected in this study. After removal, the information or samples may be used for future research or shared with other researchers without your additional informed consent.
In addition to the main study, you are being asked to allow us to keep and use your information for future research that involves examining brain imaging measures we collected with similar measures collected at other research centers.

HIPAA AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATIN (PHI).
As part of this study, we will be collecting health information about you and sharing it with others. This information is "protected" because it is identifiable or "linked" to you.

Protected Health Information (PHI)
By signing this Consent Document, as described in this consent form, you are allowing the investigators and other authorized personnel to use your protected health information for the purposes of this study. This information includes your psychiatric and medical records.
In addition to researchers and staff at UNMHS and other groups listed in this form, there is a chance that your health information may be shared (re-disclosed) outside of the research study and no longer be protected by federal privacy laws. Examples of this include health oversight activities and public health measures, safety, monitors, other sites in the study, companies that sponsor this study, government agencies such as Food and Drug Administration (FDA).

Right to Withdraw Your Authorization
Your authorization for the use and disclosure of your health information for this study shall not expire unless you cancel this authorization. This is because the information used and created during the study may be analyzed for many years and it is not possible to know when this will be complete. Your health information will be used or disclosed as long as it is needed for this study. However, you may withdraw your authorization at any time provided you notify the UNM investigators in writing. To do this, please send letter notifying them of your withdrawal to:

Juan Bustillo, MD
MSC 11 6035
UNM Center for Psychiatric Research
1 University of New Mexico
Albuquerque New Mexico 87131

Please be aware that the research team will not be required to destroy or retrieve any of your health information that has already been used or shared before the date that your withdrawal is received.

The researchers agree to only share your health information with the people listed in this document. Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws.

You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form it will not affect your:

- Current or future healthcare at the University of New Mexico;
- Current or future payments to the University of New Mexico;
- Ability to enroll in any health plans (if applicable); or
- Eligibility for benefits (if applicable).

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:

- You will send a written letter to Juan Bustillo, MD to inform him of your decision.
- Researchers may use and release your health information already collected for his research study.

The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of New Mexico Health Sciences Privacy Officer between the business hours of 8am and 5pm Mountain Pacific Time, Monday-Friday at (505) 272-1493.

Appendix 4: Subject Information to be stored for future research (e.g., registry, database, contact list).

WHAT IS A REGISTRY AND WHAT IS THE PURPOSE OF THIS REGISTRY?
The goal of the registry is to ask all participants if they would like to provide their information. Having data from many people allows the investigators to identify trends and discover better ways to diagnose, prevent, and treat many conditions.

WHERE WILL INFORMATION BE STORED AND FOR HOW LONG?
The information will be stored at the Mind Research Network.

WHAT WILL THE REGISTRY/DATABASE COLLECT AND STORE FOR RESEARCH?
We also would like to interview you for you to answer some questions on a form about your health, medical condition, medical history, and/or quality of life. You can skip any question that you do not want to answer.

HOW WILL THE REGISTRY INFORMATION BE SHARED WITH OTHER INVESTIGATORS?
Your information may be shared with University of New Mexico (UNM) investigators and investigators outside of UNM. Investigators may contact the registry to request permission to use information for their studies. An oversight committee will review the investigator's qualifications and proposed research. The committee will also determine if any additional review or approval is necessary. The registry will remove all information that could identify you such as your name, address, medical record number, etc., before sharing with investigators. The registry will not share information that could identify you without your permission.

Large-Scale Data Sharing
Investigators can do studies that are more powerful when they share with each other data or information they get from studying human samples. Information from analysis of your samples and your medical information may be put into scientific databases available on the Internet, along with information from other research participants. Your name and other information that could identify you will not be included. Therefore, no one would know just from looking at the data that the information came from you.

Privacy and Social/Psychological
There is a risk that someone could get access to the information stored in the registry. In spite of the security measures and safeguards we will use, we cannot guarantee that your identity will never become known.

Unknown
There may be risks that at this time are unknown. As technology advances, there may be new ways of linking information back to you that we cannot foresee now.

HOW IS YOUR PRIVACY AND CONFIDENTIALITY PROTECTED?
The registry will take careful steps to keep your information confidential. We will remove information such as your name or other direct identifiers from your medical information. We will label your information with a code. The coded information will be kept on a password protected server. Only select registry staff will have access to the list that links the code to you. The registry staff members sign an agreement to keep your identity a secret to the extent allowed by law. In very unusual cases, registry staff may be required to release your identifiable medical and research information in response to an order from a court of law.

DOES TAKING PART IN THE REGISTRY COST ANYTHING?
There will be no additional costs or charges to you for taking part in the registry.

ARE THERE OTHER CHOICES IF YOU DO NOT WANT TO PARTICIPATE IN THE REGISTRY?
If you do not want to take part in the registry, there are no other choices except not to take part. Your decision will not affect your current or future medical care.

WHAT IF YOU CHOOSE NOT TO PARTICIPATE OR CHANGE YOUR MIND AND WANT TO WITHDRAW FROM TAKING PART IN THE REGISTRY?
Taking part in the registry is voluntary. Choosing not to take part will not affect your care or cause you to lose benefits to which you are entitled. You may withdraw your permission to continue taking part in the registry at any time. To do so, you must send a written withdraw request to the registry at crabaca@salud.unm.edu. The registry will destroy any remaining information that has been stored. In addition, it may be possible for the registry to destroy the code that links you with your medical information. However, the information that has already been shared with other investigators or placed in shared databases cannot be withdrawn.

You have my permission to store my data in the MRN Data Sharing Repository for future research. Please initial next to your choice below.

YES _____ Initials
NO _____ Initials

We would like to request your permission to contact you for participation in future studies at the Mind Research Network. If you agree, your contact information may be shared with other scientists at MRN.

You have my permission to contact me about participation in future research studies. Please initial next to your choice below.

YES _____ Initials
NO _____ Initials

INFORMED CONSENT SIGNATURE PAGE

You are participating or are authorized to act on behalf of the participant. This consent includes the following:

- Key Information Page
- Detailed Consent
- Appendix 4

You will receive a copy of this consent form after it has been signed.

_____ _____

Signature of research subject, *or if applicable,* **Date**
**research subject's legal representative*

_____

Printed name of research subject

_____ _____

Signature of research subject, (ASSENT) **Date**

_____

**If applicable, printed name of research subject's legal representative*

*If applicable, please explain Representative's relationship to subject and include a description of representative's authority to act on behalf of subject:

_____ _____

Printed name of [authorized] person obtaining informed consent/HIPAA Authorization — Date

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Signature of [authorized] person obtaining informed consent/HIPAA Authorization

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