Consent and Authorization Document

BACKGROUND

You are being asked to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish. This form describes the purpose, procedures, benefits, recognized or known risks, discomforts, and precautions of the study including the duration and nature of your participation. It also describes recognized or known alternative therapies that may be available and your right to withdraw from the study at any time. No guarantees or assurances can be made as to the results of the study. Ask the research doctor or staff if there is anything that is not clear or if you would like more information. Take time to decide whether or not to volunteer to take part in this research study.

The purpose of the study is to evaluate the effects of 12 months of treatment with long-acting intramuscular (IM) aripiprazole in subjects with schizophrenia compared with standard of care (SOC) oral antipsychotic medications and compared with a healthy control group. Both the long-acting intramuscular (IM) aripiprazole and the oral antipsychotic medications are FDA approved standardly available treatments. You are being asked to participate in this study because you are a male or female between the ages of 18 and 35, and have a current diagnosis of schizophrenia. Long-acting IM aripiprazole and SOC oral antipsychotic medications are treatments used for schizophrenia. Otsuka America Pharmaceuticals, Inc. is paying the study center, the University of Utah, and the study doctor, Dr. Deborah Yurgelun-Todd, to conduct this study.

This is a Phase IV study. Phase IV studies are done after a drug or treatment has been marketed to gather information on the drug's effect in various populations and any side effects associated with long term use.

STUDY MEDICATION

This study involves the administration of long-acting IM aripiprazole and SOC oral antipsychotic medications. Study medication will be prescribed and administered according to recommendations contained in their respective product labeling.

The following treatments will be administered to subjects in this study:

- Aripiprazole (IM), 300 or 400 mg administered via gluteal injection, once monthly
- SOC oral antipsychotic medications, per oral (PO) including but not limited to:
    - Aripiprazole (Abilify®), 10 mg to 30 mg, daily
    - Risperidone (Risperdal®), 2 to 8 mg daily
    - Lurasidone HCl (Latuda ®), 40 to 160 mg daily
    - Quetiapine Fumarate (Seroquel®), 300 to 800 mg daily
    - Olanzapine (Zyprexa®), 10 to 30 mg daily
    - Ziprasidone HCl (Geodon®), 40 to 160 mg daily

STUDY PROCEDURES

There will be up to 80 participants in this study: approximately 60 males and females with schizophrenia and 20 healthy male and female controls. This is a randomized, open-label, parallel-group trial. "Randomized" means that participants are assigned to different groups by chance. "Open-label" means that both the researchers and participants know which treatment is being administered. "Parallel-group" means each participant is assigned to receive only one of the study treatments.

You will be asked to attend a Screening Visit, Baseline Visits, Conversion Phase (if applicable), Stabilization Phase, Treatment Period, and Follow-up Visit. Your participation is expected to last up to 14.5 months.

Screening Period

The Screening Visit will occur within 7 days prior to the receiving study drug. At the Screening Visit you will receive a full physical examination, and you will be asked some questions about your medical and social history, any medications you are taking, and your mood and personality. During your physical examination we will draw your blood and collect a urine sample for routine laboratory tests, to screen for drugs and alcohol, and test for pregnancy (in women of childbearing age); measure electrocardiogram (ECG) [a painless tracing of the electrical activity of the heart] recordings and your vital signs (blood pressure, heart rate, body temperature and breathing rate); and record your waist circumference, weight, height and body mass index (an estimate of your body fat based on your height and weight).

Randomization

After screening, you will be randomized to either the aripiprazole once monthly group or the SOC oral antipsychotic group in a 2:1 ratio.

- **Aripiprazole once monthly group:** Subjects in this group will receive aripiprazole once monthly at an approved dose based on the investigator's judgment and in accordance with product labeling administered via gluteal IM injection once monthly.
- **SOC oral antipsychotic group:** Subjects in this group will receive SOC oral antipsychotic medications prescribed by the study physician based on the investigator's judgment and in accordance with product labeling.

Baseline Visit

You will be asked to complete a Baseline Visit prior to entry into each phase of the study (i.e., Conversion Phase, Stabilization Phase, and Treatment Phase). During the Baseline Visit you will answer questions regarding your current antipsychotic therapy and any medications you are currently taking. Vital signs will be measured and body mass index (BMI) will be calculated. You will answer questions about your mood and feelings, and any adverse events or side effects you have experienced.

After the first Baseline Visit, if you:

- Are in the aripiprazole once monthly group and are not currently receiving oral aripiprazole monotherapy which means that you take only aripiprazole and no other antipsychotic medications, you will be given a prescription for your oral SOC antipsychotic medication and move into the Conversion Phase (Phase A) to begin cross-titration.
- Are in the aripiprazole once monthly group and are currently receiving oral aripiprazole monotherapy, you will move directly to the Stabilization Phase (Phase B).
- Require a washout from any prohibited medications, you will enter Phase A.
- Are in the SOC oral antipsychotic arm and do not require a washout from prohibited medications, you will move directly into the Stabilization Phase (Phase B).

Conversion (Phase A) – 4 to 6 weeks

In Phase A, if you are in the aripiprazole once monthly group and are not currently receiving aripiprazole monotherapy you will undergo cross-titration to receive oral aripiprazole monotherapy, 10 to 20 mg PO, daily. "Cross-titration" means that we will lower the dose of your current medication while simultaneously increasing the dose of another medication, in this case aripiprazole. In addition, if you are currently on a prohibited medication, you will require a washout from that medication. This means prohibited medications will be withdrawn on a schedule based on the investigator's judgment.

During Phase A, you will attend weekly visits until deemed eligible for Phase B by the investigator. The Baseline Visit for Phase B will occur during the last visit of Phase A.

Stabilization Phase (Phase B) – 4 to 12 weeks

In Phase B, you will be receiving SOC oral antipsychotic medication. All oral antipsychotic medications will be prescribed using doses consistent with their respective product labeling.

During Phase B, you will attend biweekly visits until stability criteria are met for two consecutive visits. If stability is not met within 12 weeks, you will be discontinued from the study. The Baseline Visit for Phase C will occur during the last visit of Phase B.

Treatment Period (Phase C) – 52 weeks

The Treatment Period consists of 18 Treatment Visits. Weeks 1 – 4 occur weekly; weeks 5 – 8 occur biweekly; and weeks 9 – 18 occur every 4 weeks.

- A total of 30 – 40 subjects with schizophrenia will receive aripiprazole once monthly. In addition, these subjects will continue to receive oral aripiprazole at the dose given prior to Phase C for 14 days.
- A total of 15 – 20 subjects will receive SOC oral antipsychotic medications, PO daily.
- A total of 15 – 20 control subjects will not receive any study drug; however, they will undergo all other Phase C assessments.

During Phase C, your vital signs, waist circumference, weight and height will be recorded; adverse events and any medications you are taking will be reviewed; clinical assessments regarding your thoughts and feelings will be administered; and pregnancy testing will be performed (for women of childbearing age).

After 6 and 12 months of treatment, you will receive a physical examination and ECG; provide blood and urine samples for routine laboratory tests and drug screening; and complete neuropsychological testing and an MRI protocol. The MRI protocol will last approximately an hour and thirty minutes, and the neuropsychological testing will last approximately an hour and fifteen minutes.

Follow-Up Period

If you receive at least one dose of study drug and are discontinued from the study for any reason, you will be followed for safety reasons for 30 days following the last dose of drug.

RISKS

During this study, you will be taking aripiprazole IM once monthly or SOC oral antipsychotic medications. Oral antipsychotic medications may include: Aripiprazole (Abilify®), Risperidone (Risperdal®), Lurasidone HCl (Latuda ®), Quetiapine Fumarate (Seroquel®), Olanzapine (Zyprexa®), and Ziprasidone HCl (Geodon®). The most common the side effects of antipsychotic medications are often mild such as drowsiness, rapid heartbeat, anxiety, an inner sense of restlessness, and dizziness. Other common side effects of antipsychotics may include:

- A drop in blood pressure upon standing or stretching (Orthostatic hypotension)
- Blurred vision
- Changes in cholesterol and triglyceride levels (dyslipidemia)
- Decreases in white blood cells
- Diarrhea, constipation
- Difficulty swallowing (Dysphagia)
- Dry mouth (Salivary Hypersecretion)
- Fatigue
- Increased levels of prolactin in blood (Hyperprolactinemia)
- Increased appetite, weight gain
- Increased risk of suicidal thoughts or actions
- Increases in blood sugar levels (Hyperglycemia)
- Involuntary muscle contraction (Dystonia)
- Nasal congestion, upper respiratory tract infection, Nasopharyngitis, and Pharyngolaryngeal pain
- Nausea, vomiting
- Neuroleptic Malignant Syndrome (NMS), a rare and serious condition that can lead to death
- Potential for cognitive and motor impairment
- Rash
- Seizures (convulsions)
- Tardive Dyskinesia (TD), symptoms include uncontrollable movements of face, tongue or other body parts.

- Upper abdominal pain, stomach discomfort, dyspepsia
- Weight gain

Participants receiving long-acting IM aripiprazole may also experience pain, swelling, redness, and induration at the injection site.

As part of this study, you may be asked to change your medications. During the time in which your medications are being changed, you may also notice that your symptoms are different. We anticipate minimal risk during this time and we will work closely with you to evaluate and minimize any worsening of symptoms.

During this study, you should not take any other medications without talking to the study doctor/staff. This includes over the counter medications, herbal or dietary preparations (tablets, capsules, etc.) or vitamins.

Magnetic Resonance Imaging (MRI)

There may be risks that are associated with MRI scans.
Unlike X-rays or CAT scans, magnetic resonance (MR) technology does not use 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
- Other metallic surgical hardware in vital areas
- Certain tattoos with metallic ink (please tell us if you have a tattoo)
- Certain transdermal (skin) patches such as NicoDerm (nicotine for tobacco dependence), Transderm Scop (scopolamine for motion sickness), or Ortho Evra (birth control)

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 anyone. Therefore, these types of items are not permitted in the scanning area.

The MR exams are painless, and except for pulsating sounds, the subject will not be aware that scanning is taking place. The sounds that subjects hear inside the scanner are the normal operating sounds the scanner makes. While they may be annoying, their intensity is not harmful to the subject's hearing. However, they will be given a pair of earplugs to wear to muffle the sounds as well as a set of headphones, which further reduces the noise level and permits communication with the MR technician.

The scans for this study take place on the 3.0T scanner, which is approved by the FDA for routine clinical studies in children and 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.

In rare cases, a very slight, uncomfortable tingling of the back due is induced in some people undergoing certain types of scans. Subjects are asked that, if they experience this sensation, to report it immediately so the scan can be changed to avoid this. Although these precautions will avoid all known risks associated with MRI, this procedure may involve risks that are currently unforeseeable.

Electrocardiograms (ECG)
There is no pain or discomfort during an ECG; however the patches may cause a skin reaction such as redness or itching. Taking the pads off my cause localized irritation to the skin and/or hair loss, similar to having a Band-Aid taken off.

Blood Draws
During the collection of blood samples, participants may experience pain and/or bruising at the needle injection site. Although rare, excess bleeding, clots, and infections at the injection site may occur. Lightheadedness and/or fainting may also occur during or shortly after the blood draw.

Confidentiality
Although every effort to protect personal health information will be implemented, it is possible that if confidential information is inadvertently disclosed, there could be negative effects on the participant; such as, a negative effect to employment or ability to obtain insurance.

REPRODUCTIVE RISKS
Magnetic Resonance Imaging (MRI)
If you are a female of childbearing age, a urine sample will be tested prior to MRI scanning, which will be tested to ensure that you are not pregnant. If you have a positive pregnancy result, we will inform you and you will not be allowed to participate in the study. It is important to be as sure as possible that you are not pregnant because the MRI technology being used may cause harm to an unborn child.

Study Drugs
It is unknown whether antipsychotic drugs can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Neonates exposed to antipsychotic drugs during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms following delivery. There have been reports of agitation, hypertonia (increased tightness of muscle tone and reduced capacity of the muscle to stretch), hypotonia (decreased muscle tone and strength), tremor, somnolence (sleepiness), respiratory distress and feeding disorder in these neonates. These complications have

varied in severity; while in some cases symptoms have been self-limited, in other cases, neonates have required intensive care unit support and prolonged hospitalization.

Contraception

To be in this study, you must agree to use an effective method of birth control during the course of the trial and for 30 days (female participants) and 90 days (male participants) after the last dose of oral antipsychotics, or 150 days (female participants) and 180 days (male participants) after the last dose of aripiprazole once monthly, in a manner such that risk of failure is minimized.

Two of the following methods must be used:

- Vasectomy
- Tubal ligation
- Vaginal diaphragm
- IUD
- Birth control pills
- Birth control depot injection
- Birth control implant
- Condom
- Sponge with spermicide

If you and your partner(s) are sterile (i.e., women who have had an oophorectomy and/or hysterectomy or have been postmenopausal for at least 12 consecutive months; or men who have had orchiectomy) or remain abstinent, there are no contraceptive requirements for your participation in this study.

Pregnancy

In the event that you suspect pregnancy or become pregnant, it is very important for the investigator to be informed of the pregnancy immediately. If you become pregnant prior to receiving study drug, you will not receive study drug and will be dis-enrolled from the study. If you become pregnant while taking study drug, the drug will be permanently discontinued in an appropriate manner and you will be withdrawn from the study. OAPI will monitor the course of your pregnancy, including perinatal and neonatal outcome, and the infant will be followed for a minimum of 6 months.

UNFORESEEABLE RISKS

In addition to the risks listed above, the study drugs and procedures may have unknown risks. There is always the possibility that you will have a side effect that is currently unknown or not expected. It is important that you report any and all symptoms/health problems to the study doctor/staff. You will be monitored for side effects and the study doctor may decide that you should be withdrawn from the study for your safety. If any new information becomes available during the course of the study that may affect your willingness to participate, you will be informed.

BENEFITS

Participation in this study is purely for research purposes, and will not improve your health or treat any medical problem you may have. You may benefit by having physical examinations. The results of laboratory tests done at the screening visit will be made available to you upon request; however, if you are disqualified for study participation by other screening procedures, some laboratory tests may not be conducted.

There may be no other direct benefits to you from this study. In the future, the information from this study may help others by providing important knowledge about the use of long acting IM aripiprazole versus oral antipsychotic medications for the treatment of schizophrenia.

ALTERNATIVE PROCEDURES

You may choose not to be in this study. If you choose not to participate, you may continue to receive treatment from your doctor. Standard treatments include a range of medications, taken by mouth or by injection. If you currently do not have a doctor you may wish to contact one of the following mental health resources:

- University Neuropsychiatric Institute (UNI)
  801-583-2500
- UNI Adult Behavioral Clinic
  801-585-1212
- Fourth Street Clinic
  801-364-0058
- Valley Mental Health
  Phone: 801-270-6550
  www.vmh.com
- Valley Mental Health 24-Hour Crisis Line
  Phone: 801-587-3000
- National Alliance on Mental Illness
  www.nami.org
- University of UT Counseling Center
  Phone: 801-581-6826
- University of UT Center for Student Wellness
  Phone: 801-581-7776
  http://www.wellness.utah.edu/index.htm

PERSON TO CONTACT

If you have questions, complaints or concerns about this study, or if you feel that you have been harmed as a result of participation, please call the following people:

Principal Investigator:	Deborah Yurgelun-Todd, Ph.D. (801) 587-1471 (Monday-Friday 9AM-5PM)
Co-Investigators:	Melissa Lopez-Larson, M.D. (801) 587-1554 (Monday-Friday 9AM-5PM)
	Erin McGlade, Ph.D. (801) 587-1412 (Monday-Friday 9AM-5PM)
Research Assistant:	Jennifer DiMuzio (801) 587-1471 (Monday-Friday 9AM-5PM)

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

RESEARCH-RELATED INJURY

If you are injured from being in this study, medical care is available to you at the University of Utah as it is to all sick or injured people. The University of Utah has not set aside any money to pay the costs for such care. The University will work with you to address costs from injuries. Costs would be charged to you or your insurance company (if you have insurance), to the study sponsor or other third party (if applicable), to the extent those parties are responsible for paying for medical care you receive. Since this is a research study, some health insurance plans may not pay for the costs. By signing this consent form you are not giving up your right to pursue legal action against any parties involved with this research.

The University of Utah is a part of the government. If you are injured in this study, and want to sue the University or the doctors, nurses, students, or other people who work for the University, special laws may apply. The Governmental Immunity Act of Utah is a law that controls when a person needs to bring a claim against the government, and limits the amount of money a person may recover. See sections 63G -7-101 to -904 of the Utah Code.

VOLUNTARY PARTICIPATION

It is up to you to decide whether or not to take part in this study. If you decide to take part you are still free to withdraw at any time and without giving a reason. Refusal to participate or the decision to withdraw from this study will involve no penalty or loss of benefits to which you are otherwise entitled. If you don't take part, you can still receive all standard care that is available to you. This will not affect the relationship you have with your doctor or other staff, nor decrease the standard of care that you receive as a patient. Should you choose to withdraw, you should notify Dr. Yurgelun-Todd or the research staff, and the study doctor.

You may be asked return to the study doctor for a final examination. During this final examination a physical examination, vital sign assessment, ECG, and clinical laboratory tests may be performed. A review of your current medications and any side effects you may have experienced may be assessed. Also, you may be asked to complete a clinical assessment to determine your emotional state and mood.

If your participation in the study is terminated for any reason, information related to your participation in the study that was collected prior to termination of your participation may continue to be used and disclosed by the study doctor for the purposes described in this consent form.

RIGHT OF INVESTIGATOR TO WITHDRAW

Dr. Yurgelun-Todd may make study withdrawal determinations, in coordination with participants, and their non-study treating clinician. Your study participation could be discontinued by the study doctor, without your consent, for any of the following reasons:

a. the Sponsor cancels the study;
b. the study doctor feels it is in your best interest;
c. you need medication that would interfere with the study;
d. your participation needs to be discontinued in order to comply with study requirements;
e. at the request of the subject, investigator, OAPI or designee, or regulatory authority;
f. you become pregnant;

Your participation in the trial will also end if any of the following criteria are met:

a. If any adverse event, intercurrent illness or abnormality in a laboratory assessment occurs that, in the opinion of the investigator, warrants your permanent withdrawal from the study
b. If there is an increase in suicidal or homicidal ideation, study termination/withdrawal will be at the discretion of Dr. Yurgelun-Todd, in consultation with you and their treating clinician(s). The investigators will work closely with the treating clinician(s) to maintain participant safety, and to arrange for inpatient hospitalization if it is necessary. Participants whose clinical condition necessitates a move to a higher level of care (inpatient hospitalization) in order to maintain safety will be withdrawn from the study.
c. If you are unable or unwilling to adhere to the study protocol, the Principal Investigator retains the right to withdraw them from the study without their permission.

If Dr. Yurgelun-Todd determines that the investigational drug presents an unreasonable and significant risk to you she will discontinue the investigation immediately and notify the FDA, IRB, and the co-investigators. You will be notified immediately if the study is discontinued for safety reasons.

COSTS AND COMPENSATION TO PARTICIPANTS
There is no cost to you for participation in this study, except costs of transportation to the study doctor's office. The study visits, study-related procedures and tests, and study medication will be provided free of charge.

You will be compensated up to $725.00 for your participation in this study.

Since you will be paid for participating in this study, it is necessary for us to collect your Social Security Number. You will provide this information for a Federal W-9 Form that is filed with our Accounts Payable department. Accounts Payable will have limited access to the study information (e.g. the name of the study) for payment purposes. The amount you receive for taking part in this study will be turned into the Internal Revenue Service (IRS) as taxable income. You can choose not to provide us with your Social Security Number for this form and still participate in this study; however we will not be able to pay you as outlined in this consent form.

NEW INFORMATION
You will be told by Dr. Yurgelun-Todd or her staff of any significant new findings that develop during the course of this study that may affect your willingness to continue participating in this study. You may then use this information to make a decision about remaining in the study.

NUMBER OF PARTICIPANTS
We expect to enroll 80 participants at the University of Utah.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION
Signing this document means you allow us, the researchers in this study, and others working with us to use some information about your health for this research study.

This is the information we will use and include in our research records:

- Name
- Address
- Telephone number
- Date of birth
- Social security number
- Medical and medication history
- Information from physical examinations; such as, blood pressure reading, heart rate, breathing rate, and temperature
- Information created or collected during the study

How we will protect and share your information:

- We will do everything we can to keep your information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.

- A description of this clinical trial will be available on http://www.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.

- In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:
    - Members of the research team and authorized members of the University of Utah who need the information to perform their duties (for example: to provide treatment, to ensure integrity of the research, and for accounting or billing matters);
    - The University of Utah Institutional Review Board (IRB), who reviews research involving people to make sure the study protects your rights;
    - Otsuka America Pharmaceuticals, Inc. (including its affiliates and partners), a pharmaceutical company that will make determinations regarding the disclosure of study information;
    - Food and Drug Administration, a federal agency that may inspect and/or copy the records that identify you, or health authority in other countries where this drug is being studied.

- If we share your identifying information with groups outside of the University of Utah Health Science Center, they may not be required to follow the same federal privacy laws that we follow. They may also share your information again with others not described in this form.

- If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at the University of Utah Health Sciences Center.

What if I decide to Not Participate after I sign the Consent and Authorization Form?
You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

You have a right to information used to make decisions about your health care. However, your information from this study will not be available during the study; it will be available after the study is finished.

CONSENT

I acknowledge I have been given an opportunity to ask questions regarding this research study and these questions have been answered to my satisfaction. I understand that if I have additional questions of in the event of a research-related illness or injury, I may contact Dr. Yurgelun-Todd at phone number 801-587-1471.

In the event I have any questions regarding my rights as a research subject, I may contact the University of Utah's IRB or Ethics Committee at phone number 801-581-3655.

In giving my consent, I acknowledge my participation in this research project is voluntary and I may refuse or withdraw from participation at any time without penalty or loss of benefits to which I am otherwise entitled. My signature below means I have read this consent form, understand its contents, and all my questions concerning this study have been answered by Dr. Yurgelun-Todd and her staff. It also means I agree that my personal health information may be used and transferred in the ways described in this informed consent form and that my personal health information may be added to research databases and used in the future by Sponsor, its affiliates, and licensing partners to develop a better understanding of safety and effectiveness of the study medication(s), study other therapies for patients, develop a better understanding of disease(s) included in the study, and to improve the efficiency, design and study methods of future clinical trials. I understand that I will not lose any of my legal rights as a research subject by signing this consent form.

I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.

_____
Participant's Name

_____ _____
Participant's Signature Date

_____
Name of Person Obtaining Authorization and Consent

_____ _____
Signature of Person Obtaining Authorization and Consent Date

If the participant is unable to give consent and authorization, consent and authorization is given by the authorized personal representative of the individual:

LEGALLY AUTHORIZED REPRESENTATIVE CONSENT STATEMENT:
I confirm that I have read this consent and authorization document. I have had the opportunity to ask questions and those questions have been answered to my satisfaction. I am willing and authorized to serve as a surrogate decision maker for

_____.
Participant's Name

I have been informed of my role and my obligation to protect the rights and welfare of the participant. I understand that my obligation as a surrogate decision maker is to try to determine what the participant would decide if the participant were able to make such decisions or, if the participant's wishes cannot be determined, what is in the participant's best interests. I will be given a signed copy of the consent and authorization form to keep.

_____
Name of Authorized Personal Representative

_____ _____
Signature of Authorized Personal Representative Date

Indicate the legal representative's authority to act for the individual:
☐ Spouse

☐ Adult (18 years of age or over) for his or her parent
☐ Individual with power of attorney
☐ Guardian appointed to make medical decisions for individuals who are incapacitated