

**Institutional Review Board
Informed Consent Document for Research**

Principal Investigator: Insert Name.
Study Title: Insert Title
Institution/Hospital: Insert Name(s)

This informed consent applies to adults

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form carefully and ask any questions you may have about this study. If you decide to participate a copy of this consent form will be given to you to keep.

- A) You are being asked to participate in this study because:**
- a. You have been diagnosed with _____ (insert diagnosis)
 - b. In the past seven years, you have been treated with medicine and your symptoms did not get better.

- B) Your Rights:**
- a. You may choose not to be in this study and get other treatments without changing your healthcare, services or other rights.
 - b. You can stop being in this study at any time.
 - c. You do not have to be in this study to get treated for your condition. Other drugs and treatments are available. The study doctor will discuss with you the risks and benefits of other treatments. You may be able to get this medicine from the doctor you are currently seeing.
 - d. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

The Purpose of this Study:

In this study, researchers are going to look at two strengths (doses) of a long-acting injectable medication called Risperdal Consta. One hundred and sixty patients are expected to participate in this study throughout the nation. Twenty-two patients are expected to participate here. If you participate, you will be involved in the study for about six months.

The people participating in the study will be divided into 2 groups.

Group One will get the usual dose of the medication (50 mg) given every two weeks.

Group Two will be given a higher dose (75 -100 mg) every two weeks. The researchers are trying to find out which dose is better at improving symptoms of your mental illness.

You should know three things:

1. Although (Insert name of medication) is approved by the Food and Drug Administration (FDA) to treat schizophrenia, using a higher than usual doses makes its use in this study investigational. This means it is not approved by the FDA at this dose for schizophrenia.
2. You should also know that Risperdal Consta has not been approved by the Food and Drug Administration (FDA) to treat schizoaffective disorder. However, the medications that are useful for schizophrenia are also useful for the psychosis of schizoaffective disorder.
3. The details of this study will be posted on websites for patients looking for studies in which to participate. Your personal information will not be posted.

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Participating in the Study: If, after we talk about the study and you decide you want to participate, you will be asked to sign this form that says you agreed to take part.

Screening Visit: We will conduct a screening to make sure that you are right for the study and the study is right for you. The screening visit will take about 2 hours; during that time, the following will be done or asked:

- You will be given a physical exam
- You will be asked questions about your physical and mental symptoms now and in the past.
- We will ask you to give us the name of a close relative and ways to contact them so the research staff can ask them questions about medications you have taken in the past. This person should be someone who knows about your treatment.
- Your vital signs (weight, height, waist size, blood pressure) will be checked.
- Females will be asked to give a urine sample for a pregnancy test. The pregnancy test will be repeated every two months if you enroll in the study. If you are pregnant you cannot take part in this study because this medication can hurt an unborn child. If you become pregnant after you start the study, you must withdraw from the study.

After Screening: If it is determined that you are right for the study and the study is right for you and you still want to participate, you will be scheduled for a base-line visit.

1. You will be randomized (like a flip of a coin) into one of two groups. Remember that Group One will get the usual dose of Risperdal Consta) (50 mg) given every two weeks, and Group Two will be given a higher dose (75 -100 mg) given every two weeks. **You will not be told which group you are in.**
2. You will be asked to come to the research clinic every two weeks to get your medication. People in both Group One and Two will get two injections (shots) in the hip every two weeks. If you are in Group One, one of the injections (shots) will contain a placebo. That means there is no active drug in it.
3. At the end of the six month study, you will be sent back to the doctor who prescribed medication for your symptoms before you began the research study.

The Baseline Visit: This visit takes about four hours and a lot of things will happen

1. You will be given
 - Tests to measure your memory and attention.
 - Tests to measure your movement.
 - An ECG will be done (ECG is another name for an electrocardiogram). This test checks the electrical activity of your heart to tell us about possible heart problems you may have. Electrode patches similar to a round Band-Aid will be placed on your chest. These will be read by an ECG machine to show the electrical activity of your heart.)
 - You will have 30 ml (about 2 tablespoons) of blood drawn from your arm. This will be sent to a lab at Vanderbilt University. This will measure your cholesterol, hormone levels and blood sugar.
2. You will be asked questions about your symptoms.
3. Your current medication will be stopped and the study medication, Risperdal Consta), will start. You will get two injections (shots) in your hip(s). While you are adjusting to the change from your current medication to the study medication, you will be given oral risperidone (to

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be taken by mouth) at a dose chosen by the study doctor to take daily. You will stop taking the Risperdal Consta) after Week 3 of the study. After Week 3, you will receive the injections (shots) only.

4. You will be scheduled to return to the clinic every two weeks to get your injections (shots) until the end of the study.
5. During weeks 2, 4, 10, 14, 16, 20 and 22 you will only get your shots and have your vital signs taken. In addition, all women in the study will have a pregnancy test. No other study assessments will be done.
6. During weeks 6, 12, 18 and 24 your visits will take about 4 hours. You will be asked about any medications and or drugs you are taking. You will be asked about any side effects you may be having. Your memory and attention will be tested. Tests to measure your movement will be done. You will be asked questions about your symptoms. 30 ml of blood (about 2 tablespoons) will be drawn from your arm. This will be sent to a lab at Vanderbilt University. This will measure your cholesterol, hormone levels, and blood sugar. You will be given your two shots Risperdal Consta.

Side effects & Risks: No study or medication is free of risk or side effects.

The most **common** side effects that occurred people have had taking Risperdal Consta in the treatment of schizophrenia are:

- ▶ Dizziness
- ▶ Headache
- ▶ Sleeplessness
- ▶ Jerky or slowed movement
- ▶ Leg pain
- ▶ Cold symptoms

Uncommon side effects include:

- ▶ Shaking
- ▶ Sleepiness
- ▶ Restlessness
- ▶ Upset stomach
- ▶ Diarrhea
- ▶ Constipation
- ▶ Dry mouth
- ▶ Nerve pain
- ▶ Fatigue
- ▶ Coughing
- ▶ Weight changes
- ▶ Vision changes
- ▶ Toothache
- ▶ High blood pressure
- ▶ Swelling of arms, legs

Rare side effects include:

- ▶ Unusual dreams
- ▶ Upper airway (mouth, nose or throat)respiratory tract infection
- ▶ Skin changes (acne, dry skin)
- ▶ Fever

Some studies have shown that taking medicines like an atypical antipsychotic such Risperdal Consta puts you at risk for high blood sugar so your blood sugar will be tested often during the study. You will be told to seek care from your medical doctor if necessary.

A condition known as tardive dyskinesia may occur with use of medicine like Risperdal Consta. These are slow or jerky movements of the body or face that won't go away and can't be controlled.

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A rare but serious side effect that has been reported with this kind of medicine is NMS or neuroleptic malignant syndrome. NMS causes rigid muscles and fever and can be serious.

Persons 65 and older will not be allowed to participate in the study. This is because elderly patients (aged 65 years or greater) with dementia-related psychosis related to dementia (a disease of memory loss) treated with medicines like Risperdal Consta atypical antipsychotic drugs are more likely to die at an increased risk of death compared to patients taking a no active drug (placebo).

Woman who are able to have children, must agree to not get pregnant while in this study because this treatment may hurt an unborn child. The study staff will talk with you about ways to prevent pregnancy while you are in the study. It is important that you use your birth control the right way. You and any person you have sex with must use approved birth control such as birth control pills, birth control shots, IUD, diaphragm, or condoms while you are in this study. Any changes to your birth control method during the study must be discussed first with the doctor.

If you become pregnant or father a child while you are in this study, you must tell your doctor at once. You will not be allowed to participate if you are currently breastfeeding your child. This is for the safety of you and your child.

There is a chance that your symptoms will get worse. The research staff will contact you between study visits to see if talk about your symptoms. You may be asked to come in to the clinic to see the doctor at times other than the study visits to see how you are doing. If your symptoms get worse and that makes it difficult for you to make decisions, we will ask a doctor who is not a part of this study, to assess you and determine whether you should continue to participate in this study.

There is a chance for redness, swelling or hardening at the site of the injections (shots). These injections (shots) will be given by skilled and qualified research staff to ensure your safety and to keep any discomfort as low as possible.

There is a chance for redness or irritation of the skin where the electrode patches are placed during the ECG at the screening visit.

During the scheduled blood draws, pain, redness, soreness, bruising, or infection may occur at the needle stick site. It is rare but some people feel faint. These blood draws will be done by skilled and qualified staff to ensure your safety and to keep any discomfort as low as possible.

Your medication dose may be increased or decreased if the doctor determines it is in your best interest to do so.

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Unknown Risks

Because one of the doses of Risperdal Consta used in this study is not approved by the FDA and neither dose is approved for schizoaffective disorder there may be risks we do not know about at this time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

Costs to you if you take part in this study:

You will not pay for your research visits. The study drug Risperdal Consta and procedures will be provided at no cost to you. The costs of any other medications you take will be billed to you or your insurance plan, just as they would be if you did not take part in the study. You are responsible for the costs of any other medications you take.

Payments for your time spent taking part in this study or expenses:

You will be paid \$15 for each study visit for a total of \$210 if you complete all study visits.

Payments in case you are injured while in this study:

It is the policy of the *insert institution(s) name(s)* that if you are hurt or become sick as a result of research procedures, medical treatment will be provided to you but neither institution will pay for this treatment.

If you have any questions about the legal responsibility of the *insert institution(s) name(s)*, you may call the *insert institution(s) name(s)* at *insert phone number* or the Office of Research Administration at SCDMH at during normal business hours.

You will still be responsible for the cost of treatments and tests you receive during the study that are not investigational (related to the study). These are the treatments and tests you would need whether you are in this study or not. The cost of treating your illness or underlying condition and the cost of treating any injuries that are caused by these routine tests or treatments while you are in the study will be billed to you or your insurance company. If for any reason these costs are not covered by insurance, you will have to pay the costs.

Who to call for any questions or in case you are injured:

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact *insert researcher name* during normal business hours or in an emergency outside of normal business hours please call *insert emergency number* and ask to speak with the on-call doctor.

For additional information about giving consent or your rights as a person in this study, please feel free to call *insert researcher name*.

Benefits that might result from this study:

- a) What we learn may help other patients in the future.
- b) Your symptoms of schizophrenia may improve.

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Reasons why the study doctor may take you out of this study:

The study doctor or sponsor may remove you from the study without your permission for any of the following reasons:

- if it appears to be medically harmful to you
- if you become pregnant
- if you are put in jail or are hospitalized against your will
- if you are not able to take the study drug because of side effects
- if you fail to follow directions for taking part in the study
- If we learn you do not meet what is required to be in the study

If you are taken out of the study, you will be told the reason. You may be asked to complete a final safety visit.

If you decide to stop being in this study:

If you decide to stop being part of the study, you should tell your study doctor. Choosing to not be part of the study will not change your regular care in any way. Taking part in this study is your choice. You may refuse to take part. You may drop out of this study at any time without losing your ability to get care for your illness now or in the future.

Confidentiality:

All efforts, within reason, will be made to keep your personal information in your research record confidential but we can not promise total confidentiality. Your study information will be identified only by your initials and a number known only to the research staff. Your information will be kept in a locked cabinet which only research staff can access.

Privacy of Protected Health Information:

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by the research team. The research team includes the researchers listed in this consent form, other staff involved in this study at the **insert institutional name(s)**. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, **insert researcher name** and the study team may share the results of your study and/or non-study linked data as well as parts of your medical record, to the groups named below. These groups may include people from the: Federal Government Office for Human Research Protections, the South Carolina Department of Mental Health Institutional Review Board, **insert names of all other institutional review board names**.

Federal privacy rules may not apply to these groups; they have their own rules to assure that all efforts, within reason, will be made to keep your PHI private. The sponsor may give your health data, without your name, to others or use it for other research projects not listed in this form.

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The sponsor, **insert name(s)** will keep your PHI in strict confidence, and will comply with any and all laws regarding the privacy of such information.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be destroyed. Any research data that has been put into your medical record will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI will last forever. If you change your mind, we ask that you contact **insert researcher's name** in writing and let him/her know that you withdraw your consent. The mailing address is: _____
At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality. If you need help with this please call **insert name** at **insert number**.

You have the right to see and copy the PHI we gather on you for as long as the study doctor or research site holds this data. To ensure the scientific quality of the research study, you will not be able to review some of your research data until after the research study is finished.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date Signature of patient/volunteer

Consent obtained by:

Date Signature

Printed Name and Title