Study Title: The Impact of Health Literacy on the Attitudes toward Pharmacological Treatment in Patients with Schizophrenia Spectrum Disorder

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Participant ID:

Louisiana State University Health Sciences Center - New Orleans

Consent to Participate in Research

STUDY TITLE: The Impact of Health Literacy on the Attitudes toward Pharmacological Treatment in Patients with Schizophrenia Spectrum Disorder

PRINCIPAL INVESTIGATOR: Jaudé Petrie, MD

STUDY SPONSOR: Louisiana State University Health Sciences Center- New Orleans

1. Invitation to be Part of a Research Study

Drs. Jaudé Petrie, Rahn K. Bailey, and associates from the Psychiatry Department at the Louisiana State University Health Sciences Center -New Orleans (LSUHSC-NO) and University Medical Center – New Orleans (UMCNO) are conducting a research study. A research study is a scientific way to improve or develop new methods of health care. Studies are designed to answer specific questions on how to prevent, diagnose, or treat diseases and disorders. This study is being funded by **Janssen Scientific Affairs, LLC**. The research team is asking you to be in this study because you have a new diagnosis or history of schizophrenia spectrum disorder and can provide valuable information and insight into the factors that drive medication adherence. **Research studies are voluntary and include only people who choose to take part.** The researchers will explain this study to you and this consent form will help you decide if you want to participate. Before deciding:

- You can discuss this study with friends and family.
- You can also discuss it with your health care doctor or request a second opinion.
- If you have any questions, you can ask the researchers for more information before deciding to participate.
- Even if you choose to participate, you can decide to stop participating at any time.

In this consent form, "you" always refers to the participant. If you are a legally authorized representative, please remember that "you" refers to the study participant.

2. Important Information about this Research Study

This section lists the key characteristics of this study and the basic reasons why you may or may not want to take part. It is only a summary. The sections following this summary have more details, including contact information for people who can answer any questions or

concerns you may have. Please take the time to read this whole document and ask questions before deciding if you want to take part in this research study.

Things you should know:

- The purpose of the study is to see if a person's knowledge about schizophrenia influences their likelihood of taking medications that treat schizophrenia and following up with their healthcare provider.
- In order to participate, you must be 18 years of age or older, have a new diagnosis or history of schizophrenia spectrum disorder, and be able to read and comprehend the English language.
- If you choose to participate, you will be given educational resources about schizophrenia spectrum disorders and asked to complete a series of questionnaires while you are being treated in the hospital. After you are discharged from the hospital, you will receive phone calls from our research team to ask you follow up questions on a monthly basis. You will be in the study for 12 months if you decide to stay for the whole study.
- The main risks of being in the study are not greater than everyday life. However, there is a risk that you may possibly be exposed to upsetting information or questions. If at any time you feel uncomfortable with the information or questions, you may ask to take a break or end the session.
- You might benefit from being in the study because it may expand your knowledge about schizophrenia spectrum disorders and available treatment options, and it will provide you with an opportunity to engage in one-on-one question and answer sessions with a healthcare provider trained in the field of psychiatry or psychology.
- Taking part in this research study is voluntary; you do not have to participate. If you do take part, you can stop at any time.

3. Why is this study being done?

Schizophrenia is part of a spectrum of mental health conditions in which people have difficulty forming and expressing clear thoughts. It is often associated with hallucinations, in which a person hears or sees things that are not really there. Although there are many different treatment options available, there are barriers that can make it more difficult for people to seek and obtain treatment, including the stigma around mental health conditions, lack of access to healthcare services, and poor health literacy. Health literacy is the amount of knowledge a person has in regards to their health conditions and treatment options.

Several studies have shown that better health literacy is associated with improved healthcare outcomes. This study is being performed to determine if such an association exists between knowledge about schizophrenia spectrum disorders and attitude towards treatment and medication adherence. Therefore, having a new diagnosis or history of schizophrenia is a requirement for participation. We think the attitude towards treatment and likelihood of medication adherence will be higher for patients with more knowledge about the disorders. Information collected from this study can provide guidance on how to

better educate people with mental health conditions so that they can make healthier choices and feel more empowered in their care.

4. What will happen if I take part in this study?

Before you begin the study

Before you begin the study, your chart will be reviewed to determine if you have been diagnosed with schizophrenia spectrum disorder in the past or if your current hospitalization is consistent with schizophrenia spectrum disorders. If you have a previously documented or suspected diagnosis of intellectual disability or borderline functioning, you will not be able to participate in the study, as the study will require you to read and complete multiple choice questionnaires.

During the study

If you agree to take part in this study, you will be asked to complete a series of questionnaires on different days while on the inpatient psychiatry unit. First, you will take the Knowledge about Schizophrenia Test (KAST) in order to get a health literacy baseline. Then, you will answer an assessment that asks questions on your attitude towards medications, medical care, and treatment. After that, you will be provided with educational resources in written and video format and allowed to participate in one-on-one sessions with a healthcare provider. During this time, you may ask any questions you have. Once you have completed the educational sessions, you will repeat the Knowledge about Schizophrenia Test and the attitude towards treatment questionnaires. During the study, you will still undergo labs and treatment in line with the standards of care. Once you have completed the educational phase and are discharged from the hospital, you will receive 12 monthly follow-up calls to discuss adherence to your treatment, side effects, and any concerns you may have.

Results of research testing on you or your sample(s) may be given to you or your doctor. This will be done only if the results may be necessary for your care.

5. How many people will take part in this study and how long will it last?

34 people will take part in this study at LSUHSC-NO and UMCNO.

If you complete the entire study, your participation will last 12 months. We will follow up with you once a month via telephone calls for the next 12 months.

6. What are the risks of taking part in this study?

Known risks and discomforts

We do not anticipate any risks from participating in this research. However, you may be exposed to difficult, uncomfortable, or upsetting information or questions during the study. If this occurs, you can inform the healthcare provider you will be interacting with that you are uncomfortable and would like to take a break from the session. It is the standard of care to be started on medications to treat schizophrenia while you're in the hospital. If you develop any side effects from any of the medications, please inform the investigator either during your initial hospitalization or during one of the follow-up calls.

7. Are there any benefits to participating in this study?

Possible benefits to you

There will be no direct benefit to you from participating in this study.

Possible benefits to others or society

This study will help the researchers learn more about the relationship between a patient's knowledge and their ability and willingness to stick to their treatment plan. This information may help in the treatment of future patients with schizophrenia spectrum disorder.

8. What other choices do I have if I don't take part in this study?

The alternative is not to participate.

You do not have to take part in this research study to be treated for schizophrenia spectrum disorders or any other mental health conditions you may have. You will still be able to explore treatment options while you are in the hospital, as well as with your healthcare provider once you are discharged.

9. How will my information be kept confidential?

The researchers will protect your information by creating a numerical patient ID that will replace your name, so that your name and other identifiable health related information are not directly reported in the data. We will make every effort to maintain your privacy, but we cannot guarantee complete confidentiality. For example, there is always a risk of someone breaking into a computer system where your information may be stored. Federal or state law also may require us to disclose your records. Loss of confidentiality is a potential risk of taking part in this study.

The following people or groups may review your study records for purposes such as quality control or safety:

- The study sponsor and/or representative of the sponsor
- Representatives of LSUHSC-NO and the LSUHSC-NO Institutional Review Board
- Representatives of UMCNO and the UMCNO Research Review Committee
- Other organizations or agencies if required by law.

The results of the study may be released to the funding agency Janssen Scientific Affairs, LLC. A description of this clinical trial will be available on 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. If any publications and/or presentations result from this study, they will not identify you by name.

10. Will my information or specimens be used for future research?

Data will not be used for future research.

11. Will there be any costs to me for taking part in this study?

We will bill you and/or your insurance company (or healthcare plan) for the costs of any standard medical care you receive during your participation in the study. This includes standard medical care to treat any known or unknown side effects you may experience. There is a possibility that your insurance company may not cover these costs because you are in a research study. If this happens you might have unexpected expenses. If the insurance company does pay for the standard care, you may be responsible for any co-payments and deductibles.

We do not have money to pay for any disability, damages such as lost wages, or similar outcomes that you may experience.

12. Will I be paid for taking part in this study?

You will receive a $50 ClinCard for your participation in this study. Payments will occur once you have completed the initial screening tests, educational sessions, and follow-up questionnaires. There will be no partial payment, and no payment will be received if you do not complete the previously mentioned tasks. You will be responsible for any taxes assessed on the compensation.

13. Who can profit from study results?

No researchers will profit from the study.

14. Who can I contact if I have questions about this study?

The research team:

You may contact the following individuals with any questions or concerns about the research or your participation in this study.

Principal Investigator **Co-Investigator**

Name: Dr. Jaudé K. Petrie
Address: 2021 Perdido Street, 6th Floor
New Orleans, LA 70112
Phone #: 504-270-1670
E-mail: PsychStudy8277@lsuhsc.edu

Name: Dr. Rahn K. Bailey
Address: 2021 Perdido Street, 6th Floor
New Orleans, LA 70112
Phone #: 504-702-2000
Research Injury Phone #: 504-270-1670

Office of the Chancellor, LSU Health Sciences Center - New Orleans:

You may contact the Office of the Chancellor by phone at (504) 568-4801, if

- you have questions about your rights while taking part in this study, or
- you have any concerns or suggestions, and
- want to talk to someone other than the researchers about the study.

15. What will happen if I cannot complete the study?

There are several reasons why you may not complete the study.

The researchers or the study sponsor might decide to stop the study at any time.

The researchers may end your participation in this study, without your permission, for a number of reasons including:

- Your safety and welfare are at risk.
- You do not follow instructions.
- You miss scheduled visits.
- You fail to complete study activities.

You also may decide on your own to stop participating in the study. If you are thinking about withdrawing, let the researcher know so he/she may remove you from the study safely. You also should seek medical advice for alternative treatments. The researcher will inform you of any significant new findings during the study that may impact your willingness to continue participation.

If you decide to stop being in the study, or the study is stopped, or you are removed from the study, the researcher will ask you to complete an exit telephone interview.

Information collected about you up to the point of withdrawal will remain part of the study. You may not remove this data from the study database. We will keep this information confidential.

16. Your Participation in this Study is Voluntary

Taking part in this study is your choice. You are free not to take part or to withdraw at any time for any reason or no reason at all. No matter what you decide, there will be no penalty to you and you will not lose any services, benefits or rights you would normally have. If you want more information about your rights as a research participant, please visit https://www.lsuhsc.edu/administration/academic/ors/participant_information.aspx.

Participant ID:

17. Your Consent

By signing this document, I acknowledge or am aware that:

- The researcher(s) discussed the study with me and answered all my questions.
- I will receive a copy of the consent form.
- I do not waive any of my legal rights by signing this consent document.
- I can contact the study team or the Chancellor's Office using the contact information provided above if I have any questions or concerns after signing the consent form.

Signature of Participant:

I agree to take part in this study.

Participant Signature	Printed Name	Date

Signature of Person Obtaining Consent:

I have explained the research to the subject and answered all his/her questions. I will give a copy of the signed consent form to the subject.

Signature of Person Obtaining Consent	Printed Name	Date

18. Who can I contact during evacuations or emergencies?

Please keep this card with you at all times for use during evacuations or other emergencies. Please cut along the dotted lines, fold along the solid line.

CONTACT INFORMATION	**STUDY INFORMATION**
If you need to get in touch with researchers during an evacuation or other emergency, please contact: **Name:** Dr. Jaudé K. Petrie **Phone**: 504-270-1670 *If you are unable to contact the person named above, please call the Office of Research Services at:* **504-568-4970** or (toll-free) **866-957-8472**	**Sponsor:** Louisiana State University Health Sciences Center **LSUHSC-NO IRB #: 8277** **PI: Dr. Jaudé K. Petrie** **Site:** University Medical Center **Participant ID: _____** *Please be prepared to provide this information to your healthcare provider during routine or emergency medical service.*

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Participant ID:

Louisiana State University Health Sciences Center - New Orleans
& University Medical Center - New Orleans

Permission to Use Protected Health Information for Research

STUDY TITLE:	**The Impact of Health Literacy on the Attitudes toward Pharmacological Treatment in Patients with Schizophrenia Spectrum Disorder**
STUDY IRB#:	**8277**
PRINCIPAL INVESTIGATOR:	Jaudé Petrie, MD
SPONSOR:	**Louisiana Health Sciences Center-New Orleans**
FUNDING AGENCY:	**Janssen Scientific Affairs, LLC:**

1. What is the purpose of this form?

Federal and state privacy laws protect the release and use of your health information. Under these laws, your health care provider, Louisiana State University Health Sciences Center - New Orleans (LSUHSC-NO) or University Medical Center – New Orleans (UMCNO) cannot release or use your protected health information (PHI) for research purposes unless you give your permission. The purpose of this form is to inform you of the information that will be released and how it will be used or shared, and also for you to give permission.

If you decide to give your permission and to participate in the research study named above, you must sign this form as well as the Consent Document. Your information will be released to the research team which includes the principal investigator listed above; other researchers hired by the sponsor, LSUHSC-NO or UMCNO; and people with authority to oversee the research. This research team will use and protect your information as described below and in the Consent Document. However, once your health information is released by LSUHSC-NO or UMCNO, it may not be protected by the privacy laws and might be shared with others.

If you do not sign this form, LSUHSC-NO and UMCNO will not obtain, use or share your PHI for research but you will not be able to participate in the research study. Your decision to not sign this form will not affect any treatment, medical care, enrollment in health plans or eligibility for benefits. If you have questions, please ask a member of the research team.

2. What Protected Health Information will be released or used?

If you give your permission and sign this form, you are allowing those involved in providing your care and treatment to release the following PHI. Your PHI includes health information in your medical records, financial records and other information that can identify you.

A. ☐ **Complete Medical Record** (Complete health record(s) include all records, except those listed in Section 3, as well as "other" notes or documents relating to my treatment or hospitalization);

OR

B. **One or more of the specific records checked below.**

☒ Ambulatory Clinic Records	☒ Discharge Summary	☒ Psychological Tests
☒ Progress Notes	☒ Consultations	☐ Lab & Pathology Reports
☒ Hospital Inpatient Records	☒ Emergency Department Records	☐ Financial Records
☒ Other Test Reports	☒ Imaging Reports	☒ Diagnosis & Treatment Codes
☐ Dental Records	☐ Photographs, Videotapes	☐ Other
☐ Operative Reports	☒ History & Physical Exams	

Describe "Other": Click or tap here to enter text.

3. Do I have to give my permission for certain specific uses?

Yes. Please place your initials on the line(s) corresponding to the information, if any, for which you are giving permission to release.

_____ I agree to the release of information pertaining to drug and alcohol abuse, diagnosis or treatment.

_____ I agree to the release of HIV/AIDS testing information.

_____ I agree to the release of genetic testing information.

_____ I agree to the release of information pertaining to mental health diagnosis or treatment.

_____ I DO NOT agree to the release of information listed above.

4. Who will release and/or receive my Protected Health Information?

Your Protected Health Information may be obtained, used or shared with these individuals or organizations for the following purposes:

- To the Principal Investigator listed above and the research team described in the Consent Document;
- To others with authority to oversee the research (i.e., Institutional Review Board (IRB), safety monitoring committee, oversight board, etc.);
- To healthcare providers who provide services to you or analyze your health information in connection with the research study;
- To insurance companies or others responsible for your medical bills in order to secure payment;
- To others who are required by law to review the quality and safety of the research, including: U.S. government agencies, such as the Food and Drug Administration or the Office of Human Research Protections; the research funder or the funder's representatives; other federal or state agencies; or government agencies in other countries.

LSUHSC-NO and UMCNO are required by law to protect your health information. By signing this form you authorize LSUHSC-NO and UMCNO to collect, release use or share your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them.

5. How will my Protected Health Information be shared for the research?

If you agree to be in this study, the research team may share your PHI in the following ways:

- To perform the research;
- Share it with researchers in the U.S. or other countries;
- Use it to improve the design of future studies;
- Share it with business partners of the sponsor; and/or
- File applications with U.S. or foreign government agencies to get approval for new drugs or health care products.

6. Am I required to sign this document?

No. You are **not** required to sign this document. If you decide not to sign this document, you will still receive the same clinical care, or any services you were already entitled to receive. However, if you do not sign the document, you will not be able to participate in this research study.

7. What about optional research activities?

The research study you are agreeing to participate in may have additional optional research activities such as the creation of a database, a tissue repository or other projects, as

explained to you in the informed consent process. If this is the case, please indicate your approval or disapproval for sharing your information for these optional activities by placing your initials on the appropriate line.

☒ This study does not have any optional research activities.

_____ I agree to allow my information to be disclosed for the additional optional research activities explained in the informed consent process.

_____ I DO NOT agree to allow my information to be disclosed for the additional optional research activities explained in the informed consent process.

8. Does my permission expire?

This permission to release, retain, use or share your Protected Health Information:

☒ Expires when the research ends and all required study monitoring is over.

☐ Does not expire. [**NOTE:** If researchers want to retain PHI indefinitely, a justifiable rationale for doing so must be described in the IRB application.]

9. Can I cancel my permission?

Yes, you can cancel your permission at any time. You can do this by writing to a member of the research team. Please send your written request to:

Name:	Dr. Jaudé Petrie
Title/Role:	Principal Investigator
Physical Address:	2021 Perdido Street, 6th Floor New Orleans, LA 70112
Email Address:	PsychStudy8277@lsuhsc.edu
Phone Number:	504-702-2000

If you cancel your permission, you will no longer be in the research study. You may want to ask someone on the research team if canceling will affect your medical treatment.

If you cancel, no more health information about you will be collected. However, information that has already been collected and disclosed about you may continue to be used as necessary to maintain the integrity of the study (i.e. complete the research). Also, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study.

10. What if I have more questions about my privacy rights?

Any privacy rights not specifically mentioned in this form are contained in the Notice of Privacy Practices that you received or will receive from the Principal Investigator or at the facility that you attend.

If you still have further questions about your privacy rights, you may contact the individual listed in Section 9.

11. Permission(s)

Participant:

If you agree to the release and use of your Protected Health Information, please print your name and sign below. You will be given a signed copy of this form.

Participant Name (Print) – ***Required***

Participant Signature Date

Witness:

If this form is being read to the subject because s/he cannot read the form, a witness must be present and is required to print his/her name and sign here:

Witness' Name (print)

Witness Signature Date