Official Title: **Reduction of Anticholinergic Medications Among Persons With Schizophrenia or Other Psychiatric Disorders** (RAMP)

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CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: **R**eduction of **A**nticholinergic **M**edications **P**roject (**RAMP**) among Persons with Schizophrenia or other psychiatric disorders across UPMC Behavioral Healthcare Partner Organizations using a stepped-wedge, randomized trial study design.

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Key Information

You are invited to participate in a research study because you are 18 years of age or older and have been diagnosed with a psychiatric condition. Examples: Schizophrenia, Schizoaffective Disorder, Bipolar Disorder, or Major Depressive Disorder. Based on screening done by the study team, you may be an appropriate candidate for anticholinergic medication reduction.

Participation in this research study is voluntary and only includes people who choose to take part. The research team will answer any questions you have before you make your decision.

- You will be compensated for your participation in the study.
- Study procedures include a clinical examination, an interview, questionnaires, review, and collection of information from medical records, consultation with your psychiatric treatment team, and review of the medications you are receiving.
- Risks of the study include potential anxiety while answering questionnaires or during clinical interviews, potential breach of confidentiality and potential side-effects when anticholinergic medications are reduced and/or stopped eventually. Discussion of these risks and efforts to minimize these are discussed in detail later in this document.

Purpose of this Research Study/Project

This project aims to reduce and/or stop anticholinergic medications that may no longer be needed in your treatment. The anticholinergic medications which may no longer be needed include benztropine (also known as Cogentin), and /or trihexyphenidyl (also known as Artane). You may be receiving one or more of these medicines. These medications were likely prescribed to decrease muscle stiffness, hand tremors, or restlessness caused by the psychiatric medications you are taking. However, these side effects may have resolved, and you may not need these medications anymore. Importantly, these anticholinergic medications have their own side effects, e.g., dry mouth, constipation, blurred vision, bladder problems, and memory problems and can affect the quality of life.

If you choose to volunteer for the project, we will gather information from your medical records, your healthcare team, and through questionnaires.

You will be receiving services at one of four UPMC Western Behavioral Health (WBH) Clinics and Programs in Pennsylvania.

1. Western Psychiatric Hospital (WPH) BH Clinics and Ambulatory Programs in Pittsburgh, Pennsylvania
2. UPMC Western Behavioral Health (WBH) at Mon Yough, McKeesport, Pennsylvania

3. UPMC Western Behavioral Health of the Alleghenies in Altoona, Pennsylvania
4. UPMC Western Behavioral Health at Safe Harbor in Erie, Pennsylvania

Each site will begin the project at a different time, for example one site could start in a particular month and another site could begin 2 to 4 weeks later. This means that we will be collecting some data on your participation before your team begins to reduce the anticholinergic medication. The purpose is to get some baseline information before the anticholinergic medication is reduced and/or eventually discontinued.

What procedures will be performed for research purposes?

If you agree to take part in this project, you will undergo the following procedures that are not part of routine care in the clinic.

1. Baseline or first visit:

    a. You will review and sign this informed consent document if you decide to participate.
    b. Your eligibility will be determined by a combination of interviews, review of medical records, including medications you receive, talking to your healthcare team and a clinical assessment for muscle stiffness, tremors, or restlessness.
    c. A questionnaire assessing anticholinergic side effects such as dry mouth, constipation, blurred vision, and whether these impact your quality of life. A short memory test will be undertaken.

    The project team will work with your healthcare team (psychiatrist/nurse practitioner/ physician assistant) to reduce the anticholinergic mediations slowly. Between visits, if you are worried about a return of muscle stiffness or tremors or restlessness, you can call or meet your healthcare team members, to work with them to, go back to the previous dosage or slow down the reduction of the anticholinergic medicine.

2. Second Visit:

    This will happen approximately 4-8 weeks after the first visit. We will assess you clinically by interview, the use of questionnaires, and review of your medication and medical records, to check how you are doing with the reduction of the anticholinergic medication.

    The questionnaires that were given to you in the first visit will be repeated. Some of the questionnaires may look a little different from the first version to avoid what is called “practice effects” but both versions measure the same memory tasks.

3. Third Visit:

   This will happen approximately 12 to 16 weeks after the first visit. Once again, we will assess your clinical situation using a combination of clinical interviews, review of medical records and medications, and the use of questionnaires. This is the final visit of the project. At this visit, we will request your healthcare team to fill out a survey on how the project was seen from their point of view, and a survey for you to see how you thought of your participation in the project.

The baseline or first visit will take nearly 1.5 hours to complete, the second visit will take about 30 minutes, and the final visit will take about one hour to complete.

What are the possible risks, side effects, and discomforts of this research study?

Interviews and questionnaires: some people may find interviews and filling out questionnaires make them a little nervous. The study staff will be sensitive to your needs and will work with you to make you as comfortable as possible, and you don't need to answer questionnaires that make you uncomfortable.

Reduction and/or stoppage of anticholinergic medication: some of the side-effects for which these medications were originally prescribed may re-emerge and result in muscle stiffness or tremors or restlessness. Some people may experience headaches, nausea, or loose stools when these medications are stopped and that is why this reduction in medicine is done slowly and not suddenly. The study team of doctors and staff will work closely with you and your healthcare team to return you to the previous dosage of the medication and monitor you to see these re-emergent side-effects decrease and/or resolve.
A rare side effect called Neuroleptic Malignant Syndrome (NMS) has been reported in association with dose reduction or discontinuation of trihexyphenidyl (Artane). The clinical symptoms and signs include very high fever, muscle rigidity, mental confusion, and irregular blood pressure, fast heartbeat, sweating and heart rhythm changes. If any of these symptoms occur, please call 9-1-1 and go to an emergency room as this can be a medical emergency.

Physical Assessments - Simpson Angus ScaleThe Simpson Angus scale is used to evaluate side effects of medication. During the evaluation, we will observe how you walk and whether you are experiencing things like stiffness, tremors and/or excess salivation. Sometimes being observed causes subjects to feel uneasy or anxious, but our study team is always mindful of this and of putting you at ease.

Breach of Confidentiality:
In rare cases, people not associated with this project may unintentionally see the identifiable research results. Study staff will attempt to prevent this from happening by keeping all research records in

locked files or password protected databases, and by identifying all medical information by a research record number, rather than by name. The file that links your research record number to your name and personally identifiable information will be kept separately, accessible only by members of the research team.
Text Messages may not be encrypted or secure during their transmission or storage and it is possible they could be intercepted and used by others not associated with this study.
Emails may not be encrypted during transmission or storage and may be intercepted and used by others not associated with this study.

What are benefits from taking part in this study?

There is no guarantee of direct benefit from participating in this project. It is possible that reduction of the anticholinergic medications may improve some of the anticholinergic medication side effects such as dry mouth, constipation, blurred vision, or memory problems. Moreover, your participation may lead to knowledge that might help others.

Reduction of Anticholinergic Medication

The study team of doctors and pharmacists will work closely with your healthcare team to plan the reduction of anticholinergic medications. You will remain in contact with your clinical team and if you need to be seen more often than you see them, arrangements will be made for you to see them. The speed or slowness of the reduction of anticholinergic medications will be a decision shared with you and your healthcare team. The study team will consult with your clinical team for purposes of individualizing the reduction of the anticholinergic medication and for safety monitoring, and study visits.

Clinical programs at UPMC Western Psychiatric Hospital and Western Behavioral Health have protocols in place to monitor and decrease risks associated with medication reduction. As part of your clinical care, you will undergo ongoing medical evaluations with your treatment team to confirm you are appropriate for and can continue with reduction of the medication.

Who is being asked to take part in this research study?

People invited to participate in this study are adults 18 years or older who have been diagnosed with schizophrenia or schizoaffective disorder or Bipolar disorder or Major Depressive Disorder or other psychiatric conditions. You will be using one or more of the anticholinergic medications (benztropine, and/or trihexyphenidyl) for 6 months or more, and your healthcare team will let us know you have been clinically stable. Your study or healthcare team will confirm that you do not have muscle stiffness or tremors or restlessness anymore.

What treatments or procedures are available if I decide not to take part in this research study?

The usual care you receive for your condition will continue to be available to you regardless of whether you participate in this study.

If I agree to take part in this research study, will I be told of any new risks that may be found over the course of the study?
You will be promptly notified if, during the conduct of this research study, any new information develops which may cause you to change your mind about continuing to participate.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?

Neither you, nor your insurance provider, will be charged for the costs of any of the procedures performed for this research study (i.e., the Screening Procedures, filling out scales or doing a short memory test, or Follow-up Procedures described above). You will be charged, in the standard manner, for any clinic visit as part of your routine medical care.

Will I be paid if I take part in this research study?

Payments: You will be paid $100 for participating and completing the entire study. Participants will receive $30 for Visit 1, $20 for Visit 2, and $50 for Visit 3. These participant payments will help to defray the cost of participation in this study, (baby-sitting, or missing work, etc.).
In addition, transportation/parking fees related to your participation in this study may be paid for by the study grant if the team caring for you considers this will assist in your participation.

All compensation is taxable income to you regardless of the amount. If you receive more than $600 in a calendar year for participation in studies from one organization, that organization is required by law to file a Form 1099 – Miscellaneous with the IRS and provide a copy to the taxpayer. You may still participate in the research if you do not provide a social security number, but the IRS requires that 24% of the payment be sent by the institution to the IRS for 'backup withholding;' thus you would only receive 76% of the expected payment.

Who will know about my participation in this research study?

Any information about you obtained from this research will be kept as confidential (private) as possible. All records related to your involvement in this research study will be stored in a locked file cabinet or secured database. Your identity on these records will be indicated by a case number rather than by your name (de-identified), and the information linking these case numbers to your identity will be kept separate from the research records.

You will not be identified by name in any publication of the research results.

With your permission, we can provide information from the study to your doctors or health care team members.

Will this research study involve the use or disclosure of my identifiable medical information?

This study will involve the use of your past, current and future identifiable medical information. The research staff will use your medical information from the UPMC- Western Psychiatric Hospital and Western Behavioral Health Network clinics and programs to help determine whether you are eligible to participate. Additionally, if you are found eligible, Dr. Chengappa and/or the members of the study teams will continue to access your medical record and monitor your clinical progress for the duration of this study for purposes of safety and to communicate with your healthcare team.

If identifiable medical information from a non-UPMC provider is requested, the staff member will ask you to sign a release of records authorization form.

This research study will not involve the disclosure of your identifiable medical information to individuals who are not investigators or research staff members for this study. If you wish to withdraw your consent to use your medical record information, you must submit it in writing to Dr. Chengappa at the address on page 1. If you decide to withdraw your consent to use your medical record information, you will not be allowed to continue in this study.

Who will have access to identifiable information related to my participation in this research study?

In addition to the investigators listed on the initial pages of this consent form and their research staff, the following individuals will or may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study:

Authorized representatives of the University of Pittsburgh Office of Research Protections may review your identifiable research information (which may include your identifiable medical information) for the purpose of monitoring the appropriate conduct of this research study.

In unusual cases, the investigators may be required to release identifiable information (which may include your identifiable medical information) related to your participation in this study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

We will store your data indefinitely. We may share data with other researchers and/or federal repositories in the future, but those researchers will not be able to identify you (de-identified). De-identified information may be used by other researchers for future studies. Your data may be used in any type of research. If this happens, we will not contact you for additional consent. Authorized representatives of the sponsor of this research study, the NCATS/NIH, may review and/or obtain identifiable information (which may include your identifiable medical record information) related to your participation in this research study for the purpose of monitoring the accuracy and completeness of the research data and for performing required scientific analyses of the research data. This study has a data sharing plan consistent with NIH policy. Final data that has not yet been published will be shared after acceptance of publication of the relevant paper. Data will be de-identified before sharing on the agreement that once the data analysis is complete, the data will be returned or destroyed. While the study sponsor understands the importance of maintaining the confidentiality of your identifiable research and medical record information, UPMC-WPH and UPMC-WBH and University of Pittsburgh cannot guarantee the confidentiality of this information after it has been obtained by the study sponsor. The investigators involved in the conduct of this research study may receive funding from the sponsor to perform the research procedures and to provide the sponsor with identifiable research and medical record information related to your participation in the study.

Authorized representatives of the UPMC hospitals or other affiliated healthcare providers may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of (1) fulfilling orders, made by the investigators, for hospital and healthcare services (e.g., laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and/or (3) for internal hospital operations (i.e. quality assurance).

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

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?

The investigators may continue to use and disclose, for the purposes described above, identifiable

information (which may include your identifiable medical information) related to your participation in this research study for a minimum of seven years after final reporting or publication of a project.

Is my participation in this research study voluntary?

Your participation in this research study is completely voluntary. You may choose to discuss this study with your family or your personal physician prior to agreeing to participate. You may refuse to take part in this research study, or you may stop participating at any time, even after you sign this consent form. Your decision will not affect your relationship with or the care you receive from Western Psychiatric Hospital and Western Behavioral Health Clinics and Programs of UPMC.

Your doctor may be involved as an investigator in this research study. Before agreeing to participate, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not obligated to be a part of any research study offered by your doctor.

May I withdraw, at a future date, my permission for participation in this research study?

To withdraw from this study, you will need to contact the investigator listed on the first page of this consent form. If you withdraw from this study, we will continue to use the information we have collected from your medical records and any of the interviews and/or group sessions up to the date of your withdrawal.

FDA Clinical Trial Registry [21 CFR 50.25]

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by US 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 I agree to take part in this research study, can I be removed from the study without my consent?

It is possible that we may remove you from the research study, if you cannot complete the study as requested, such as failure to consistently attend sessions. Also, if you have a serious relapse(s) of your psychiatric condition, or a medical disorder, or continued abuse of illicit drugs or alcohol.

What if I am injured during this research study?

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals and clinics affiliated with UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. Currently, there is no plan for any additional financial compensation. You do not waive any rights by signing this form.

Your data and specimens used in this research study may contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by the investigators and the University of Pittsburgh for use in other research or the development of new products. You will not retain any property rights, nor will you share in any money that the investigators, the University of Pittsburgh, or their agents may realize.

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VOLUNTARY CONSENT

The above information has been explained to me and my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during this study, and that such future questions will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns, or complaints be addressed by a listed investigator.

I understand that I may contact the Human Subjects Protection Advocate of the Research Protection Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that occurred during my participation.

By signing this form, I consent to participate in this research study and authorize the use of my medical records. A copy of this consent form will be given to me.

_____	_____	_____
Participant's Signature	Printed Name of Participant	Date

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named

individual(s) and I have discussed the potential benefits and risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____	_____
Printed Name of Person Obtaining Consent	Role in Research Study
_____	
Signature of Person Obtaining Consent	Date