**INFORMED CONSENT AND AUTHORIZATION**

**INSERT TITLE OF RESEARCH STUDY**

**Instructions for this template:**

1. Place the following into the footer of each page: Version #, Date, Page # of #. Create at least a 1.4-inch margin at the top of each page to make sure the IRB stamp in the right-hand corner will not block any of the content.
2. Highlightedor **red font** gives directions/guidelines. **Delete these instructions and all highlighted text before finalizing the document.**
3. Consent forms should be written at an appropriate reading level to ensure that the subject matter is accessible to the target population.
4. Plain text is **suggested/sample** wording. Plain text separated by ***OR*** indicates that there are several options. Pick one and delete the others.

Investigator(s) name, Degree, University Department, & address:

Sponsor(s) name and address: (if externally funded)

Site(s) where study is to be conducted:

Phone number for subjects to call for questions

**Introduction**

**Inform the subject that they may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want to participate or not. Assure the subject that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they can ask questions now or later.**

**If this is a federally-funded study that will be initiated on or after January 21, 2019, you must replace this Introduction sections with the Key Information Summary. The Key Information Summary template can be found** [**here**](https://www.wright.edu/research/compliance/policies-procedures-and-forms)**.**

The purpose of this consent form is to give you information about this research study. It will describe the purpose, procedures, benefits, risks, and discomforts of this study. The principal investigator and/or the study staff will discuss this study with you and explain everything in detail. Please ask them to explain any words or information that you do not clearly understand.

It is up to you to decide whether or not to take part in this study. If you choose not to participate your decision will not affect your current or future relationship with **Wright State University or Premier Health nor will it affect your health care at Premier Health**.If you decide to participate, you are free to withdraw at any time without affecting that relationship. Please read this entire consent form and take your time to make your decision. We encourage you to talk to **your doctor, your family, and/or your friends** before you decide.

**Who is conducting and funding this research study?**

**All consent forms should disclose which agencies, institutions, cooperative groups, foundation or industry sponsor are funding the research. If the study is not being funded by an external agency, then the internal founding source should be identified. Include information about any financial relationships the investigators may have with the funding source.**

Wright State University (WSU) or Premier Health (PH) will be conducting this trial under the direction of **Dr. Z**, principal investigator. The study will be funded by **(insert sponsor name)** and **Dr. Z** and **WSU/PH** will be compensated for conducting the study.

**OR**

Wright State University (WSU) will be conducting this trial under the direction of **Dr. Z**, principal investigator. This study is being carried out with funds received from the WSU Department of Psychology.

**Why is this research study being done?**

**Insert protocol specific text to describe the purpose of the study in lay language.**

The purpose of this study is to compare standard treatment, combined with drug X, to standard treatment plus a placebo. The use of drug X in this study is considered investigational, meaning it has not been approved by the FDA for marketing in the United States for the use being testing in this research. A placebo is an inactive substance which looks like the active drug, i.e. a “sugar pill”.

**Why am I being asked to participate in this research study?**

**State why this subject has been chosen for this research: people often wonder why they have been chosen to participate and may be fearful, confused or concerned.**

You are being asked to take part in this study because you haveseizures that have not responded well to the medications currently available.

**How many people will be in this study?**

**Complete the sentence with the maximum number of subjects you are requesting to be enrolled. You will have approval for this number only so make sure it is sufficiently high. If a multicenter trial, add the total number of subjects anticipated for the whole study and the number of sites.**

A total of 1,000 subjects will participate in this study at 30 sites internationally. Wright State University would like to enroll 10 subjects.

**OR**

Approximately 100 subjects may be involved in this research at Wright State University.

**What will happen if I take part in this research study?**

**After reading this section, the subject must be able to understand what will happen to them and what they will be expected to do as part of the research. Describe or explain the exact procedures that will be followed on a step-by-step chronological basis, the tests and research procedures that will be done, and any drugs that will be given.**

**Distinguish which items and services are experimental or for research purposes only and which are standard care for the subject’s condition and would occur whether or not they participated in the research.**

**Include the frequency and the total length of time for participation. Use lay language to define technical terms or tests.**

If you agree to be in this study, the following will happen:

**Before you begin the study – Screening Procedures**

You will need to have the following exams, test or procedures to find out if you can be in the study. These items will take about 1 hour to complete:

**List only the tests and procedures conducted for research purposes do not include a description of standard of care (SOC) tests and procedures. However, if SOC tests and procedures will be reviewed and recorded as part of the research, include a statement to that effect.**

* History and physical examination which will include checking your heart rate, blood pressure and temperature.
* Height and weight measurements.
* Blood tests (about 1 tablespoon) to measure blood counts, blood mineral levels, and check liver and kidney function.
* A pregnancy test if you are capable of becoming pregnant.
* Review of medications and supplements you are currently taking.

During the Study

This research will take place at **(insert location)**.

OR

If different procedures will take place at different locations, specify accordingly.

If the screening exams, tests or procedures show that you can continue to be in the study, and you choose to take part, then the following will be done.

If you agree to take part in this study, you will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance (like pulling numbers out of a hat). A computer program will place you in one of the study groups. Neither you nor your doctor can choose the group (also referred to as an “arm”) you will be in. You will have anequal chanceof being placed in any group.

If you are in **Arm A** you will be given the current standard treatment for this type of cancer plus Drug X. Side effects and quality of life information will also be collected and compared with Arm B.

If you are in **Arm B** you will be given the current standard treatment for this type of cancer plus a placebo. Side effects and quality of life information will be compared with Arm A.

You will receive study treatment for 48-weeks, returning for visits at week 1, 4, 8, 20, 24, 32, 44 and 48 after the first dose of study drug. These visits will last approximately 1 hour.

The following procedures will be completed:

* You must have no food or drink except water for 8 hours prior to arriving at the study site.
* You will be asked questions about your medical history, and information about any drugs that you are taking from your last visit.
* A physical exam including vital signs (blood pressure and heart rate), will be performed.
* Your hips and waist circumferences will be measured by the research study staff.
* An electrocardiogram (ECG) will be collected. An ECG is a test that measures the electrical activity of your heart. Electrodes will be attached to the outer surface of the skin.
* You will have blood drawn for routine lab work. (About 6mL or 2 teaspoonfuls of blood will be drawn).
* CT scan: You will have a computed tomography (CT) scan of your **(insert body part)** to check for***(*insert reason)*.*** A CT scan uses special x-ray equipment to make detailed pictures of body tissues and organs. For the CT scan you will lie still on a table with your **(insert body part)** inside a large donut-shaped machine. **{Explain what will happen during the procedure, what the patient will experience, how long it will take, etc. If using a contrast agent, explain what it is, why it is being used and how it will be given.}**

MRI (magnetic Resonance Imaging)

MRI machines use a strong magnet and radiofrequency magnetic fields to make images of the body interior. The scanning procedure is very much like an X-ray or CT scan. You will be asked to lie on a long narrow table for a certain amount of time **(insert duration)** while the machine gathers data. During this time you will not be exposed to x-rays, but rather a strong magnetic field and radiofrequency magnetic fields, which you will not feel. You will, however, hear repetitive tapping noises that arise from the Magnetic Resonance scanner. We will provide earplugs or headphones that you will be required to wear. The space within the large magnet in which you lie is somewhat confined, although we have taken many steps to relieve the "claustrophobic" feeling.

**How long will I be in this research study?**

**Include a statement about the time commitments of the research for the subject including both the duration of the research and follow-up, if relevant. If there is a wash-out period, address this in lay terms specifying the length of time. This information could be included in a table which might be easier for the subject to understand.**

If you choose to take part, you will be on the study for a minimum of 59 weeks from the first Screening Visit through the final follow-up procedures.

***OR***

You will receive the study intervention for 8 weeks and if randomized to Arm B you will receive an additional 12 weeks of study intervention.

After you are finished with treatment on the study, you will need to visit the office for follow-up exams every 3 months for the first two years and then every 6 months for the next three years after completion of your study treatment. If for any reason you are not able to complete study treatment we will still ask you to visit your doctor’s office for follow up exams and we will continue to collect data on your health status from your medical records during this period.

**Can I stop being in this research study?**

**Explain the procedures for the orderly termination of participation by the subject. If applicable, explain the consequences of a subject's decision to withdraw from the research. List any reasons specific to the study that a patient could be removed, if applicable. Describe any other circumstances for withdrawal.**

If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without any penalty. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled. If you withdraw from the study, or the study medication is stopped for any reason:

* **Add anticipated consequences, if any, of discontinuing the study drug or device.**
* **Clearly state the protocol-specific termination procedures.**
* **Instruct subjects that they must return all study-related supplies, including unused study drug.**

The principal investigator or study staff may also withdraw you from the study **and the study medication may be stopped [if applicable]**, without your consent for one or more of the following reasons: **(Note: Check your protocol; you may use these reasons and/or add some of your own).**

* Failure to follow the instructions of the research study staff.
* Pregnancy.
* You need treatment not allowed in the study.
* The study is cancelled.
* The principal investigator believes it is in your best interest.

**What are the potential risks and discomforts from being in this research study?**

**This section is required in all informed consent forms. For certain minimal risk research studies, it may suffice to say that “there are no known risks associated with the research”.**

**For all others risks, use lay language and bulleted lists to explain the possible risk and discomforts associated with each procedure, including the likelihood, severity and reversibility of each risk. If applicable, the side effects should be labeled according to frequency (e.g., likely, less likely, rare) and severity (e.g., serious, minor).**

**Identify each intervention/treatment/procedure with a subheading and then describe any reasonable foreseeable risks and discomforts. In addition to physical risks/discomforts, describe any psychological, social, legal or financial risks that might result from participating in the research.**

**If the study is a Phase I drug study, subjects should be informed that there may be adverse events that are unknown and include risks that may be permanent, severe or life-threatening.**

**If the study involves x-rays or other exposure to radiation such as CT scans, include the risks of the radiation exposure.**

**Include the following statement if the research involves a possible risk of a breach of privacy or confidentiality (i.e., identifiers, links to identifiers or code lists exist):** A risk of this research is a loss of privacy (revealing to others that you are taking part in this study) or confidentiality (revealing information about you to others to whom you have not given permission to see this information).

Risks of an MRI:

Magnetic fields do not cause harmful effects at the levels used in the MRI machine. However, the MRI scanner uses a very strong magnet that will attract some metals and affect some electronic devices. If you have a cardiac pacemaker or any other biomedical device in or on your body, it is very important that you tell the operator/investigator immediately. As metallic objects may experience a strong attraction to the magnet, it is also very important that you notify the operator of any metal objects (especially surgical clips), devices, or implants that are in or on your body before entering the magnet room. All such objects must be removed (if possible) before entering the magnet room. In some cases, having those devices means you should not have an MRI scan performed. In addition, watches and credit cards should also be removed as these could be damaged. You will be provided a way to secure these items. If you have any history of head or eye injury involving metal fragments, if you have ever worked in a metal shop, or if you could be pregnant, you should notify the operator/investigator.

**Risks and side effects for Arm B:**

**Likely:**

* Fatigue
* Low white blood cell counts which may make you more susceptible to infection
* Low red blood cell counts which may cause tiredness or shortness of breath
* Decrease in kidney function causing extra fluid and toxins to build up in your body
* Loss of appetite and weight loss
* Diarrhea, constipation, nausea and vomiting, and abdominal pain
* Numbness and pain of the hands and feet
* Skin rash
* Changes in taste
* Ringing in the ears and hearing loss
* Changes in electrolytes in the blood such as magnesium and potassium which may cause muscle weakness or twitching, irregular heartbeat, confusion or blood pressure changes

**Less Likely:**

* Allergic reactions which may be life-threatening with wheezing and low blood pressure
* Chills and fever with aches and pains
* Low platelet count which may make you bruise more easily and bleed longer if injured
* Sores in mouth and throat (that can lead to difficulty swallowing and dehydration)
* Vision changes: blurred vision, sensation of flashing lights or spots, inability to distinguish colors, blindness
* Complete hair loss

**Unknown:**

There may be risks from the **study drug/device** that are not known at this time.

**What are the reproductive risks?**

**This section is required only if applicable – delete paragraphs/sentences/sections that do not apply.**

**If you are a woman:** Participating in this research may involve risks to pregnant women and/ or an unborn baby which are currently unknown. To protect against possible side effects of the study drug, if you are pregnant or nursing a child you may not take part in this study. If you are a woman of childbearing ability, you and the study doctor must either agree on a method of birth control to use or you must agree to be abstinent (i.e., not have sex) throughout the study.

* **If applicable, specify the time period after stopping study treatment or completing study that contraceptive control should continue.**
* **Describe acceptable forms of birth control (i.e., oral contraceptive, double barrier method, etc., if applicable).**

If you think that you have become pregnant during the study, you must tell the doctor immediately. **(Add the following when true:** If you become pregnant, your participation will be stopped.)

**If you are a man:**  To protect against possible side effects of the study drug to an unborn baby, you must not get a partner pregnant while taking the study drug and for **(Insert the number of days/weeks/months)** after the last dose.

You and the study doctor must agree on a method of birth control to use throughout the study or you must agree to remain abstinent (i.e. not have sex).

* **Describe acceptable forms of birth control (i.e., oral contraceptive, double barrier method, etc., if applicable).**

**Are there benefits to taking part in this research study?**

**This section must be in all informed consent forms. However, the way it is included may vary depending on the type of research. The purpose of this section is to describe the benefits of participating for the subject and for others. Language in this section should not give the appearance of being coercive, enticing or self- serving. The following should be included in this section; 1) potential benefits to the subject; and 2) potential benefits to others.**

**NOTE: Payment given to the subject for participation in the study is not a benefit, it is a compensation for subject’s time and any expenses that s/he could incur as a result of participation in the study, and should not be included in this section.**

You may not receive any personal benefit from being in the study. The researchers hope that information learned from your participation in this study will increase knowledge about which way is best to treat patients like you. This knowledge will help make it possible to provide the best type of treatment for patients in the future. While you may or may not personally benefit from being in this study, your participation will provide a benefit to others with this condition and to society.

**What other options are there?**

**Pick the most appropriate following option:**

You have the option to not participate in this study.

***OR***

If you decide not to participate in this study, there is other care available to you, such as:

* Getting treatment or care without being in a study
* Taking part in another study
* Getting no treatment

The study doctor will discuss these with you.

**What about privacy and confidentiality?**

**This section must outline how all confidential information and or materials will be treated, stored, and maintained and for what lengths of time, as well as how materials will be disposed of at the end of the study period. Privacy and confidentiality measures must be addressed in this section.**

The people who will know that you are a research subject are members of the research study staff, and if appropriate, your physicians and nurses. No information about you, or provided by you, during the research, will be disclosed to others without your written permission, except if necessary to protect your rights or welfare or if required by law.

The following groups will have access to study records that identify you: **(Retain the applicable items from this list and delete the others):**

* Food and Drug Administration (FDA)
* Funding Agency, such as the National Institutes of Health
* Name of commercial sponsor or manufacturer of the drug, device or biologic
* Authorized Representatives of the Sponsor
* Wright State University Institutional Review Board (IRB, including the WSU IRB Office and the Office of Research and Sponsored Programs
* Office of Human Research Protections, under the Department of Health and Human Services
* **List any others.**

A possible risk of the research is that your participation in the research or information about you and your health might become known to individuals outside of the research team.

**Give a brief description of how personal information, research data, and related records will be coded, stored, etc., to prevent access by unauthorized personnel. If applicable, explain the final disposition of the research data. If data or biological specimens will be stored or provided to other investigators after study completion, explain measures to protect confidentiality. State if and when individual data will be stripped of all direct and indirect identifiers or destroyed following analyses of the data or publication of the findings or results.**

 **For research that involves the collection of identifiable private information or identifiable biospecimens, you must include one of the following statements:**

Identifiers might be removed from your identifiable private information (or/and identifiable biospecimens). After such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without your (or your legally authorized representative’s) consent.

**OR**

Your information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

**If photographs, videos, or audiotape recordings will be used, explain how the subject’s identity will be protected or disguised. Describe the subject's right to review/edit tapes, who will have access, and when they will be erased.**

**FDA Clinical Trial Registry**

**This section is required only if applicable – delete paragraphs/sentences/sections that do not apply.**

**If the research study is an “applicable” clinical trial listed on www.clinicaltrials.gov website the following statement must be included verbatim in the consent form:**

“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.”

**Certificate of Confidentiality**

**This section is required only if applicable – delete paragraphs/sentences/sections that do not apply.**

**Some studies may receive a Certificate of Confidentiality from NIH. Include this information only if your study received a Certificate of Confidentiality based on the type of information shared in the study and the funding source:**

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. 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, see below); 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.

[You may use the following language as applicable] The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by **[THE AGENCY]** which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

[Language such as the following should be included if researcher intends to disclose information covered by a Certificate, such as potential child abuse, or intent to hurt self or others in response to specific federal, state, or local laws.] The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of **[list what will be reported, such as child abuse and neglect, or harm to self or others].**

[Language such as the following should be included if researcher intends to disclose information covered by a Certificate, with the consent of research participants.] The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document **[restate what will be disclosed, such as including research data in the medical record].**

**What if I am injured as a result of my participation in the research study?**

**Include this section only if this is a risk study.**

If you feel that you have been injured as a result of participating in the research, contact the researcher (**Insert principal investigator)** at **(Insert phone number)** to talk to them about your illness or injury. **{Emergency contact information should also be included here.}**

There are no plans for Wright State University to provide free medical care or to pay for research-related illnesses or injuries, or to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illnesses or injuries.

**If sponsor would pay:**

The study sponsor will pay the reasonable and necessary medical expenses needed to treat an illness or injury caused by the study drug or device or procedures required to be done as part of the research study.

The study sponsor does not plan to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illness or injury.

By signing this form you will not give up any legal rights.

**If there would be no sponsor payment:**

You or your insurance company will be billed for this medical care. Your insurance company may not pay for some or all of this medical care because you are participating in a research study.

By signing this form you will not give up any legal rights.

**What are the costs for participating in this research study?**

**Research subjects must be informed of any costs incurred by participation in the research study.**

There are no costs to you for participating in this research.

***OR***

If you take part in this study, you may have to pay extra costs. The following items and services will be provided by **(Insert sponsor)** at no cost to you: **(List any items/services that the sponsor is paying in full).**

You or your insurer will be responsible for paying for the cost of the following**: (Itemize and estimate the charges that subjects will be expected to pay).**

***OR***

If you decide to participate in this study, the sponsor will pay for the expenses of all study tests and procedures that are not part of your regular medical care. You and your insurance carrier will be responsible for the costs associated with the regular diagnosis and treatment of your medical condition. You should check with your insurance company to verify coverage or payments of these procedures.

**Use of Genetic Samples**

**For research involving biospecimens, if the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen), include a statement stating so.**

This research involves whole genome sequencing (i.e., looking at your entire genetic inheritance). You may be concerned that someone could get access to your genetic information and that it could be misused. For example, if your information suggests something serious about your health, it could be used to make it harder for you to get a job or health insurance. Also, by having genetic information about people from your ethnic group, researchers may make statements about your group identity that you or members of your community may disagree with.

You should discuss any concerns or questions regarding use of your genetic information with Dr. XX, members of the study team and your family before deciding to participate.

**This section is required for federally-funded protocols that involve the collection and use of genetic material. The following statement must be included in the consent form:**

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

* Health insurance companies and group health plans may not request your genetic information that we get from this research.
* Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
* Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

You should also know that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

**Will I be reimbursed for any of my expenses or paid for my participation in this research?**

**Describe for the subjects the amount they will be paid as well as when and how they will be paid. If the payments are prorated or partial payments will be made for different activities please describe these. Research subjects can be reimbursed for expenses associated with the research or compensated for their time and effort. Compensation should not be so large as to constitute undue influence or be coercive.**

**If subjects receive compensation in excess of $600 per year, the income must be reported to the Internal Revenue Service on Form 1099 Misc. The filing of these forms requires that the name and social security number of the subject be collected and released to Accounts Payable. The informed consent document must include notice that this information will be collected and released should they be paid more than $600.**

You will not be reimbursed for participating in this research study.

***OR***

You will be reimbursed $20.00 per visit on the day of your visit for this study. The money is meant to assist you in paying any travel expenses, lost wages from work, or child care costs, that you may have as a result of participating in this study. You could possibly receive a total of $320.00 for completion of the study.

**If the study involves subjects’ biospecimens, include a statement that his/her biospecimens (even if identifiers are removed) may be used for commercial profit and whether he/he she will or will not share in this commercial profit.**

Your biospecimens (i.e., blood, tissue collected during the study) may be used for commercial profit and there is no plan for you to share in this profit.

**OR**

Your biospecimens (i.e., blood, tissue collected during the study) may be used for commercial profit and **(insert description of how profits will be shared with subjects).**

**Will I be told about new information that may affect my decision to participate in this research study?**

**Include this section only if this is a risk study.**

During the course of the study, you will be informed of any significant new research information (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the research. If new information is provided to you, you may be asked to sign a consent form that includes the new information.

**If applicable, include a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to the subject, and if so, under what conditions.**

**Who should I contact if I have questions?**

Contact the researcher **(Insert principal investigator)** at **(Insert phone number)** if you have any questions about this study or your part in it or if you have questions, concerns or complaints about the research.

If you have any questions about your rights as a research subject, you may call the Wright State University Institutional Review Board (IRB) at (937) 775-2709. The IRB is an independent committee composed of members of the University community, staff of the institutions, as well as lay members of the community not connected with these institutions. The IRB has reviewed this study. **(Do not state “approved”.)**

**What are my rights/responsibilities as a research subject?**

As a subject, your responsibilities include: **(Choose applicable points; refer to your protocol to ensure subjects know what is expected of them):**

* Follow the instructions of the research study staff.
* Take the study drug as instructed **(if device, explain what is required for study compliance).**
* Keep your study appointments. If it is necessary to miss an appointment, please contact the research study staff to reschedule as soon as you know you will miss the appointment.
* Tell the research study staff about any side effects, doctor visits, or hospitalizations that you may have.
* Tell the research staff if you believe you might be pregnant or have gotten your partner pregnant.
* Keep the study drug in a safe place, away from children and for your use only.
* Keep your diaries as instructed.
* Complete your questionnaires as instructed.
* Ask questions as you think of them.
* Tell the research staff if you change your mind about staying in the study.

While participating in this research study, you should not take part in any other research project without approval from the research staff of each study.

**Authorization to Use and Disclose Your Health Information**

**This section is required if you will be accessing, using or creating PHI for this study via a covered entity (e.g., Premier Health, physician office, Dayton Children’s etc…)**

State and Federal laws, including the Health Insurance Portability and Accountability Act (HIPAA), require researchers to protect the privacy of your health information. This section of the consent form describes how researchers, with your authorization (permission), may use and release (disclose or share) your protected health information (PHI) for this research study. **Please read this section of the consent form carefully.**

If you sign this document, you give permission to (**insert name of PI)** and his (or her) **Wright State/Premier Health** research team to use or disclose (release) the following protected health information: ***(List PHI to be used, created or disclosed for this study in a specific and meaningful way.)***

* **Your medical records for past medical conditions and medications related to your heart health**
* **All information (research records and medical records) created during your participation in this research study**
* **All information related to illness or hospitalizations that occur during your participation in this study**

The research team needs this information to conduct the study.This is a study to test **(add simple language describing the purpose of the study. For example,** **whether a device called an XYZ can increase the likelihood of survival in patients at risk of a stroke or heart attack.)**

To maintain the integrity of this research, you might not have access to any health information developed as part of this study until it is completed. At that point, you generally would have access to your health information.

**Disclosure of your protected health information**

If you sign this form, the researchers may share your health information during the conduct of the study with:

* Non-WSU/PH researchers or organizations working with WSU/PH researchers.
* Law enforcement or other agencies, when required by law
* WSU’s Institutional Review Board (or other IRB of record), which oversees our research
* The sponsor (the organization paying for) of this research study: **insert name(s) here**
* Representatives of government agencies in the United States and other countries (i.e. Food and Drug Administration and the Office of Human Research Protection)
* Other authorized WSU/PH Officials who oversee research and clinical care

The people listed above will use and share your health information to review the quality, safety, and results of the research and may also do additional research.

Please understand that these persons/organizations who may receive your health information may not be required by U.S. Federal privacy laws (such as HIPAA) to protect it and may share your information with others without your permission.

This authorization does not have an expiration date*.*

However, you can change your mind and cancel this authorization at any time. To cancel this authorization, you must write the study investigator listed at the beginning of this consent form.

If you cancel this authorization, you will no longer be allowed to take part in the research study. If you cancel this authorization, health information you had already allowed us to obtain may still be used and disclosed by researchers in order to maintain the integrity and reliability of the research, and to report any adverse (bad) effects that may have happened to you.

If study involves optional activities use the following language: You can cancel your authorization for the optional part(s) of the study and remain in the main study.

**Right to refuse to sign this Authorization**

You have the right to refuse to sign and give your authorization. If you do not sign this form, your non-research related treatment, payment or enrollment in any health plans, or your eligibility for other medical benefits at Premier Health will not be affected in any way.

However, if you do not sign this form, you will not be able to participate in this research study.If study includes optional activities use the following language: You can still be in the main part of the study even if you do not authorize the use and sharing of your information for the optional part(s) of the study.

**Signature of Subject**

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research and authorize the use and disclosure of my protected health information for this study. I will be given a copy of this signed and dated form.

Signature Date

Printed Name

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Obtaining Consent and Authorization

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Person Obtaining Consent and Authorization

 \_\_\_\_\_\_\_\_\_\_\_

Signature of Legally Authorized Rep. Date

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Description of LAR’s Authority (add highlighted section if LAR approved by IRB)