INFORMED CONSENT FORM (ICF)

QUARTET USA:
A double blind randomized controlled trial to assess the efficacy and safety of a quadruple ultra-low-dose treatment for hypertension

NCT03640312

Version: July 21, 2020

IRB Number: STU00205834

Permission to Take Part in a Human Research Study

Do not sign this consent if today's date is later than the stated expiration date above.

Title of Research Study: ***A double blind randomized controlled trial to assess the efficacy and safety of a quadruple ultra-low-dose treatment for hypertension (QUARTET).***
Protocol Number: 00205834

Investigator: ***Mark Huffman, MD, MPH***

Supported By: This research is supported by the National Heart, Lung, and Blood Institute.

Key Information:
The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?
We are asking you to take part in this research study because you are a patient at Access Community Health Network (ACCESS) with a history of high blood pressure. We are also asking you to take part in this study because you are either not currently taking medicine for your high blood pressure or are taking one medicine but have not achieved blood pressure control.

What should I know about a research study?
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?
ACCESS has partnered with researchers from Northwestern University to better understand if combining four different types of medicines for high blood pressure into one pill can help lower high blood pressure with fewer side effects. The medicines being used in this study - amlopdipine, bisoprolol, candesartan, and indapamide - are all approved by the Food and Drug Administration (FDA) and commonly prescribed by medical providers to help treat high blood pressure. In this study, they will be combined into one pill (a "4-in-1 pill") at ultra-low doses. In this study, the 4-in-1 pill will be compared to Candesartan, an FDA-approved drug that is commonly used to treat high blood pressure.

While the (FDA) has not approved the 4-in-1 pill for general use, the FDA has approved the use of the pill as an investigational new drug for purposes of this study. Results from a smaller study suggest that the 4-in-1 pill is safe and effective to use but further testing is needed.

We cannot guarantee any direct benefits to you, but you will be receiving medication that is a known therapy prescribed to patients with high blood pressure. If this study is successful, then we will develop a larger study to try to discover how well the 4-in-1 pill can help prevent heart attacks, stroke, and heart failure.

From this point on, the 4-in-1 pill will be referred to as the "study drug".

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How long will the research last and what will I need to do?
We expect that you will be in this research study for about 12 weeks (3 months).

You will be given the study drug or candesartan and asked to complete up to 5 study visits in order to perform tests and procedures.

More detailed information about the study procedures can be found under the section **What happens if I say "Yes, I want to be in this research"?**

Is there any way being in this study could be bad for me?

- You may be taking the study drug, which has not been approved by the FDA for treatment of high blood pressure even though the medicines in the pill are approved.
- There is a chance that your blood pressure may go up while you are in this study. If this does happen, you will be given an additional 5mg amlodipine. Amlodipine is FDA-approved and commonly used to help control blood pressure.
- In addition, blood pressure lowering medicines can cause side effects in some people. Some of the more common side effects include irregular or slow heartbeat, headache, swelling of legs or ankles and feeling faint or lightheaded or falling.

More detailed information about the risks of these medicines can be found under **"Detailed Risks: Is there any way being in this study could be bad for me?"**

Will being in this study help me any way?

- We cannot promise any benefits to you or others from your taking part in this study.
- However, possible benefits include additional knowledge about the effects and safety of the study drug for high blood pressure.
- While you take part in this research study, you will receive blood pressure-lowering medication, which may help control your blood pressure.

What happens if I do not want to be in this research?
Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled. Instead of being in this research study, you may continue normal care through your healthcare provider.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, you can talk to the research team. You can call or email us.

- Hiba Abbas, Study nurse: hiba.abbas@achn.net | (872) 772-0389
- Fallon Flowers, Study nurse: fallon.flowers@achn.net | (872) 772-0423
- Abigail Baldridge, Project director: abigail.baldridge@northwestern.edu | (312) 503-3911

If you have any questions regarding your study medication, please contact Abigail Baldridge.

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This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?
We expect about 364 people in the Chicago area to participate in this study. There are also ongoing studies in other countries that include about 1000 other people.

What happens if I say "Yes, I want to be in this research"?
If you decide you would like to participate in this study, you will be asked to come to one of the following locations for study visits:

- Martin T. Russo Family Health Center, at 245 S Gary Ave., Bloomingdale IL, 60108
- Ashland Family Health Center, at 5159 S. Ashland Ave., Chicago IL, 60609

From this point on, the Martin T. Russo and Ashland Family Health Centers will be referred to as the "study site".

The study team may contact you over the phone, by text messaging, or by electronic communication through MyChart, a web-based portal used to access your health information.

If you qualify to take part in the study, you will be randomized at Visit 2, into one of the following groups:

- Study drug: Candesartan (2 mg), amlodipine (1.25 mg), indapamide (0.625 mg), bisoprolol (2.5 mg); or
- Candesartan (8 mg)

Which of these 2 treatments you receive is chosen at random, which means that you will be put into one treatment group by chance. A computer will randomly select your treatment. This allows the treatments to be compared more fairly. The chance you will receive the study drug or candesartan is 1 in 2 (50%). Neither you nor the study doctor will know which treatment you receive. But the study doctor can find out if necessary, for example, if there is a problem.

During the study, you will be instructed to take the study drug or candesartan by mouth, once a day. Do not crush or chew the study drug.

Below is a list of study procedures that will take place at each visit during your participation in the study:

Screening Visit (Visit 1):
To help the study doctor determine if you are eligible to participate in this study, you will be asked to come to the study site or contacted via telehealth for a screening visit. This may be done today if you decide to participate. The Screening Visit will last approximately 3 hours with approximately 1 hour in the clinic setting. The following activities will be performed:

- You will be asked to read and sign this consent form.

- A review of your health and medical history and your demographics (such as your gender, income, and other background information), and any medications (prescription, nonprescription, and over-the-counter herbal and dietary) you have taken and are currently taking will be done.
- You will be asked about your alcohol and smoking use.
- You will have your vital signs (heart rate and blood pressure) taken as well as your height and weight.
    - An additional visit to the study site will be needed if the initial screening process is completed via telehealth.

If you have not had certain tests recently (within the last 3 months), we will:

- Ask you to provide us with blood samples to run a series of lab tests (i.e. lipid panel, glucose, sodium).
    - We will use a needle to take about two teaspoons (approximately 10 mL) of blood from your arm and collect it in two vials.
- Ask you to provide a urine sample.
    - We will ask you to pee into a cup to give us around 4 teaspoons (approximately 10 mL) of urine.
- Do an electrocardiogram test (ECG). An ECG is a test that give a measure of the heart's electrical activity.

You will be given the option to be fitted with a 24-hour blood pressure monitor.

- You will be asked to take the blood pressure monitor home and wear it for 24 hours.
- You will be asked to log what activities you did while wearing the blood pressure monitor. The study staff will provide you with information about how to complete your activities log.

Selected procedures in visit 1 may instead be completed during visit 2.

Study Visit 2:

1 day after after Visit 1, you will be asked to return to the study site for Study Visit 2. This visit will last approximately 1 hour. The following activities will be performed:

- If you chose to complete the 24-hour blood pressure monitors, you will bring it back along with the activities log.
- The study team will review results from your electrocardiogram, laboratory tests, and blood pressure readings and monitor if it was completed – these results will help us determine full eligibility.
- If you are eligible, then we will randomize what type of treatment you get – which is like choosing by chance, like flipping a coin. Neither you nor the study team will choose what treatment you get.
- You will receive 6 weeks worth of the study drug or candesartan, depending on what group you get randomized into.
- You will receive an Omron 3 Series BP7100 upper arm blood pressure monitor that is yours to keep after the study.

Please be aware: you will be receiving a known therapy for your high blood pressure regardless of which of the two study medicines you receive.

Study Visit 3 (Week 6):

6 weeks after Visit 2, you will be asked to return to the study site or complete a telehealth appointment for Study Visit 3. This visit will last approximately 1 ½ hours. The following activities will be performed:

- You will bring back the bottle of study drug or candesartan, with any unused study medication. The study team will ask you about any times you missed taking the study drug or candesartan.
- You will be asked how you are feeling and what medications you are taking and have taken since your last visit. This can be completed during the telehealth appointment.
- You will have your vital signs (heart rate and blood pressure) taken.
    - If you complete your visit through telehealth, you will be asked to check your blood pressure with the Omron 3 Series BP7100 monitor. The study staff will train and guide you through this process.
    - If your blood pressure is greater than 130/80 mmHg, then we will give you an additional pill of amlodipine 5 mg to take each day in addition to your study drug or candesartan.
- We will ask you to provide us with blood samples to run a series of lab tests (i.e. lipid panel, glucose, sodium).
    - You will need to come to the study site to complete this.
    - For this, we will use a needle to take about two teaspoons of blood from your arm and collect it in two vials.
- We will ask you to provide a urine sample.
    - We will ask you to pee into a cup to give us around 4 teaspoons (approximately 10 mL) of urine.
- After we obtain your lab results, you will be asked to come to the study site to receive 6 more weeks worth of the study drug or candesartan, depending on what group are are randomized to.

Study Visit 4 (Week 12):
6 weeks after after Visit 3, you will be asked to return to the study site or complete a telehealth appointment for Study Visit 4. This visit will last approximately 1 ½ hours. The following activities will be performed:

- You will be asked how you are feeling and what medications you are taking and have taken since your last visit.This can be completed during the telehealth appointment.
- You will have your vital signs (heart rate and blood pressure) taken.
    - If you complete your visit through telehealth, you will be asked to check your blood pressure with the Omron 3 Series BP7100 monitor. The study staff will guide you through this process.
- We will ask you to provide us with blood samples to run a series of lab tests (i.e. lipid panel, glucose, sodium).
    - You will need to come to the study site to complete this.
    - For this, we will use a needle to take about two teaspoons of blood from your arm and collect it in two vials.
- We will ask you to provide a urine sample.
    - We will ask you to pee into a cup to give us around 4 teaspoons (approximately 10 mL) of urine.

Regardless of whether you completed the 24-hour blood pressure monitor during the baseline visit, you will be asked if you are willing to be fitted with a monitor at this visit.

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- You will be asked to take the blood pressure monitor home and wear it for 24 hours.
- You will be asked to log what activities you did while wearing the blood pressure monitor. The study staff will provide you with information about how to complete your activities log.

If you are not going to be fitted for the 24-hour blood pressure monitor, then you will bring back the bottle of study drug or candesartan, with any unused study medication. The study team will ask you about any times you missed taking the study drug or candesartan.

- You will be asked how you are feeling and what medications you are taking and have taken since your last visit.
- You will answer a series of questions about the study drug or candesartan and your opinion(s) about it.

Study Visit 5 (Week 12):
1 day after after Visit 4, you will be asked to return to the study site for Study Visit 5. This visit will last approximately 1 hour. The following activities will be performed:

- You will bring back the blood pressure monitor and the activities log for the 24-hour blood pressure monitor.
- You will bring back the bottle of study drug or candesartan, with any unused study medication. The study team will ask you about any times you missed taking the study drug or candesartan.
- You will be asked how you are feeling and what medications you are taking and have taken since your last visit.
- You will answer a series of questions regarding about the study drug or candesartan and your opinion(s) about it.
- Schedule a visit with your primary care provider to transition you out of the study for continued care.

Study Activities	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
Sign consent form	X[1]				
Demographic questions	X*	X*			
Take your blood pressure and heart rate	X		X[1]	X[1]	
Electrocardiogram (ECG)	X				
Take your measurements (i.e. weight, height)	X				
Ask you questions about your medical and medicine use history	X*	X*			
Additional questions about your medicine use	X*	X*	X[1]	X[1]	
Questions about your general health	X*	X*		X[1]	
Blood and urine tests	X		X	X	
Fit 24-Hour Blood Pressure Monitor	X[2]			X[2]	
Return 24-Hour Blood Pressure Monitor		X			X[3]

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Check for full eligibility	X	X			
Dispense study medication		X	X		
Collect any unused study medication			X	X	X
Ask questions about medication adherence			X		X
Ask questions about your health service utilization			X[1]	X[1]	X[1]
Capture if you have been experiencing any side effects	X[1]	X[1]	X[1]	X[1]	X[1]

"X*" means that these activities may be completed either at Visit 1 or Visit 2 and via a telehealth visit.
"X[1]" means that these activites may be completed through a telehealth visit.
"X[2]" means that these activites are optional.

What are my responsibilities if I take part in this research?
If you take part in this research, then we will ask you to attend all 5 study visits to the study site or through a telehealth visit. We will ask you to take your study drug or candesartan as prescribed and to tell the research team accurate information on how often and how much you took.

What happens if I say "Yes", but I change my mind later?
You can leave the research at any time; it will not be held against you. If you decide to leave the research, please let the study team know so we can work with you and your provider to schedule a close-out visit, which will include the assessments planned for the final visit. Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

If you stop participating in the research, data that has been already collected may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, then these data will be handled the same as research data.

Detailed Risks: Is there any way being in this study could be bad for me?

<u>Study Drug Risks</u>
The known side effects of each of these medicines are shown below. These side effects typically go away after stopping the medication. If any of these side effects occur while you are in the trial, then they will be reported as adverse events.

Very common:	More than 1 out of 10 people have reported this side effect
Common:	From 1 to 10 out of 100 people reported this side effect
Uncommon:	From 1 to 10 out of 1,000 people have reported this side effect
Rare:	From 1 to 10 out of 10,000 people have reported this side effect
Very rare:	Less than 1 in 10,000 people have reported this side effect

Reported Side Effects	Amlodipine	Bisoprolol	Candesartan	Indapamide
Allergic reactions like skin rash,	Uncommon	Rare	Rare	Common

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Reported Side Effects	Amlodipine	Bisoprolol	Candesartan	Indapamide
itching or hives, or swelling of the face, lips, or tongue				
Anxiety	-	Uncommon	-	Uncommon
Blurred vision or changes in vision or hearing	Uncommon	-	-	Common
Breathing problems	Uncommon	Uncommon	Uncommon	-
Change in sex drive or performance	-	Uncommon	Uncommon	-
Chest pain	Rare	Common	Common	-
Cold, tingling or numb hands or feet	-	Common	-	-
Confusion	-	Uncommon	-	-
Cough	-	-	Uncommon	-
Depression	-	Uncommon	-	-
Diarrhea	-	Common	-	Common
Dry mouth	Uncommon	-	-	Rare
Dry or burning eyes	-	Uncommon	-	-
Facial flushing	Uncommon	-	-	-
Feeling faint or lightheaded or falling	-	-	Very common	-
Headache	-	Common	Common	Common
Infection or flu-like symptoms	-	-	-	Common
Irregular or fast heartbeat	Uncommon	-	Uncommon	Common
Irregular or slow heartbeat	-	Very common	-	Common
Loss of appetite	-	-	-	Common
Muscle aches and pains	-	Common	-	Common
Muscle cramps or spasms	-	-	-	Common
Nausea, vomiting	Uncommon	Common	Common	Uncommon
Passing less urine	-	-	Common	-
Redness, blistering, peeling or loosening of the skin, including inside the mouth	-	-	-	Very rare
Stomach gas, pain	Common	-	Common	-
Sweating	-	Uncommon	-	-
Swelling of hands or feet	-	-	Uncommon	-
Swelling of legs or ankles	Very common	Uncommon	-	-
Tremors	-	Uncommon	-	-
Trouble sleeping	Uncommon	-	-	-
Unusually weak or tired	Uncommon	-	-	Common

" – " means that there have been no reported side effects

Blood Draw Risks

The risks of taking blood include pain, a bruise at the point where the blood is taken, redness and swelling of the vein and infection, feeling lightheaded, and a rare risk of fainting.

Questionnaire Risks
Some of the questions asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, then you may skip it and go to the next question.

Controlling Blood Pressure Risks
Depending on what treatment group you received, there is a chance that your blood pressure may go up while you are in this study. If this does happen you will be given extra medication to help control your blood pressure.

Unknown Risks
In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death, but this is not expected.

Personal Health Information
This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to decrease the chance of this happening. See the section below titled: **"What happens to the information collected for the research?".**

What do I need to know about reproductive health and/or sexual activity if I am in this study?
The study drug or candesartan may also hurt a pregnancy or fetus in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

You should not be or become pregnant, breastfeed, father a baby, or donate eggs/sperm while on this research study.

If you are sexually active, then both men and women should use at least one effective type of birth control while participating in this research study. According to the World Health Organization and the United States Centers for Disease Control and Prevention, the most effective forms of birth control include complete abstinence, surgical sterilization (both male and female), intrauterine devices (IUDs), and the contraceptive implant. The next most effective forms of birth control include injectables, oral contraceptive pills, the contraceptive ring, or the contraceptive patch. Acceptable but least effective methods of birth control include male condoms (with or without spermicide) and female condoms.

If you or your partner become pregnant while participating in this research study or for 1 month after you complete the study, then it is important that you tell the study doctor or other research team member immediately. You may be required to stop participation in this study; however, other treatment options will be discussed with you at that time if necessary.

If you or your partner are / is considered to be postmenopausal, then you are not required to use contraception while participating in this research study. Postmenopausal women rarely become pregnant. If you or your partner become pregnant while participating in this research study or for 1 month after you complete the study, then it is important that you tell the study doctor or other research team member immediately. You may be required to stop participation in this study; however, other treatment options will be discussed with you at that time, if necessary.

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Will it cost me anything to participate in this research study?
Taking part in this research study will not lead to any costs to you.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see which services will be covered by your insurance and which you will be responsible to pay.

Will being in this study help me in any way?
We cannot promise any benefits to others from your taking part in this research. Possible benefits include additional knowledge about the effects and safety of the study drug for high blood pressure. While you take part in this research study, you will receive blood pressure-lowering medication, which may help control your blood pressure.

What happens to the information collected for the research?
Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution.

Blood and urine samples collected for this study will only be used for this study and will be destroyed after testing.

The study sponsor (National Heart, Lung, and Blood Institute), monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), and the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are allowing them to get that access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this clinical trial is available at www.ClinicalTrials.gov (Identifier: NCT03640312), as required by U.S. Law. This website will not include information that can identify you. After the trial is completed, then the website will include a summary of the results. You can search this website at any time.

Data Sharing
De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or change the code of any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot completely guarantee anonymity of your personal data.

Can I be removed from the research without my OK?
The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include occurrence of an adverse event that your treating physician feels may be related to the study treatment. If you are removed, a member from the study team will reach out to you to notify you. S/he will also help

you schedule an appointment with your primary care provider so they can continue with your medical care and treatment of high blood pressure.

What else do I need to know?
If you become ill or are injured as a result of this study (medications, devices or procedures), then you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study staff about any illness or injury so we may be able to communicate your participation in the study with your primary care provider.

The researchers and clinical staff will not pay for medical care required because of a bad outcome resulting from your participation in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.

Compensation
If you agree to take part in this research study, we will compensate you for your time and effort based on the following schedule. If you require transportation assistance, please speak with a study team member as we may be able to provide you with transportation assistance in the form of PACE, CTA, or Lyft service (up to $5 per ride). The maximum amount to be paid by participating in this study is $115.

Compensation	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
Incentive (cash)	$15 if ineligble to continue	$30	$30	-	$30
PACE, CTA, Lyft or equivalent	$5	$5	$5	$5	$5
Home blood pressure monitor		1 monitor			

Some participants may be ineligible after completing procedures during Visits 1 and 2. If you have attended a single visit and have been determined ineligible, you will be compensated $15. If you have attended two visits, you will be compensated $30 regardless of whether you are ineligible or eligible (able to participate in the study).

Study Dissemination
After all participants have completed the research study:

- You will receive a letter indicating if you received the study drug or candesartan while you participated in the study.
- The study staff will host an open forum at the Access Center for Discovery and Learning to share the study results.
- The study staff will be available for you to call or email if you have questions about the results of the study.
- Research findings will be available at www.ClinicalTrials.gov (Identifier: NCT03640312) within 1 year.
- The research findings will be published in the form of research articles and presentations at scientific meetings.

The study sponsor, the National Heart, Lung, and Blood Institute of the National Institutes of Health, requires that all research papers from this study be made freely available to the public through PubMed Central (https://www.ncbi.nlm.nih.gov/pmc/) within 12 months of publication.

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HIPAA Authorization
We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Health information we may collect and use for this research includes:

- All information in your medical record

You have the right to inspect and copy the mental health and developmental disabilities records that will be collected as part of this study.

This consent expires on December 31st, 2032. After this date, Northwestern University may not gather new information about you, use or disclose your personal health information collected in this study for any purpose other than the research study described in this consent unless Northwestern University obtains permission to do so from you. Illinois State Law permits use and disclosure of your mental health information only to the extent specified in this document.

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy except that such information may be viewed by the study sponsor and its partners or contractors at the Principal Investigators' offices.

The following entities may receive your health information:

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).
- The following individuals or organizations may also access, receive, or use your personal health information: Access Community Health Network.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission. The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Also, Federal law/42 CFR Part 2 prohibits unauthorized disclosure of these records.

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The results of this study may also be used for teaching, publications, or presentation at scientific meetings.

Unless you revoke your consent, it will expire on December 31st, 2032.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

Principal Investigator (PI) Name: Mark Huffman, MD, MPH
Institution: Northwestern University
Department: Preventive Medicine
Address: 680 N Lake Shore Drive Suite 1400, Chicago IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study if you do not authorize it. If you do not authorize the use or disclosure of your health information, then it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, nor will it affect your eligibility for benefits.

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

My signature below documents that the information in the consent document and assent process and any other written and verbal information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

_____ _____
Signature of Witness to Consent/Assent Process Date

Permission to Take Part in a Human Research Study
Do not sign this consent if today's date is later than the stated expiration date above.

_____
Printed Name of Person Witnessing Consent/Assent Process