MIDWESTERN UNIVERSITY
CONSENT TO BE PART OF A RESEARCH STUDY

You might be able to join a research study. This form has information to help you choose if you want to be part of it. Make sure you read it carefully. Talk to the researchers about the study and ask them questions. You could also talk to your family, friends, doctor, or other healthcare providers about joining. If you decide to join, you'll need to sign this form before you start doing anything for the study. But before you do that, make sure you know what the study is about and what could be good (benefits) or not so good (risks) about it. If you don't want to join, you don't have to. And if you do join, you can stop anytime you want.

KEY INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

Study title: Insert study title.

External company or agency supporting the study (if applicable): List study support (e.g., monetary, in-kind contributions such as supplies, etc.) or "None" as appropriate.

Study personnel:

Names and degrees of study personnel	Affiliations (e.g., Midwestern University College of Health Sciences	Role (Principal investigator, Student investigator, Study coordinator, etc.)

The information below provides an overview of important information that will help you decide whether you want to participate in this research study. More detailed information is included on the following pages.

Why is this study being done?	*This table is necessary to meet the "Key Information" requirement of the Common Rule for consent documents. This should be information that is an overview of information that individuals would reasonably need to decide if they want to participate. Think of this as an abstract. This table together with the above information should not exceed 2 pages total. [Please delete these instructions.]* [Provide a brief (1-2 sentence), plain language description of the study's purpose. If applicable, include a rationale for drug/device (e.g., prior drugs have not worked for this patient population.]
Are you eligible to participate in this study?	Provide a brief, plain language description of inclusion and exclusion criteria. This does not need to be detailed inclusion/exclusion criteria or processes that may be described elsewhere. Detailed information will be provided later in Question 1 of the main document. This can be a broad overview, such "You may be able to participate in this study if you have a diagnosis of diabetes and take medications to manage your diabetes."
What will you be asked to do during this study?	Provide a brief, plain language description of the ***main*** research activities, such as investigational treatments or the extra procedures that are performed for research purposes. Detailed information will be provided later in Question 2a.

How much time will you spend on this study?	Provide a clear summary of the time commitment required to participate in the study. Include both the overall length of participation and the amount of time required for individual study visits or other study-related activities that are relevant (e.g., "If you participate, you will be asked to attend three (3) study-related visits over the course of four (4) weeks. Each visit should last approximately 45 minutes."). ***Do not*** detail each visit or study procedure. These details will be provided later in Question 2b. Use ranges of time, frequency of visits, comparisons with standard care, and similar strategies. Include any long term follow up requirements.]
What are the main benefits to you if you decide to participate?	Provide a clear *summary* of the ***direct*** benefits to the individual if they decide to participate. A detailed description of the direct benefits will be included in Question 3d (repeating information in this section as necessary). Receiving payment or a chance to "win" some sort of reward (e.g., Amazon gift card) are ***not*** benefits and should not be included
What are the main risks if you participate and what is being done to minimize those risks?	PI should determine what information should be included here. • If this is a clinical study, this information is similar to what a healthcare provider would convey to a patient in a clinical setting. • A complete listing of risks MUST be detailed in Question 3a (repeating information in this section). If death is a reasonable possibility, this risk must be stated here.
What are other options besides participating in the study?	If this is a study of an active treatment (e.g., a drug or therapeutic procedure), then this section must be included. For studies that do not involve an active treatment, this row can be deleted.] If you decide not to enter this study, other care is available to you, such as [*describe care here*]. Someone from the study team will discuss these with you. You do not have to be in this study to be treated for [*describe condition and/or symptoms here.]*

Detailed Information:
The rest of this document includes detailed information about this study. Please take time to read this information. If you have any questions or need clarification, a member of the research team can help you.

1. WHO MAY PARTICIPATE IN THE STUDY?

Taking part in this study is *completely voluntary*. You do not have to participate if you don't want to. You may also leave the study at any time. There will be no penalty to you if you choose to leave before finishing this study. You will not lose any benefits to which you are otherwise entitled.

a. Who can take part in this study?
Describe criteria to participate in this study including any relevant inclusion or exclusion criteria and screening procedures.

b. How many people are expected to take part in this study and how many research locations will be involved?
Enter the expected sample size and state the number of sites that will be included if this is a multi-site study. If this is a multi-site study, include the total number of participants at MWU and overall total number of participants.

2. WHAT DO YOU HAVE TO DO TO PARTICIPATE IN THE STUDY?

a. What will happen to you in this study?
Describe the study procedures in chronological order here and include what is expected of study participants. If participants will be audio or video recorded, mention this in a separate paragraph within this section.

b. How much of your time will be needed to take part in this study?
Describe how much time will be expected of the participant. If the study involves multiple sessions, be specific about the number of sessions and expected time at each session. Remember to be liberal in your estimations of time (i.e., rounding up or overestimation is usually good here).

c. When will your participation in this study be finished?
Describe how long the study will last (e.g., 6 months) both in terms of the individual's participation and the overall study.

3. WHAT ARE THE POTENTIAL RISKS AND BENEFITS IF YOU PARTICIPATE IN THIS STUDY?

We're trying to make this study as safe as possible, but you could still have issues or side effects, even if we're careful. If you have any problems during the study, let someone from Question #9 know.

a. What are the risks of participating in this study?
Describe the potential risks associated with participating in this study in terms of physical risks, psychological risks, socioeconomic risks, legal risks, and loss of confidentiality. It is not acceptable to say "there are no risks." If the risks are reasonably assumed to be no greater than those encountered in everyday life (i.e., minimal risk), then you may state that. If the study involves treatment, then an explanation of whether the study treatment is different from standard of care and any associated risks is required. If applicable, describe risks to the embryo or fetus, if participants are or may become pregnant. For experimental treatments or procedures, include a statement that there may be risks that are currently unforeseeable.

b. How will the researchers keep you safe from these risks?
Describe strategies to minimize risks to the participants. Remember to include strategies related to data storage and confidentiality.

We're trying to make this study safe, but you could still have issues or side effects, even if we're careful. If you have any problems during the study, let someone from Question #9 know.

c. What if you get hurt or sick because of this study?
The study is believed to be safe, and you should not get hurt or sick because of being in the study. If you do happen to get hurt or sick because of being in this study, you should know that Midwestern University is not able to give you a lot of help. Midwestern University can only give you direction to help you get treatment at the nearest medical clinic or hospital. You will have to pay for that treatment. If you have health insurance, that health insurance might help pay for some of the cost for the medical treatment you may need. Midwestern University does not have a way to pay you directly or to pay for your treatment. This does not mean you have no rights. By being part of this study, you are not giving up any of your legal rights.

d. How could you benefit from being in this study?
Describe any potential direct benefits to participants.

e. How could others benefit if you're in this study?
Describe how participation in this study may help others.

f. How will researchers tell you if they learn new important things about the study?
Describe how the researchers will notify participants and explain any changes to the risk/benefit profile of the study.

Sometimes additional information regarding the risk-benefit ratio becomes evident during the course of a study. It is important that this information be shared with research participants, especially if having that information may change their decision to continue their participation. Describe how researchers will notify participants of any individual clinically significant results or general results that impact all participants that change the risk/benefit profile of the study.

g. Can you be in other studies if you're in this one?
Being in more than one study at the same time or different times could be risky for you and could change the results. Usually, you shouldn't be in more than one study without asking the researchers from each study. If you're thinking of joining another study while in this one, contact the first person in Question #9.

4. WHAT SHOULD YOU DO IF YOU WANT TO END YOUR PARTICIPATION IN THIS RESEARCH STUDY?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record.

Describe what will happen to any data collected from the participant before they leave the study. For example, a participant may have completed only 1 of 3 study questionnaires. Will that set of responses be used or not? Any important instructions or precautions related to the study procedures that participants must know about

leaving the study early (e.g., tapering medication, abruptly stopping therapy, etc.), must be described here. Also, any potential risks for withdrawing early, such as those related to stopping treatment for an active disease/condition, must be included in the risks section

If you decide to leave before finishing the study, please tell the Principal Investigator listed below in the Contact Information section (Question #9).

5. COULD THE RESEARCHERS TAKE YOU OUT OF THE STUDY EVEN IF YOU WANT TO CONTINUE TO PARTICIPATE?

Yes. In certain situations, the researchers may need to end your participation in the study even if you want to continue. Some possible reasons include

- The researcher believes that it is not in your best interest to stay in the study because of health or safety reasons.
- Your condition changes and/or you need treatment that is not allowed while taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

It is not common for researchers to remove participants from a research study. If this happens, the researcher will notify you and explain why you were removed from the study. They will also explain what will happen to any information collected from you. If you are removed from the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled.

6. WILL BEING IN THIS STUDY COST YOU ANYTHING?

Describe any financial costs associated with participating in the study.

7. WILL YOU BE PAID FOR BEING IN THIS STUDY?

Describe any reimbursement or compensation for participating in the study. If compensation requires additional forms to be completed or information to be collected, describe this briefly here.
****[Pick one of these two options, and remove the other one.]****
Your samples might be used to make new drugs or products that make money. The money won't be shared with you.

Your samples might be used to make new drugs or products that make money. If that happens, we might give you some of the money. For questions, ask Dr. James Woods, Assistant Vice President of Research at (630) 515-6173 or jwoods@midwestern.edu.

8. WHAT HAPPENS TO YOUR INFORMATION IN THIS STUDY?

We want you to know that your information is safe. The research team at Midwestern University is dedicated to keeping your information private. We follow all the rules and laws that protect your privacy, like federal, state, and local laws. These rules are especially important when it comes to your personal health information. Some laws let certain people see your information, but only in specific situations. Here's how we're going to make sure your privacy and research records stay safe in this study:

a. <u>What personal information will researchers collect?</u>
Describe any potential identifiable data that may be collected. Be as specific as possible.

b. Will any of your protected health information (PHI) be collected or accessed as part of this research study?

Medical information and billing records are referred to as protected health information (PHI). State and federal laws, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA), provide specific requirements about how researchers can use your PHI and how they must protect that information. By signing this form, you are giving your permission for *[INSERT PI NAME] [add "*and the research team*" if applicable]* to create, obtain, use, store, and share your protected health information for this research study. This permission will last until the study is over or you contact the researchers (see Question #9) and withdraw your permission.

The health information includes all information created and/or collected during the research as described in this consent form and/or any health information in your medical record that is needed for the purposes of the current research study. For example, the researcher may require access to your medical records to verify that that you are eligible to participate in this study. This research study may include the following protected health information:

- Personal identifiers including [insert specific identifiers being collected and clarify which will be maintained with research data]
- Results of physical examinations
- Medical history
- Blood tests, x-rays and other diagnostic and medical procedures (being as specific and detailed as is necessary)
- Certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about study medication or drugs
- Records about study devices
- Billing information
- HIV testing results
- Substance use disorder information: [Specify.]
- Mental Health information: [Specify.]
- Genetic testing information: [Specify.]
- Genetic counseling information
- Sexual Assault/Abuse
- Domestic Abuse of an Adult with a Disability
- Child Abuse and Neglect
- Sexually Transmitted Illnesses (Minors)
- Pregnancy (Minors)
- Birth Control (Minors)

****[If PHI will be collected, delete the paragraph below. Then update the information above by inserting PI information and editing the list of bullets to include only those elements being collected for this study. Make sure these bullets align with the explanation of the procedures earlier in this consent and the methods description in the IRB submission.****

****PLEASE NOTE: If your study involves psychotherapy notes that are not part of the medical record, please contact ORSP staff for guidance since this requires additional consent****

****If no PHI is being used delete the above information and leave only the following paragraph.]****

No protected heath information will be collected as part of this study, so the provisions of the Privacy Rule as noted in the Health Insurance Portability and Accountability Act (HIPAA) do not apply. The researchers are still committed to protecting your information as described in other sections of this document.

c. How will researchers protect your personal information?
We promise to keep your information private, but we can't promise absolute secrecy. Here's how we'll keep your information safe:

Explain how information collected as part of this study will be protected (both physically and electronically, as appropriate). If identifiable information is being collected, there must be an explanation of how long potentially identifiable information will be kept (if indefinitely, state that). Explain how long research information will be maintained (identifiers kept separate from the other data, encoded through some mechanism, etc.) and whether it will be destroyed. If you plan to destroy research data, be sure to follow the current MWU policy on research data retention unless required to use some other guidance.

If the information from this research is shared in public, like at a conference, nobody will know you took part in the study.
Explain how participants' identity will be protected during publication/presentation. Include wording about protections if photographs or audio/video recordings are involved.

d. Could your information be used for future studies?
The information we collect might be used in other studies. If it is, we'll take away anything that could identify you. This information might be used in other studies without asking you.

e. How can your information be used outside of this study?
We'll only share your information with those who need it for this study. In general, we won't share your information without your permission. But sometimes, the law or special situations might make us share it with people, like:

- Reviewers from Midwestern University
- People from agencies like the Food and Drug Administration (FDA)
- People from an independent safety board
- Those handling payment (if applicable)
- People from the study sponsor (if applicable)

****[Select the appropriate statement regarding posting information to study registries. If neither applies, please delete the draft language.]****

*If your study is an **applicable clinical trial (ACT) regulated by FDA**, the following statement must be included verbatim. Contact ORSP for guidance on whether your study is an ACT.*
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

If you plan on posting the study even if it is not an ACT, amend the following statement to reflect the appropriate registry. Keep in mind that NIH-funded studies are generally required to be registered on ClinicalTrials.gov and ICMJE recommends that medical journals require registration of all trials

prior to enrollment as a requirement of consideration for publication. Individual journals vary in enforcing this requirement.
A description of this research study will be available on http://www.CliniclaTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Remember, your information is important, and we're working hard to keep it safe!

9. WHO CAN YOU CONTACT ABOUT THIS RESEARCH STUDY IF YOU HAVE QUESTIONS OR CONCERNS?

Please contact the researchers and/or MWU research official listed below if you want to

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you
- Report an illness, injury, or other problem
- Leave the study before it is finished
- Express a concern about the study

Contact information:

Name, Principal investigator	Mailing address	Telephone (with area code)	E-mail

If you have any questions regarding your rights as a research subject, please contact the MWU Official(s) listed below.

Name	Mailing address	Telephone	E-mail
Dr. James Woods Assistant Vice President of Research	Midwestern University 555 31st Street Downers Grove, IL 60515	630-515-6173	jwoods@midwestern.edu

10. WHAT DOCUMENTS WILL BE GIVEN TO YOU IF YOU CHOSE TO PARTICIPATE IN THIS RESEARCH STUDY?

You will be provided with a copy of this document for your records.

Study Title: Enter study title.

PI: Enter full PI name.

Submission/Revision Date: Click or tap to enter a date.

SIGNATURES

Consent to participate in the research study

I have read the information on this form or had it read to me. I have had all my questions answered to my satisfaction and understand the purpose of the research study and the potential risks and benefits. I agree to participate in this research study. If I have additional questions, I will contact the researchers listed in the contact information section (Question #9 above). If I chose to stop participating in this study, I will contact the principal investigator and formally withdraw my consent.

In the provided spaces on the next page, please print the name of the individual participating in this research study. Then sign, print, and date in the appropriate areas.

Name of individual participating in the research study:

Printed name of individual providing consent:

Relationship to individual participating in the research study:

- ☐ Self
- ☐ Parent
- ☐ Legal guardian
- ☐ Medical power of attorney/representative
- ☐ Healthcare surrogate
- ☐ Other – Please describe:

Signature of individual providing consent: Date:

Printed name of individual obtaining consent:

Signature of individual obtaining consent Date:

Printed name of individual witnessing consent (if applicable)

Signature of witness Date: