MIDWESTERN UNIVERSITY
STUDY INFORMATION SHEET

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.)

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.

The information below provides an overview of important information that will help you decide whether you want to participate in this research study.

Why is this study being done?	Provide a brief (1-2 sentence), plain language description of the study's purpose. If applicable, include a rationale for studying any interventions that may be used (e.g., prior interventions have not worked for this patient population.
Are you eligible to participate in the study?	Provide a brief, plain language description of who can and cannot participate in the study. 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." You can use bullets to provide more specific information about inclusion/exclusion criteria.
What will you be asked to do during the study?	Provide a brief, plain language description of the research activities. This should provide the potential participant with sufficient information to know what is being done and what they will be expected to do. If there are multiple study sessions/visits, you can provide a general overview of what may happen at each one. If you want to provide more detail, a separate study information handout can be provided. If audio or video recording is taking place, be sure to include it here. If there are multiple parts of the study (e.g., a survey and follow-up focus groups), be clear whether an individual can opt out of recording and still participate in other aspects of the study.

How much time will you spend on the study?	Provide a clear summary of the time commitment required by the study. Include both the overall length of participation and the amount of time required for study visits or other study-related activities 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."). You ***do not*** need to provide details about each visit or study procedure. You can provide this separately in a detailed study overview handout if needed. 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.
What are the main risks if you participate and what is being done to minimize those risks?	Provide a clear overview of the main risks to the individual if they choose to participate.

What information will be collected about you?	Provide a clear description of the data that will be collected. This could be the name of instruments being administered (e.g., EQ5D or Maslach Burnout Inventory) or any other information being collected. If identifiable information will be collected, you *must* describe what identifiers will be collected and explain in the next row how that is being collected and might be shared (two rows down). 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 final row of this table) 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. *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.
What is being done to protect information collected about you?	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.
Will information being collected about you be shared with others?	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) 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. If the information from this research is shared in public, like at a conference, nobody will know you took part in the study.
How much will participation in the study cost?	Describe any financial costs associated with participating in the study.
Will you be paid or compensated for your participation?	Describe any reimbursement or compensation for participating in the study.

What are other options besides participating in the study?	If this is a study of an active intervention (therapeutic procedure, a new educational technique, etc.), then this section must be included. If an active intervention is not being used, then this row can be deleted. Please contact ORSP if you have questions about whether this row should be included for your project. Depending on the study, you should explain what options an individual has if they choose not to participate. For example, a study of some classroom intervention may be applied to the entire class, but students have the option to participate in the actual study (completing surveys, using their assignment scores, etc.). If a student chooses not to participate in the study, they will still participate in the educational activities and have access to the standard educational support offered as part of the course.
Who should you contact if you have questions?	If you have any questions about this study, please contact PI Name via e-mail (XXXX@midwestern.edu) or at (630) 515-XXXX. If you have any questions regarding your rights as a research subject, please contact Dr. James Woods, Assistant Vice President of Research at (630) 515-6173.