**INSTRUCTIONS**: **Use this template to structure your consent form. Text in brackets and capitals are instructions for content for each section and should be deleted. The text in each section is provided as a suggestion. Some of the information in this form may not be relevant to your study and can be deleted. You should also add any information that applies to the study but is not in this template.**

**DELETE THIS BOX PRIOR TO SUBMITTING YOUR CONSENT FORM TO THE UHSRC.**

**Informed Consent Form**

Project Title:

Principal Investigator: [Name, institutional affiliation]

Co-Investigator: [IF APPLICABLE][Name, institutional affiliation]

Faculty Advisor: [ONLY FOR STUDENT PI] [Name, institutional affiliation]

Sponsor: [IF APPLICABLE]

**Invitation to participate in research**

You are invited to participate in a research study. In order to participate, you must [LIST ELIGIBILITY CRITERIA]. Participation in research is voluntary. Please ask any questions you have about participation in this study

**Important information about this study**

* The purpose of the study is [BRIEFLY DESCRIBE STUDY PURPOSE].
* Participation in this study involves [BRIEFLY DESCRIBE STUDY PROCEDURES AND TASKS].
* Risks of this study include [BRIEFLY DESCRIBE STUDY RISKS].
* The investigator will protect your confidentiality by [BRIEFLY DESCRIBE DATA STORAGE PROCEDURES].
* Participation in this research is voluntary. You do not have to participate, and if you decide to participate, you can stop at any time.

**What is this study about?**

The purpose of the study is [DESCRIBE STUDY PURPOSE]

**What will happen if I participate in this study?**

Participation in this study involves

* [LIST STUDY PROCEDURES HERE]
* [INDICATE ANY PROCEDURES THAT ARE EXPERIMENTAL]
* [IF THERE ARE MULTIPLE STUDY VISITS, DESCRIBE WHAT HAPPENS AT EACH VISIT USING SEPARATE SUB-SECTION HEADINGS: VISIT 1, VISIT 2, ETC.]
* [EXPLAIN HOW LONG PARTICIPATION LASTS, OVERALL AND BROKEN DOWN BY DAYS/SESSIONS/ETC.]

[IF CLINICALLY RELEVANT RESULTS WILL BE SHARED, MODIFY TEXT IN CAPS AND ADD: We may learn information about your health as a part of this research. We WILL/WILL NOT share this information with you. EXPLAIN HOW INFORMATION WILL BE RETURNED, IF APPLICABLE]

[IF AUDIO/VIDEOTAPING, MODIFY TEXT IN CAPS AND ADD: We would like to AUDIO/VIDEO record you for this study. If you are AUDIO/VIDEO recorded, it will be possible to identify you through your VOICE/IMAGE. If you do not agree to be AUDIO/VIDEO recorded, you may not be eligible to participate in this study.]

[IF RANDOMIZATION WILL OCCUR, MODIFY THE TEXT IN CAPS AND ADD: You will be assigned by chance (like the flip of a coin) to one of [XX] groups. One group will [DESCRIBE GROUP PROCEDURES] and the other group will [DESCRIBE GROUP PROCEDURES. ADD DESCRIPTIONS FOR EACH GROUP]. You or the investigator cannot choose which your group. You have an equal chance (1 out of XX) of being assigned to either study group.]

[IF BIOLOGICAL SAMPLES ARE COLLECTED, MODIFY THE TEXT IN CAPS AND ADD: This research WILL/WILL NOT involve whole genome sequencing. Please ask the investigator any questions you have about how your genetic information will be used.]

**What types of data will be collected?**

We will collect data about [LIST GENERAL TOPICS ABOUT WHICH DATA WILL BE COLLECTED. IF COLLECTED, THE FOLLOWING TYPES OF DATA **MUST** BE SPECIFIED: RACIAL OR ETHNIC ORIGIN; POLITICAL OPINIONS; RELIGIOUS OR PHILOSOPHICAL BELIEFS; TRADE UNION MEMBERSHIP, GENETIC INFORMATION; BIOMETRIC DATA FOR THE PURPOSES OF UNIQUE IDENTIFICATION; HEALTH DATA; OR SEX LIFE OR SEXUAL ORIENTATION INFORMATION]

**What are the expected risks for participation?**

[LIST RISKS HERE. YOU MAY CHOOSE FROM SAMPLE TEXT BELOW AND ADD ADDITIONAL TEXT. TIME AND INCONVENIENCE ARE NOT RISKS.]

There are no expected physical or psychological risks to participation.

The primary risk of participation in this study is a potential loss of confidentiality.

Some of the [SURVEY/INTERVIEW/FOCUS GROUP] questions are personal and may make you feel uncomfortable. You do not have to answer any questions that make you uncomfortable or that you do not want to answer. If you are upset, please inform the investigator immediately.

[IF AUTOMATED PROCESSING WILL BE USED FOR DECISION MAKING, ADD: Your information will be processed by an automated system (e.g., a computer program) for the purposes of ADD PURPOSE HERE].

**Are there any benefits to participating?**

[LIST BENEFITS HERE. MOST STUDIES WILL NOT DIRECTLY BENEFIT SUBJECTS. USE SAMPLE TEXT BELOW AND ADD ADDITIONAL TEXT. COMPENSATION OR LEARNING ABOUT ONESELF OR THE RESEARCH PROCESS ARE NOT BENEFITS.]

You will not directly benefit from participating in this research.

Benefits to society include [LIST BENEFITS TO SOCIETY].

**How will my information be kept confidential?**

[EXPLAIN MEASURES YOU WILL USE TO KEEP DATA SECURE. YOU MAY CHOOSE FROM THE SAMPLE TEXT BELOW AND ADD ADDITIONAL TEXT]

We plan to publish the results of this study. We will not publish any information that can identify you. [IF IDENTIFIABLE DATA WILL BE PUBLISHED: We would like to publish your identifiable information, with your permission. We will ask you to initial a statement at the bottom of this form to give us permission to identify you in publications. Please note that once your identifiable information is published, it cannot be removed, even if you are unhappy with the publication.]

We will keep your information confidential by [STATE CONFIDENTIALITY MEASURES: USING A CODE TO LABEL DATA WITH THE CODE LINKED TO IDENTIFIABLE INFORMATION IN A KEY STORED SEPARATELY FROM DATA, NOT COLLECTING ANY IDENTIFIABLE INFORMATION (INCLUDING YOUR NAME), ETC.]. Your information will be stored in a [STATE HOW DATA WILL BE STORED: PASSWORD-PROTECTED FILE ON A PASSWORD-PROTECTED COMPUTER, LOCKED FILING CABINET, ETC.]. We will store your information for at least five years after this project ends, but we may store your information indefinitely.

We will make every effort to keep your information confidential, however, we cannot guarantee confidentiality. The principal investigator and the research team will have access to the information you provide for research purposes only. Other groups may have access to your research information for quality control or safety purposes. These groups include the University Human Subjects Review Committee, the Office of Research Development, the sponsor of the research, or federal and state agencies that oversee the review of research, including the Office for Human Research Protections and the Food and Drug Administration. The University Human Subjects Review Committee reviews research for the safety and protection of people who participate in research studies.

[IF MANDATORY REPORTER, ADD: If, during your participation in this study, we have reason to believe that elder abuse or child abuse is occurring, or if we have reason to believe that you are at risk for being suicidal or otherwise harming yourself or others, we must report this to authorities as required by law. We will make every effort to keep your research information confidential. However, it may be required by law that we have to release your research information. If this were to occur, we would not be able to protect your confidentiality.]

[IF FOCUS GROUP OR GROUP INTERVIEW, MODIFY TEXT IN CAPS AND ADD: The investigators will ask you and the other people in the group to use only first names during the FOCUS GROUP/INTERVIEW session. The investigators will also ask you not to tell anyone outside of the group about anything that was said during the group session. However, we cannot guarantee that everyone will keep the discussions private.]

**Storing study information for future use**

We WILL/WILL NOT store your information to study in the future. Your information will be labeled with a code and not your name. Your information will be stored in a password-protected or locked file and will be stored indefinitely.

We may share your information with other researchers without asking for your permission, but the shared information will never contain information that could identify you. We will send your de-identified information by email and only upon request.

**What are the alternatives to participation?**

[LIST ALTERNATIVES HERE. YOU MAY USE SAMPLE TEXT BELOW. IF COURSE CREDIT IS OFFERED FOR PARTICIPATION, LIST ALTERNATIVE METHODS OF OBTAINING SUCH CREDIT – COMPLETING ALTERNATE ASSIGNMENT, ETC.]

The alternative is not to participate.

The study treatment offered in the study is experimental in nature and is not available outside of this research study. If you would like to seek alternate, standard of care treatment, the investigator can provide you with resources.

You do not have to participate in this research study to earn course credit. If you choose not to participate, your instructor will inform you of alternate ways to obtain course credit.

**Are there any costs to participation?**

[LIST COSTS OF PARTICIPATION. TIME IS NOT A COST]

Participation will not cost you anything.

You will be expected to pay for the study treatment provided at a reduced rate of $[XX] per session. You are being charged for study treatment because the treatment used is considered standard of care and is accessible whether or not you participate in this research study.

**Will I be paid for participation?**

[DESCRIBE COMPENSATION FOR THE STUDY. YOU MAY USE THE SAMPLE TEXT PROVIDED BELOW OR ADDITIONAL TEXT. REFRESHMENTS DO NOT CONSTITUTE COMPENSATION. INCLUDE INFORMATION ABOUT COURSE CREDIT IF APPLICABLE]

You will not be paid to participate in this research study.

You will receive [XX] hours of course credit if you complete this study. If you do not complete this study, course credit will be prorated with [XX] credit hours earned per [XX] hours of participation.

You will be paid $[XX] for completing this study. If you do not complete this study, you will be paid $[XX] for each hour of participation.

You will be given a gift card for $[XX] for participating in this research study.

**What happens if I am injured while participating in the research? [THIS SECTION IS OPTIONAL. IF THE STUDY IS NOT GREATER THAN MINIMAL RISK OR IF PHYSICAL INJURY IS NOT LIKELY, REMOVE THIS SECTION]**

If you are injured as a result of participating in this study, we will assist you in getting necessary medical treatment. You or your insurance company will be responsible for the cost. Eastern Michigan University does not provide any form of compensation for injury.

**Who will profit from the study results? [THIS SECTION SHOULD ONLY BE USED IF BIOLOGICAL SPECIMENS WILL BE COLLECTED AND RETAINED]**

The biological specimens and/or your personal information may be used by the investigator and by Eastern Michigan University for commercial profit. If this happens, you will not be notified. You will not share in the profit.

**Study contact information**

If you have any questions about the research, you can contact the Principal Investigator, [PI NAME], at [EMAIL ADDRESS] or by phone at [PHONE NUMBER]. [STUDENT INVESTIGATORS MUST ADD THE FOLLOWING TEXT: You can also contact [NAME]’s adviser, [ADVISER’S NAME], at [ADVISER EMAIL ADDRESS] or by phone at [ADVISER PHONE NUMBER].

For questions about your rights as a research subject, contact the Eastern Michigan University Human Subjects Review Committee at human.subjects@emich.edu or by phone at 734-487-3090.

**Voluntary participation**

Participation in this research study is your choice. You may refuse to participate at any time, even after signing this form, without repercussion. You may choose to leave the study at any time without repercussion. If you leave the study, the information you provided will be kept confidential. You may request, in writing, that your identifiable information be destroyed. However, we cannot destroy any information that has already been published.

**Statement of Consent**

I have read this form. I have had an opportunity to ask questions and am satisfied with the answers I received. I give my consent to participate in this research study.

**Signatures** [REMOVE SIGNATURE LINES FOR WAIVER OF DOCUMENTATION OF CONSENT]

IF IDENTIFIABLE DATA WILL BE PUBLISHED, MODIFY TEXT IN CAPS AND ADD:

\_\_\_\_\_\_\_\_\_\_\_ I agree to allow information that will directly identify me to be published.

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

 Name of Subject

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

Signature of Subject Date

I have explained the research to the subject and answered all their questions. I will give a copy of the signed consent form to the subject.

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

Name of Person Obtaining Consent

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

Signature of Person Obtaining Consent Date