**INFORMED CONSENT FORM FOR RESEARCH BEING CONDUCTED UNDER THE AUSPICES OF**

**MISERICORDIA UNIVERSITY**

**INTRODUCTION:** The name of this research study is, “[*title of the study*]”. The person(s) working on this project is/are [*name(s) and title(s) of the researcher(s)].* [*If a faculty mentor is involved, insert faculty mentor name and title*]. This document defines the terms and conditions for consenting to participate in this research study.

**WHY IS THIS RESEARCH STUDY BEING DONE?** *[Briefly (1-2 sentences) explain the purpose/objectives of the research in simple words.]*

**WHAT IS THE KEY INFORMATION I NEED TO HELP ME DECIDE IF I SHOULD TAKE PART IN THIS STUDY OR NOT?** ***Give a concise and focused presentation of key information that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in this research, to include:***

* ***What am I being asked to do?*** If you agree to be in this study, you are being asked to: ***(Describe the procedures that participants will follow****), any audio/visual recordings and expected duration of participation (number of sessions/appointments;* ***time for each session/appointment******and*** *the* ***total******time expected****), use wearable technology (ex. Fitbit), the identification of any procedures that are experimental; ORGANIZED IN A WAY TO FACILITATE BETTER UNDERSTANDING (using bullet points, pictures, diagrams, etc.)*
* ***Any possible risks or discomforts?*** *State that there are no foreseeable risks or discomforts associated with this study* OR *list any physical or psychological risks/discomforts. If applicable, explain any procedures that are experimental.*
* ***Any direct benefits for me?*** *State “no”* OR *state the direct benefits.*
* ***Any paid compensation for my time?*** *State that participants will not get paid for their participation* OR *explain what they will get and any instructions/information on how and when they will receive their payment/compensation.*
* ***How will my information and/or identity be protected?*** *Will researchers be able to link participant data back to them? Explain if data will have identifiers or not, how will the data be secured? How long? Who will have access?*
* ***What are the total number of subjects the researcher(s) will try and recruit for this study?*** *Give your total number of subjects you expect/hope to recruit.*

**WHAT POSSIBLE RISKS OR DISCOMFORTS CAN I EXPECT FROM TAKING PART IN THIS STUDY?** [***Explain any reasonably foreseeable risks or discomforts to participants. Identify any procedures that are experimental.]*** ***Pick 1 of the 2 statements below that apply to your study and delete the other.***

**(1)** There are no known risks to you for participating in this study.

**or**

**(2)** [*Explain any possible physical or psychological risks.]*

**WHAT POSSIBLE BENEFITS CAN I EXPECT FROM TAKING PART IN THIS STUDY?**

***[Pick 1 of the 2 statements below that apply to your study and delete the other.*** *NEVER include any compensation or extra credit in this section. (Payment is NOT a benefit. USE the payment/compensation section)*

* ***Any direct benefits for me?*** **(1)**There are no direct benefits to you for participating in this study.**or (2)** [*Explain their direct benefit(s)]*
* ***Any indirect benefits for me or others?*** *Explain any indirect benefits to them or others (society, etc.).*

**WHAT ARE THE CONDITIONS OF MY PARTICIPATION AND CAN I LEAVE THE STUDY BEFORE IT ENDS?** *[Begin this section by adding any specific selection or exclusion criteria, to include: age, gender, health conditions, etc.]* You must be at least 18 years old to participate in this study.Participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. Your participation in this study is over [\_\_\_\_\_]. However, you can leave the study at any time, even if you have not finished, without any penalty or loss of benefits to which you are otherwise entitled.

**HOW WILL MY IDENTITY AND/OR MY DATA BE PROTECTED?**

* ***Will researchers ever be able to link my data/responses back to me?*** *State “no” or explain how and why.*
* ***Will my data include information that can identify me (names, addresses, etc.)?*** *Answer.*
* ***Will researchers assign my data/responses a research ID code to use instead of my name?*** *State “no” or explain.*
  + ***If yes, will researchers create a list to link names with their research ID codes?*** *State “N/A” or explain.*
  + ***If yes, how will researchers secure the link of names and research ID codes? How long will the link be kept? Who has access? Approximate destroy date?***  *State “N/A” or explain. Answer each question.*
* ***How will my data be protected (electronic and hardcopy)? Where? How long? Who will have access? Approximate destroy or de-identification date?*** *Answer each question.*
* ***Where and how will the signed consent forms be secured?*** *Explain how secured and if the signed consent forms are stored separately from the data.*

**\*(FOR ANY RESEARCH THAT INVOLVES THE COLLECTION OF IDENTIFIABLE PRIVATE INFO. OR IDENTIFIABLE BIO-SPECIMENS) \*[*This section can be deleted if not applicable to your study*]**

**CAN MY INFORMATION COLLECTED FROM THIS STUDY BE SHARED OR USED BY OTHERS?**

*[Pick 1 of the 2 statements below that apply to your study and delete the other. Also change the language to clarify if the statement is about bio-specimens, private identifiable information, or both.]*

**(1)** Once identifiers (name, address, etc.) are removed from the identifiable private information or identifiable bio-specimens collected for this study, the de-identified information or bio-specimens could be used for future research studies or distributed to other investigators for future research studies without additional informed consent from you or your legally authorized representative.

**or**

**(2)** Your identifiable information (name, address, etc.) or identifiable bio-specimens collected for this research study will ***not*** be used or distributed to other investigators for future research studies, even if your identifiers are removed.

**HOW WILL THE RESULTS BE USED?**  *[Briefly explain how you will be presenting this data: published? publically presented? Will the data be grouped or will you also include individual data? Will participants be able to be identified in the data findings? ]*

**WILL I BE PAID/COMPENSATED FOR BEING IN THIS STUDY?**

***[Either state that participants will not get paid to participate or explain the payment/compensation.***

*- If course extra credit is being offered, please include any non-research extra credit option available.*

*- Explain any payment/compensation****.*** *that are provided in increments and what criteria these increments are based on. Also explain if participants still receive these payment/compensation if they withdraw early and if they will receive a portion of the payment/compensation for what they’ve completed before they withdrew.*

*- If there is raffle/lottery, you must state the estimated odds of winning.*

***\*Explain any instructions/information on how and when they will receive their payment/compensation.]***

**WHO CAN ANSWER MY QUESTIONS ABOUT THIS STUDY?**

You should contact the principal investigator [Insert name of the PI and contact email address and phone number and (if applicable) add Faculty Mentor name and email address].

**WHO CAN ANSWER QUESTIONS ABOUT MY RIGHTS AS A RESEARCH SUBJECT?**

You should contact Misericordia University IRB at 570-674-6218 or via e-mail at irb@misericordia.edu or the researcher listed above.

**PARTICIPANT’S RIGHTS**

* You have been given an opportunity to read and discuss the informed consent and ask questions about this study;
* You have been given enough time to consider whether or not you want to participate;
* You have read and understand the terms and conditions and agree to take part in this research study;
* You understand your participation is voluntary and that you may stop participation at any time without penalty.

**Your signature means that you understand your rights listed above and agree to participate in this study**

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Signature of Participant or Legally Authorized Representative Date