[Follow instructions in red font and remove all red font and instructions before submitting to IRB]

MARQUETTE UNIVERSITY

AGREEMENT OF CONSENT FOR RESEARCH PARTICIPANTS

(insert title of project)

(insert Principal Investigator’s name)

(insert Academic Department)

**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:

* **Why is the study being done?** Briefly state the purpose of the study

• **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), expected duration of participation (number of sessions/appointments; time for each session/appointment and the total time expected), 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.

**Taking part in this research project is voluntary. You don’t have to participate, and you can stop at any time.**

**Please take time to read this entire form and ask questions before deciding whether to take part in this research project.**

**PURPOSE:**

* This study involves research.
* The purpose of this research study is (insert a short, concise, statement that can be clearly understood by individuals with no knowledge of the researcher’s field – avoid jargon.)
* You will be one of approximately X participants in this research study.

**PROCEDURES:**

* Include a detailed step-by-step account of study procedures involving the subject
* Make sure to describe the specific topics that will be covered in surveys or interviews.
* State where the procedures will occur
* If recording include “You will be [audio or video] recorded during the interview portion of the study to ensure accuracy. The tapes will later be transcribed and destroyed after X years beyond the completion of the study. For confidentiality purposes, [your name will not be recorded/will be recorded and will be removed during transcription]”
* If research involves biospecimens include a sentence stating if the research will or might include whole genome or exome sequencing
* (If applicable) Include a sentence stating whether or not clinically relevant research results will be given to the subject and under what conditions this would occur

**DURATION:**

* Your participation will consist of (describe the number of sessions, minutes, hours, days, etc. they will be actively engaged in the research and the total duration of study participation.)

**RISKS:**

* If there are identifiable risks, list the risks and describe the safeguards in place to avoid these risks.
* (If minimal risks involved include: The risks associated with participation in this study are no greater than you would experience in everyday life.)
* (if the study involves online surveys) Collection of data and survey responses using the internet involves the same risks that a person would encounter in everyday use of the internet, such as hacking or information being unintentionally seen by others.
* If study has the potential to discover child abuse or neglect elder abuse or intent to harm self or others include the following: Although your privacy is very important, if you talk about actual or suspected abuse, neglect, or exploitation of a child or elder, or if you talk about hurting yourself or others, the researcher or other study team member must and will report this to the Bureau of Milwaukee Child Welfare, the Wisconsin Department of Children and Families Services, or law enforcement agency.
* [If applicable include:] The treatment or procedure in this study may involve risks that are currently unforeseeable.
* Any significant new findings developed during the course of this study that may impact your willingness to continue participating will be shared with you.

**BENEFITS:**

* Describe any direct benefits to the subject OR state There are no direct benefits to you for participating in this study. This research may benefit society by (insert societal benefit here).

**CONFIDENTIALITY:**

* Data collected in this study will be [pick one: anonymous or kept confidential]
* (include if using study IDs) All your data will be assigned an arbitrary code number rather than using your name or other information that could identify you as an individual.
* Describe where the key linking names to ID numbers will be stored and how it will be secured
* Describe data security measures-encrypted, password-protected, etc…
* Include one of the following statements: The data and/or samples collected in this study may be deidentified and used for future research or give to another investigator for future research without additional informed consent. **OR** The data/samples collected in this study will not be used or distributed for future research even if they have been deidentified.
* If applicable, describe how audio/video recordings will be secured and stored and when they will be erased.
* When the results of the study are published, you will not be identified by name.
* State if direct quotes will be used in reports or publications
* The data will be destroyed by shredding paper documents and deleting electronic files (number of years or months etc.) after the completion of the study. [Delete if data will be kept indefinitely]
* If using online surveys: Although your responses will be deleted from the survey provider website (state when), your data may exist on backups or server logs beyond the timeframe of this research project.
* If conducting focus groups include: Everyone who participates in the focus group will be instructed to keep discussions confidential. However, the researchers cannot guarantee that all focus group participants will respect everyone’s confidentiality.
* For research that is regulated by the Food and Drug Administration, include a statement that indicates the research records may be inspected by the Food and Drug Administration.
* If applicable, include a sentence stating that biospecimens, even if deidentified, may be used for commercial profit and whether/if that profit will be shared with the subject.
* This study is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot share any information that might identify you in any legal proceedings or used as evidence in any trials unless you give them permission to release the information. Data without identifying information may be used for these purposes if needed.
* Even with the Certificate of Confidentiality, the researchers are still required to share information with authorities if they discover any evidence of child abuse or neglect or if you indicate you are going to harm yourself or others.
* Data with identifiable information can be released to the agency that funded this study for evaluation or auditing purposes and the Institutional Review Board (also include FDA if applicable).
* You can choose to release your identifiable data to an insurer, medical provider or other person not involved in the research. To do this you must agree to this release.
* Your research records may be inspected by the Marquette University Institutional Review Board or its designees, the National Institutes of Health (or the name of federal funding agency) and (as allowable by law) state and federal agencies.
* If the study meets the NIH definition of a clinical trial include (see <https://grants.nih.gov/policy/clinical-trials/CT-decision-tree.pdf> ) the following required statement: A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US 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.
* Data collected from this study may be placed in a publicly accessible repository as a requirement of publication. The study data that are stored there will not contain any links to you or your identifying information.

**COMPENSATION:** (delete this section if not applicable)

* Describe the amount of compensation, how and when it will be distributed, and in what form.
* If pro-rated payments will be paid to subjects for early withdrawal or another purpose, clearly state this.

**Extra Costs to Participate:** (Delete this section if not applicable.)

* Describe any fees the subject will be asked to pay related to research participation for example, campus parking fees, transportation to and from study side, etc…

**Injury or Illness:** (Delete section if not applicable)

* If you think you have experienced a research-related injury, illness, or adverse event, you should contact the researcher (see Contact Information below).
* Marquette University does not have money set aside to pay for treatment, lost wages, lost time, or pain. However, you do not waive any rights by signing this consent form.

**Voluntary Nature of Participation:**

* Participating in this study is completely voluntary and you may withdraw from the study and stop participating at any time without penalty or loss of benefits to which you are otherwise entitled.
* Describe if data will be used or destroyed if subject withdraws from study. If the study involves anonymous data collection state: Your data will be used even if you withdraw from the study.
* You may skip any questions you do not wish to answer.
* If there are circumstances under which the subject’s participation may be terminated by the investigator please state them
* Your decision to participant or not will not impact your relationship with the investigators or Marquette University. [modify statement to include grades and relationship with instructors if class-based recruitment is proposed, or employment and relationship with employers if employment-based recruitment is proposed]

**ALTERNATVES TO PARTICIPATION**:

* (If no alternatives) There are no known alternatives other than to not participate in this study.
* If you do not wish to participate in this study you can choose to (describe the alternatives here).
* If offering extra credit incentives, describe the non-research alternative here (required).

**Contact Information:**

* If you have any questions about this research project, you can contact (insert PI name and contact information, plus the name and contact information for any additional research personnel that also serve as a contact for participants.)
* If you have questions or concerns about your rights as a research participant, you can contact Marquette University’s Office of Research Compliance at (414) 288-7570.

I HAVE HAD THE OPPORTUNITY TO READ THIS CONSENT FORM, ASK QUESTIONS ABOUT THE RESEARCH PROJECT AND AM PREPARED TO PARTICIPATE IN THIS PROJECT.

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 (Printed Name of Participant)

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(Signature of Participant) Date

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(Printed Name of Individual Obtaining Consent)

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 (Signature of Individual Obtaining Consent) Date