INFORMED CONSENT FORM

IRB Approval Number: _____

This study has been reviewed and approved by The University of Wisconsin-Whitewater's Institutional Review Board (IRB). The IRB has determined that this study meets the ethical obligations required by federal law and University policies. If you have questions or concerns regarding this study, please contact the Principal Investigator.

The Federal regulations, 45 CFR part 46 for the protection of human subjects in research, require that an investigator obtain the legally effective informed consent of the subject or the subject's legally authorized representative. ALL the items addressed on this form must be presented *and agreed to by the participant prior to participation in a research study.*

Study Information

Title of Study: _____

Principal Investigator:

Name: _____ Department: _____

Address: _____

Email: _____Phone: _____

Other Researchers - UWW or Unaffiliated (as applicable):

Name: _____ Institution: _____

Email: _____Phone: _____

Student Investigators (Name; Email) (as applicable):

(1): _____

(2): _____

KEY INFORMATION FOR PARTICIPANTS

Invitation to Participate

You are invited to participate in a research study. This form provides information to help you decide whether you wish to participate. Please read it carefully before making your decision. Research studies include only people who voluntarily choose to participate. Your participation is entirely voluntary, and you may decline to participate or withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled.

Please ask the research team any questions you have before deciding whether to participate.

Purpose of the Study

The purpose of this study is to:

Description of the Study and Procedures

If you agree to participate, you will be asked to:

The study procedures may include (check all that apply):

- ☐ Survey
- ☐ Interview
- ☐ Focus group
- ☐ Review of existing records
- ☐ Experimental intervention
- ☐ Observation
- ☐ Audio recording
- ☐ Video recording
- ☐ Collection of biological specimens
- ☐ Other: _____

Expected Time or Duration of Participation

Your participation is expected to last approximately:

Risks or Discomforts

While participating in this study, you may experience the following risks or discomforts:

If there are no foreseeable risks beyond those encountered in everyday life, state:

There are no known foreseeable risks beyond those ordinarily encountered in daily life.

There may also be risks or discomforts that are currently unforeseeable. If significant new information becomes available that may affect your willingness to continue participating, you will be informed.

Benefits

Benefits to You – If applicable:

Benefits to Others – If applicable:

It is hoped that the knowledge gained from this research will contribute to:

Costs and Compensation

Costs

☐ There are no anticipated costs associated with participation.

☐ Participants may incur the following costs: _____

Compensation

☐ Participants will not receive compensation.

☐ Participants will receive: _____

Your Rights as a Participant

Your participation is voluntary.

You may choose not to participate or discontinue your participation at any time without penalty, loss of benefits, or adverse consequences.

Your decision whether to participate will not affect your relationship with the investigator, your institution, your employer, your instructor, your healthcare provider, or any services to which you are entitled.

Confidentiality or Safeguarding the Identity of Participants

Every reasonable effort will be made to maintain the confidentiality of your research records.

Research data will be stored securely in electronic and/or physical locations and protected to the extent permitted by law.

Only authorized members of the research team, institutional oversight officials, or regulatory agencies may review identifiable research records when necessary.

Information obtained from this study may be presented in publications or professional presentations; however, your identity will not be disclosed unless required by law or unless you provide additional permission.

If applicable, indicate plans for sharing de-identified data: _____

Audio or Video Recording (*Complete only if applicable*)

During your participation, you may be audio and/or video recorded. The recordings will:

- Be used only for purposes described in this study, including for education, publications, professional presentations and training;
- Be stored securely; and be accessible only to authorized research personnel unless additional permission is obtained; and
- Be retained according to institutional and regulatory requirements before being securely destroyed or permanently de-identified.

Please indicate your preference:

☐ I agree to be audio/video recorded.

☐ I agree to participate but decline to be recorded (if participation without recording is possible).

Future Use of Data

Data collected during this study, with all identifying information removed, may be retained indefinitely and used in future research by the investigators or by other researchers without additional consent.

Right to Withdraw

Your participation is entirely voluntary. You may stop participating at any time without penalty. If your responses are collected anonymously, data already submitted may not be identifiable and therefore may not be removable after submission.

STATEMENT OF CONSENT

You do not have to sign this form. If you choose to sign below, you acknowledge that:

- You have read this form. You have had an opportunity to ask questions. Your questions have been answered satisfactorily. You voluntarily agree to participate in this research study.

Adult Participant

☐ I certify that I am 18 years of age or over and agree to participate in this research study.

Signature of participant

_____ Date _____

Printed name of participant _____

Signature of person obtaining consent

_____ Date _____

Printed name of person obtaining consent_____

Parent/Guardian or Legally Authorized Representative (For Minors or others, as applicable)

Printed name of child/other _____

Signature of parent or individual legally authorized to consent

_____ Date_____

Signature of person obtaining consent

_____ Date_____

Printed name of person obtaining consent _____

INSTRUCTIONS FOR COMPLETING THIS INFORMED CONSENT TEMPLATE

These instructions are intended for investigators preparing an IRB submission. Remove this section before distributing the consent form to participants unless your institution requires otherwise.

General Guidance

- **Please download the form, complete and attach a completed copy with your application**.
- Write in plain language that can generally be understood by individuals with approximately an eighth grade reading level.
- Avoid technical, legal, or scientific jargon whenever possible.
- Organize information clearly using headings and short paragraphs.
- If a minor is involved, please ensure that the Assent form is completed and submitted with the consent form.
- Ensure that all required information is complete before IRB submission.

Title of Study. Insert the official title of the research study approved by the IRB.

Principal Investigator

Include: Full name; Institutional affiliation; Office address; Telephone number and Email address. The PI is the Primary Contact for the research.

List only co-PI(s) and Student Investigator(s) to minimize future revisions.

Purpose of the Study

Describe why the research is being conducted.

Avoid technical terminology.

If deception is involved, explain as much as possible without compromising the study and ensure the IRB has approved the approach.

If investigational drugs or devices are involved, clearly explain what "investigational" means.

Description of Study Procedures

Describe exactly what participants will do. Include:

- Types of activities

- Number of visits or sessions
- Data collection methods
- Approximate location
- Whether interviews, surveys, focus groups, observations, or experimental procedures are involved
- Whether participants will be audio, video, or screen recorded
- Whether biological specimens or genetic analyses will be collected
- Any experimental procedures or interventions

Participants should be able to understand precisely what participation involves.

Expected Duration

Provide a realistic estimate of participation time.

If participation varies among individuals, provide a range (for example, "approximately 30–45 minutes").

Risks or Discomforts

Describe foreseeable risks using language understandable to the general public. Potential examples include:

- Emotional discomfort; Embarrassment; Loss of confidentiality; Fatigue; Mild physical discomfort; Blood draw risks; Medication side effects; Motion sickness; Skin irritation; and Allergic reactions

If applicable, explain how risks will be minimized.

If no foreseeable risks exist, clearly state this.

Benefits

Describe anticipated benefits separately for: Participants and/or Society or future research

Do not describe compensation as a benefit.

Avoid overstating potential benefits.

Costs and Compensation

Explain: Any participant costs; Amount of compensation; Form of payment; Timing of payment; Whether partial compensation will be provided if participants withdraw

Compensation should never depend upon completing the entire study.

If extra credit is offered to students, describe an equivalent alternative activity.

Participant Rights

Clearly explain that participation is voluntary.

Include statements addressing situations where investigators have authority relationships with participants (such as instructors, supervisors, or employers), making clear that participation or refusal will not affect grades, employment, recommendations, healthcare, or other benefits.

Confidentiality or Safeguarding the Identity of Participants

Describe: How data will be stored; Who may access identifiable information; How confidentiality will be protected; Whether de-identified data may be shared with other researchers; and any legal limitations on confidentiality. Avoid overly specific storage procedures that may change over time unless required by your institution.

Audio/Video Recording

Complete this section only if recordings will occur.

Specify: Purpose of recording; Who will access recordings; Storage procedures; Retention period; Future uses (if any)

Provide participants with the opportunity to consent separately to recording whenever appropriate.

Future Use of Data

Either: De-identified data may be retained indefinitely for future research; or Data will not be used in future research and will be retained only for the period approved by the IRB before destruction.

Right to Withdraw

State clearly that participation is voluntary and participants may withdraw without penalty.

If anonymous data cannot be withdrawn after submission, explain this limitation.

STATEMENT OF CONSENT

If the research is done online or via audio or video, on the signature line for participant(s), instead of a signature of the participant the Principal Investigator or Researcher shall indicate the

same and themselves sign as witness.