

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Valparaiso University

Note to Investigators:

Use this template when creating informed consent forms. Use of alternative wording or format is permitted, but doing so may slow down the review process. Information in italics is for the researcher's information and should be deleted from the actual consent form. The material in brackets should be completed with relevant information. When creating informed consent forms, keep language and vocabulary as basic and straightforward as possible (around an 8th-grade reading level). All sections of the consent form, except the "Consent" section, should be written in the second person ("You are invited...").

TITLE OF STUDY

[Insert title]

PRINCIPAL INVESTIGATOR/RESEARCHER

[Name]

[Department]

[Address]

[Phone]

[Email]

FACULTY SUPERVISOR *(delete if the PI is a faculty or staff member)*

[Name]

[Department]

[Address]

[Phone]

[Email]

SUMMARY

If your informed consent document is very long (i.e., more than about 5 pages) provide a concise summary with the key points of your study. If your informed consent document is not long, delete this section.

PURPOSE OF STUDY

You are being asked to take part in a research study. Before you decide to participate in this study, it is important that you understand why the research is being done and what it will involve. Please read the following information carefully. If anything is unclear or you need more information, please ask the researcher.

The purpose of this study is to *[Briefly describe the purpose of the study.]*

STUDY PROCEDURES OR STEPS

List all procedures or steps, preferably in chronological order, which will be used in the study. Point out any procedures that are considered experimental. Clearly explain technical terminology using non-technical language. Include the following information and any additional relevant information.

- *Provide the time period over which this study will be conducted.*
- *State the amount of time required of participants per session, if applicable, and for the total duration of the study.*
- *State the approximate number of subjects involved in the study.*
- *If the study includes audiotaping, videotaping, or photographing any part of your participation, provide information about the use of these products.*

RISKS AND DISCOMFORTS

In simple, non-scientific, or non-technical language, describe all reasonably foreseeable risks and discomforts, if any, of each of the procedures to be used in the study including,

- *Emotional risks (e.g., feelings of sadness or anxiety)*
- *Legal risks (e.g., the possibility of discovering activities that may require reporting to authorities, the possibility of being arrested)*
- *Physical risks (e.g., nausea, muscle aches, rashes, infection, discomfort)*
- *Social or economic risks (e.g., loss of confidentiality; effect on financial standing, employability, or insurability)*

Include a statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable.

Also, describe any measures that will be used to minimize the risks. Provide information regarding where to obtain help if the subject experiences any discomfort from participation. For example, contact information for the student counseling center if participation in the study causes emotional or psychological unease.

BENEFITS

List the benefits you anticipate will be achieved from this research. Include benefits to participants, others, or the body of knowledge. If there is no direct benefit to the participant, state so. For example, “There will be no direct benefit to you for your participation in this study. However, we hope that the information obtained in the study may”

CONFIDENTIALITY

Your responses to this [survey] will be anonymous. Please do not write any identifying information on your [survey].

OR

For the purposes of this research study, your comments will not be anonymous. Every effort will be made by the researcher to preserve your confidentiality including the following:

[State measures taken to ensure confidentiality, such as those listed below:

- *Identifying Information*

- *De-identification of data - Assigning code names/numbers for participants that will be used on all research notes and documents.*
- *If you will de-identify data or keep identifying information separate from research data (e.g. signed consent forms kept separate from the survey data and the two will not be connected).*
- *If you plan to keep identifying information with the data, state this here.*
- *If you are not planning to collect any identifying information at all (as in anonymous surveys).*
- *Describe the physical security of data/research files and how will sensitive data be kept secure in an electronic environment - Keeping notes, interview transcriptions, and any other identifying participant information in a locked file cabinet in the personal possession of the researcher or a secured electronic file that only the research team members have access to.*
- *Who will have access to identifying information - For example, only the Principal Investigator and their collaborator(s) will have access to the data.*

FUTURE USE OF YOUR DATA

Your data will be kept confidential as described above. Your data will be used by the Principal Investigator and research team members or collaborators who are involved with this study. This collaboration may include researchers outside of Valparaíso University *[if known, provide names and check applicable boxes.*

- € *De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee the anonymity of your personal data.*
- € *Identifiers might be removed and the de-identified information used for future research without additional consent.*
- € *Identifiable information might be used for future research with obtaining your consent.*
- € *Your information will not be used or distributed for future research studies.]*

If you do not agree with this use of your data, you may voluntarily withdraw from the study at any time.

AUDIO/VIDEO RECORDING AND PHOTOGRAPHY

If audio and/or video recording and/or photography devices will be used, explain why these are needed and what will be done with the recordings and images upon completion of the research (kept indefinitely, archived after transcription, destroyed after X years). See separate consent below. If audio/video recordings and photography will not be used, delete this section and the corresponding section of the consent form below.

INCENTIVES FOR PARTICIPATION/COMPENSATION

Indicate what participants will receive for their participation in this study. Indicate other ways participants can earn the same amount of credit or compensation (for example, extra credit for students). State whether participants will be eligible for compensation if they withdraw from the study prior to its completion. If there is no compensation, delete this section.

CONTACT INFORMATION

If you have questions at any time about this study, or you experience adverse effects as a result of participating in this study, you may contact the researcher whose contact information is provided on the first page. If you have questions regarding your rights as a research participant, or if problems arise that you do not feel you can discuss with the principal investigator, please contact the Valparaiso University Institutional Review Board at valpoirb@valpo.edu or 219-464-5798.

VOLUNTARY PARTICIPATION

Your participation in this study is voluntary. It is up to you to decide whether to participate in this study. If you decide to take part in this study, you will be asked to sign a consent form. After you sign the consent form, you are still free to withdraw at any time and without giving a reason. Withdrawing from this study will not affect your relationship with the researcher, if any. If you withdraw from the study before data collection is completed, your data will be returned to you or destroyed. You may decline to answer any or all questions and you may terminate your involvement at any time if you choose.

CONSENT FORM

Note: Please delineate the "Consent" section of the Informed Consent Form by drawing a line across the page (like the one above this paragraph). This delineation is important because the consent form grammar shifts from second person to first person, as shown in this example.

CONSENT FOR PARTICIPATING IN THE RESEARCH STUDY

I have read and I understand the information provided and have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and without cost. I understand that I will be given a copy of this consent form. I voluntarily agree to take part in this study.

Participant's Printed Name_____

Participant's signature _____

Date

Researcher's Printed Name _____

Researcher's signature _____

Date

CONSENT FOR RECORDING/PHOTOGRAPHY

Please sign below if you are willing to have this interview recorded or photographed. You may still participate in this study if you are not willing to have the interview recorded. Check applicable boxes.

- I do not want to have this interview recorded.

€ Audio
€ Video
€ Photography

- I am willing to have this interview recorded:

€ Audio
€ Video
€ Photography

Participant's signature _____

Date