

**DO NOT USE THIS TEMPLATE IF YOU ARE COLLECTING BIOSPECIMENS**

*Note to Investigators:*

*When creating informed consent letters, investigators are encouraged to keep language and vocabulary as basic and straightforward as possible (around an 8th grade reading level). Investigators are also encouraged to use this template when creating informed consent letters. Use of alternative wording or format is permitted, but doing so may slow down the review process. All sections of the consent form, except the "Consent" section, should be written in second person ("You are invited...").*

*\*\*Information in italics is for your information and should be deleted from the actual consent form. Material in brackets should be completed with relevant information.\*\**

**TITLE OF STUDY**

[Insert title]

**PRINCIPAL INVESTIGATOR**

[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) you will need to include 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. Please ask the researcher if there is anything that is not clear or if you need more information.

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

## STUDY PROCEDURES

*List all procedures, preferably in chronological order, which will be employed in the study. Point out any procedures that are considered experimental. Clearly explain technical and medical terminology using non-technical language. Explain all procedures using language that is appropriate for the expected reading level of participants.*

*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 audio taping, videotaping, or film procedures are going to be used, provide information about the use of these products.*

## RISKS

*List all reasonably foreseeable risks, if any, of each of the procedures to be used in the study, and any measures that will be used to minimize the risks.*

*Include a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.*

## 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 from this study may...."*

*When applicable, disclose alternative procedures or courses of treatment, if any, which might be advantageous to participants.*

## 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:*

- Assigning code names/numbers for participants that will be used on all research notes and documents*
- Keeping notes, interview transcriptions, and any other identifying participant information in a locked file cabinet in the personal possession of the researcher.]*

## COMPENSATION

*If there is no compensation, delete this section.*

*Indicate what participants will receive for their participation in this study. Indicate other ways participants can earn the same amount of credit or compensation. State whether participants will be eligible for compensation if they withdraw from the study prior to its completion.*

*Indicate if there are any additional costs to the subject that may result from participation in the research*

## CONTACT INFORMATION

If you have questions at any time about this study, or you experience adverse effects as the 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 which you do not feel you can discuss with the Primary 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 or not to take part 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 the relationship you have, if any, with the researcher. 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.

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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

I have read and I understand the provided information 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 signature \_\_\_\_\_ Date \_\_\_\_\_

Investigator's signature \_\_\_\_\_ Date \_\_\_\_\_