

<u>Sample Adult Consent Information Letter</u> [Note: Remove all Instructions from the final document]

INFORMED CONSENT DOCUMENT

[Insert Study Title]

You are being asked to participate in a research study about [*insert general statement about study*]. You are selected as a possible participant because [*explain how subject was identified*]. Please read this form and ask any questions before agreeing to be in the research.

[Insert "this study is being done as part of the requirements for my ______degree at Lourdes University" or "this study is being done by researchers at Lourdes University.]

BACKGROUND INFORMATION

The purpose of this research is [*explain the research question and purpose*]. You are being invited to join this research because [*explain why this person is being invited to join*].

I/We hope that [insert the maximum number of participants] will agree to join the study.

PROCEDURES

If you agree to be a participant in this research, we will ask you to do the following things.

- Describe the procedures to be followed (include audio taping or videotaping if applicable)
- State the duration (subject time commitment) and location of the study.
- Add eligibility requirements such as "You must be 18 years of age or older to participate."
- <u>If applicable</u>, explain any special circumstances under which you would terminate the subject's participation.

RISKS AND BENEFITS

This research has the following risks....

- Explain any expected risks or discomforts a subject may experience and the likelihood of the risks/discomforts. Risks may be physical, emotional, social, academic, financial (such as risks to employment) etc. If there are no known risks/discomforts to participation say "There are no known risks associated with this research." If there is a <u>significant</u> risk or discomfort, the subject should be told under what conditions the researcher will terminate the study.
- <u>If applicable</u>, subjects will be informed of appropriate care that will be made available or an appropriate referral that will be made available if a particular problem is discovered and if they have an adverse physical or psychological reaction to the study.

The benefits to participation are....

• *Explain benefits of participation that will be gained by the participants or others (Note compensation is not a benefit)*

COMPENSATION

You will receive the following compensation for your participation...

• Explain the amount of compensation such as college credit, food, gift certificate. If there is no compensation say "There is no compensation for participation."

ALTERNATIVES

• List any alternatives to the study (i.e. subject may choose to do an alternative class assignment for extra credit instead of participating in the research.) If there are no alternatives you can exclude this section.

PRIVACY

- List the extent to which confidentiality or anonymity of the data and privacy of the subject will be maintained.
- State who will have access to the data.
- State that data may be published or presented at a conference (or how it will be publicly presented) and how privacy will be maintained.
- <u>If applicable</u> and with respect to confidentiality and/or anonymity, explain how data and/or consent forms will be distributed, collected, returned, and handled (i.e. will consent forms or surveys be sealed by subjects in separate envelopes before they are returned, will consent forms and surveys be collected and stored separately, etc.)
- <u>If applicable</u>, state how tape or video recordings will be made and used (i.e. transcribed, copied, etc.), who will have access to them, and when they will be erased or destroyed.
- <u>If applicable</u> (for class instructors), state that consent forms will be kept in a sealed envelope and not viewed until grades are posted to address potential coercion.
- <u>If applicable</u>, state that data will be collected or shared with a third party and explain why this will be done and what steps will be taken to protect the subject's privacy.
- <u>If applicable</u> (web based surveys), inform subjects of the security (i.e. is the web site secure or encrypted, who will collect the data, will the data be collected with or without identifiers.)

VOLUNTARY PARTICIPATION

Your participation is voluntary. There is no penalty if you choose not to participate, and you are free to withdraw at any time. [Note that a subject cannot withdraw once an "anonymous" survey is submitted; however, a subject may choose not to complete the survey.)

- <u>If applicable</u>, add a statement such as "There is no loss of benefits if you choose to withdraw" or state how compensation will be prorated.
- <u>If applicable</u>, state that a subject may skip any questions they do not feel comfortable answering.
- <u>If applicable</u>, state that the subject may request the audio or video tape to be turned off at any time.

CONTACTS and QUESTIONS

The researcher(s) conducting this study is/are [*Responsible Investigator and Co-Investigators, if applicable*]. If you have questions, you may contact them at [*contact information*].

If you have questions about the rights and welfare of research participants, please contact the Lourdes University Institutional Review Board:

Institutional Review Board Administrator Lourdes University 6832 Convent Boulevard Sylvania, OH 43560 irb@lourdes.edu

OR

Barb Tassell DNP, RN, EBP-BC, NPD-BC Chairperson, Institutional Review Board <u>btassell@lourdes.edu</u>