CONSENT DOCUMENT
[Note: Remove all Instructions from the final document]

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. If you agree

[*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...in collaboration with ProMedica Health System.]*

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]*.

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, videotaping, or mobile device use if applicable)*
- *If the study includes surveys or interviews or focus groups, include the type of questions that participants will be asked (for example: you will be asked questions about …).*
- *If a study's results are intended to change a process within ProMedica, state whether or not the questions are from a scientifically validated tool (additional ProMedica approval may be necessary).*
- *State the duration (subject time commitment) and location of the study.*
- *If applicable, explain any special circumstances under which you would terminate the subject's participation.*
- *Add eligibility requirements such as "You must be 18 years of age or older to participate."*

RISKS AND BENEFITS

This research has the following risks….

- *Explain reasonably foreseeable risks, discomforts or inconveniences to the participant including physical, legal, loss of confidentiality, protected health information (PHI), economic and psychological risks and stating the likelihood and seriousness of the risks. Also state how the researcher(s) will minimize these risks, discomforts or inconveniences.*

- *If there are no known risks/discomforts/inconveniences to participation say* "There are no known risks associated with your participation in this research, however, there may be risks not yet identified."
- *If the study includes a focus group, please inform participants that due to the nature of the study, complete confidentiality cannot be guaranteed. (for example:*
- *<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)*

<u>COMPENSATION</u>

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."
- *If there are frequent interactions, please list the number of visits and the prorated compensation amount for each visit. Inform participants here that if they withdraw or if the researcher removes them from the research, they will be compensated for the last visit of actual participation.*
- *If the compensation amount is greater than $599, please inform participants that the for taking part in this study, the [insert institution] will collect your name, address, social security number, payment amount, and related information.*

<u>ALTERNATIVES</u>

- *If there are no alternatives, state that they do not have to participate.*
- *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.)*

<u>PRIVACY</u>

- *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. (Please note that in research publications or presentations, individually identifiable information cannot be shared unless the researcher(s) explicitly obtain written informed consent from participants. In addition, if the information includes ProMedica, ProMedica needs to be referred to as "a health system in the Midwest")*
- *<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 (state who the third party will be) 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.)*

<u>VOLUNTARY PARTICIPATION</u>

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.)* "There is no loss of benefits if you choose to withdraw"

- *<u>If applicable</u>, state that a subject may skip any questions they do not wish to answer.*
- *<u>If applicable</u>, state that the subject may request the audio or video tape to be turned off at any time.*

<u>CONTACTS and QUESTIONS</u>

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

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

Institutional Review Board Administrator Lourdes University 6832 Convent Boulevard Sylvania, OH 43560 irb@lourdes.edu	**OR**	ProMedica IRB Office 2142 North Cove Blvd. CJT 900 Toledo, Ohio 43606 (419) 419-291-5362 phsirb@promedica.org

<u>RETURN INSTRUCTIONS</u>

- *Add any other instructions such as how to return the survey or consent forms (i.e. seal the consent form in the self-addressed envelope provided, return the survey to the instructor, etc.)*
- *If you would like a copy of the research results, please inform the researcher.*

<u>STATEMENT OF CONSENT</u>

I have read and understand the information above and I willingly give my consent to participate in this research study.

By signing this form you are not giving up any of your legal rights as a research participant.

Name (Please Print):_____

Signature:_____

Date:_____

INVESTIGATOR ASSURANCE

I have given the participant an opportunity to ask questions about the research.

Investigator _____ Date_____

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP