Appendix 2: Informed Consent Template and Implied Consent Template

FORT LEWIS COLLEGE
INFORMED CONSENT TO PARTICIPATE IN A RESEARCH PROJECT

[You are encouraged to model your consent form after this consent form. If you choose not to use this format, your consent form must at a minimum include the same elements as this model. Before using this model, delete all text in brackets. Consent documents should be written in simple language, so that they may be understood easily by people with ninth grade education.]

TITLE OF PROJECT:

NAME OF PRINCIPAL INVESTIGATOR: [Faculty supervisor, if this is a student research project]

NAME OF CO-INVESTIGATOR: [Student, if this is a student research project]

CONTACT NAME AND PHONE NUMBER FOR QUESTIONS\PROBLEMS ABOUT RESEARCH: [This should be the primary investigator's name]

CONTACT NAME AND PHONE NUMBER FOR QUESTIONS\PROBLEMS ABOUT RESEARCH-RELATED HEALTH PROBLEMS: [Usually this is either the participant's own health-care provider or, if the research subjects are students, it is the Fort Lewis College Health Center]

CONTACT NAME AND PHONE NUMBER FOR QUESTIONS\PROBLEMS ABOUT PARTICIPANT RIGHTS OR ETHICAL CONSIDERATIONS: [Becky Clausen (970) 247-7237 or Missy Thompson (970) 247-7580]

SPONSOR OF THE PROJECT: [funding agency or company, if there is one]

PURPOSE OF THE RESEARCH:

[Explain that the study involves research and describe its purpose]

PROCEDURES /METHODS TO BE USED:

[Use *lay language* so participants clearly understand how the study will be conducted and what will be expected of them. Explain the techniques and procedures that participants will experience. Identify and describe any experimental or non-standard procedures, methods, drugs, or devices. Tell them if they will be videotaped or audio taped.]

[Insert the page # and space for subject initials and date on each page.]

RISKS INHERENT IN THE PROCEDURES:

[Describe any reasonably foreseeable risks of discomforts to the participants. Include any physical, psychological, social, economic, or legal risks. If the research involves physical risks, include a statement informing the subject that if she is or may become

pregnant, the particular research may involve risks to the subject or embryo, which are currently unforeseeable. Also consider adding the following statement: *It is not possible to identify all potential risks in an experimental procedure, but the researcher(s) have taken reasonable safeguards to minimize any known risks.* State "There are no known risks" if there are none.*]*

BENEFITS:

[Describe any benefits to the participants or to others that may reasonably be expected for the research. Monetary compensation should not be categorized as a benefit.]

ALTERNATIVE PROCEDURES:

[If relevant, inform the participant of any alternative ways to achieve the same benefits that may or may not involve the same risks. If this is not relevant, just delete this section.

COSTS/COMPENSATION:

[Tell the participants if they will receive remuneration for participation and under what conditions. Inform participants of any costs to them that may result from participation in the study.]

CONFIDENTIALITY:

[Describe how confidentiality or records identifying the participants will be maintained. When individual names will not be recorded except on the informed consent form, and those names will not appear on the final document, please consider using this standard statement: *While one cannot ever guarantee complete confidentiality, steps will be taken to prevent anyone from associating participants' names with the data gathered. The individual names of research participants will not appear on any of the papers on which the data are recorded, nor will they appear in the final research document. The only place the names of participants will appear is on this signed informed consent form. The consent forms will be stored separately from the data. In addition to the researchers, the federal research regulatory bodies and the Fort Lewis College Institutional Review Board may have access to the research records*.]

OTHER CONSIDERATIONS:

[List any other considerations that may affect a person's willingness to participate. Inform the participant if the investigator or sponsor has a significant financial interest in the outcome of this particular study or research. If there are no other considerations, delete this section]

LIABILITY:

[The following statement **must** be included on the form: *In the event that you suffer a research-related injury, your medical expenses will be your responsibility or that of your third-party payer, although you are not precluded from seeking to collect compensation for injury related to-fault, or blame on the part of those involved in the research. However, the Colorado Governmental Immunity Act determines and may limit Fort Lewis College's legal*

*responsibility if an injury happens because of this study. Claims against the College must be filed within 180 days of the injury***.]**

PARTICIPATION:

[Include these paragraphs with minimal modification. Do not have signatures appear on a page without this text.]

Your participation in the research is **voluntary**. If you decide to participate in the study, you may withdraw your consent and stop participating at any time without penalty or loss of benefits to which you are otherwise entitled. If at some point during the research, there are new findings that may affect your willingness to participate in the study, you will be informed of those findings.

[Include a description of circumstances in which the subject's participation may be terminated by the investigator without the subject's consent.]

Your signature acknowledges that you have read or have had read to you the information stated and willingly sign this consent form. Your signature also acknowledges that you have received, on the date signed, a copy of this document containing 3 pages.

_____

Participant's Name (printed)

_____ _____

Participant's Signature Date

_____ _____

Investigator or co-investigator Date

[Use the following block only if parental\guardian consent is required. Include the text explaining to what the parents are agreeing.]

FOR MINOR

As parent of guardian you authorize_____ (print name) to become a participant for the described research. The nature and general purpose of the project have been satisfactorily explained to you by _____ and you are satisfied that proper precautions will be observed.

_____

Minor's date of birth

_____

Parent\Guardian name (printed)

Parent\Guardian signature_____ Date_____

Subjects initials _____ Date _____

Implied Consent Template

This is the statement you include in your IRB application:

In lieu of a signed informed consent form, subjects will be given the following information prior to their participation. This alternative form of providing participants with necessary information is preferable because it protects the participants' confidentiality by not collecting any names. The research is minimal risk, and this alternative will not adversely affect participants' rights or welfare. While the research could be conducted with signed inform consent forms, doing so would increase risks to the participants.

The following is an example of an Implied Consent form, which may be used in lieu of an informed consent form when appropriate. It should appear as the cover to a survey instrument for example.

Fill in your details in the {bold brackets}

Thank you for agreeing to participate in this research study about **{put brief information about your topic here}**. Your participation is completely voluntary, and there are no direct benefits to participants, but we appreciate your time and effort. You will be asked to fill out a short questionnaire about **{whatever your study is about}**. If these questions bring up issues that you would like to discuss further, the Fort Lewis College Counseling Center has professional counselors available. Personal counseling is confidential and services are free to students on a short-term basis, and the contact information is listed below.

This survey should only take a few minutes to complete, and you can feel free to leave any questions blank if you would prefer not to answer. There are no foreseeable risks to your participation. To protect your confidentiality, only aggregate data will be reported and no names will be collected.

If you have any questions about this research, or would like to know the results of the study, please contact **{PI's name and contact information}.**

If you have questions about your rights as a research participant, contact Becky Clausen (970) 247-7237 or Missy Thompson (970) 247-7580.

The Counseling Center is in 260 Noble Hall, and can be reached Monday - Friday 8:00 a.m. to 12:00 p.m. and 1:00 p.m. to 5:00 p.m. at (970) 247-7212.