Casper College Institutional Review Board

ELEMENTS OF INFORMED CONSENT

Researchers must obtain the signed *informed consent* of all human subjects. For subjects under the age of 18, signed informed consent of the minor's parent or legal guardian and reasonable attempts to obtain assent of each participant must be made prior to a subject's participation in the study.

Informed consent documents must include the following in sequential order and in language which the subject can understand:

1. Statement of the purpose of the study.

2. Short description of the research methodology and duration of participant involvement.

3. Statement of risks/benefits to the subjects for participating in the study.

4. Statement of data confidentiality.

5. Statement regarding the right of the subject to withdraw from the study at any time without negative consequences.

6. An offer to answer any questions the subject may have.

7. Contact information of all Principal Investigators, and also contact information for Casper Institutional Review Board.

8. Line for signature of participants and/or parents or legal guardian except for questionnaire research in which return of questionnaire gives implied consent.

9. Statement that participant is 18 years of age or older unless parent or legal guardian has given consent.

In situations where participants will be **deceived**, items 1 and 2 are omitted and participants are told (on the signed form) that disclosure of the purpose and/or methodology could bias the outcome of the study. In this case, **after the study is complete**, each participant must be presented with a description of the purpose and methodology as carried out and this document must be signed by the participants "after the fact" in order to guarantee informed consent.

CASPER COLLEGE INFORMED CONSENT FORM TO PARTICIPATE IN RESEARCH

Dear Research Participant:

A study is being conducted to ______. In this study, you will be asked to ______. Your participation should take between _____.

The only identified risks to you as a participant in this study is potential stress associated with completing a ______. The benefits of participating include ______.

All information will be handled in a strictly confidential manner, so that no one will be able to identify you when the results are recorded/reported. All data will be reported in aggregate format.

Your participation in this study is totally voluntary and you may withdraw at any time without negative consequences. If you wish to withdraw at any time during the study, simply tell the researcher.

Please feel free to contact ________ if you have any questions about the study. Or, for other questions, contact Casper College's IRB Chair by email at <u>irb@caspercollege.edu</u> or by phone or mail using the contact information found here: https://www.caspercollege.edu/offices-services/irb/

I understand the study described above. I understand I can withdraw from this study at any time. I understand my participation in this research is voluntary. I further understand there is minimal risk to me for participating in this study. I am 18 years of age or older and agree to participate in this study.

If the participant is of age (18 years old or older), use:

I understand the study described above and have been given a copy of the description as outlined above. I am 18 years of age or older and I agree to participate.

Signature of Participant Date

If the participant is not of age, use:

I understand the study described above and have been given a copy of the description as outlined above. I agree to allow my child/ward to participate with his/her assent when possible.

Signature of Parent/Guardian Date

ASSENT format:

I understand what I must do in this study and I want to take part in the study.

Signature of Child/Ward Date

Casper College Human Subjects Research Project Informed Consent Checklist

| N/A | YES | NO | |
|-----|-----|----|---|
| | | | 1. Is the consent form free of jargon? |
| | | | 2. Is the consent form free of any language requiring subjects to waive |
| | | | their legal rights, including any release of the investigator, sponsor |
| | | | or college or its agents from liability for negligence? |
| | | | 3. If minors are included in the study, are provisions made for |
| | | | obtaining parental consent and minor assent to research |
| | | | participation? |
| | | | 4. Does the consent form include each of the following basic elements |
| | | | of informed consent? |
| | | | a. A statement the subject's involvement is for research purposes; |
| | | | b. An explanation of the purposes of the research and the expected |
| | | | duration of the subject's participation; . |
| | | | c. A description of the procedures to be followed; |
| | | | d. A description of any benefits to the subject or others; |
| | | | e. A description of any reasonably foreseeable risks or discomforts; |
| | | | f. A statement describing the extent to which confidentiality of |
| | | | records identifying the participant will be maintained; |
| | | | g. Information regarding whom to contact for answers to questions |
| | | | about the research study and the research subject's rights; |
| | | | h. A statement that research participation is voluntary, refusal to |
| | | | participate will involve no penalty or loss of benefits, and the |
| | | | participant may discontinue participation at any time without |
| | | | penalty or loss of benefits; and |
| | | | i. Appropriate FERPA notice and waivers (if appropriate). |

If there was a "NO" response to any of the above questions, the consent form must be revised accordingly unless the investigator can satisfactorily justify why is it appropriate as submitted.