

Casper College
Institutional Review Board
EXEMPTED REVIEW OF RESEARCH FORM
(revised 4/12/2017)

ACTIVITIES EXEMPT FROM COMMITTEE REVIEW

Research activities involving human subjects in the following categories may be exempt from review by Casper College's Institutional Review Board (IRB). The principal investigator/project director is authorized to make the first determination of eligibility for exemption; however, the college IRB bears the responsibility for concurring in that determination based on information provided by the principal investigator.

*The following exemptions do **NOT** apply when (a) **deception** of subjects may be an element of the research; (b) subjects are **under the age of eighteen**; (c) the activity may **expose the subject to discomfort or harassment** beyond levels encountered in daily life; (d) **fetuses, pregnant women, human in vitro fertilization, children, or individuals involuntarily confined or detained in penal institutions** are subjects of the activity; or (e) intended human subjects do not have the mental capacity to make competent independent decisions regarding their participation in the research study.*

EXCEPT FOR THE ABOVE EXCLUSIONS, the six federally-approved Categories of Exemption are:

1. Research conducted in established or commonly accepted educational settings involving normal educational practices, such as: (a) research on regular and special education instructional strategies; (b) research on the effectiveness of instructional techniques; (c) comparison of instructional techniques curricula; or (d) classroom management methods.
2. Research involving the use of educational tests (e.g., cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; **and** (b) any disclosure of the human subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving the use of educational tests (e.g., cognitive, diagnostic, aptitude, or achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under Category 2 if: (a) the human subjects are elected or appointed public officials, or candidates for public office; **or** (b) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.
5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies: (a) if wholesome foods without additives are consumed; or (b) if a food is consumed that contains a food ingredient or at or below the level and for a use found to be safe; or (c) agricultural chemical or environmental contaminant at or below the level found to be safe by the U.S. Food and Drug Administration or approved by the U.S. Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Exempting an activity from review does not absolve the investigator(s) of the activity from ensuring that the welfare of subjects in the activity is protected and that methods used and information provided to gain subject consent are appropriate to the activity.

Questions about whether a research activity may be exempt from human subjects review can be directed to the Casper College IRB Chair.

____/____/____
Date Submitted

Casper College
Institutional Review Board

IRB File Number

Exempt Protocol Summary Form

Title of Research Project

Principal Investigator/Project Director Department Phone Extension Email address

Co-investigator/Student Investigator Department Phone Extension Email address

Co-investigator/Student Investigator Department Phone Extension Email address

Anticipated Funding Source:

Projected Duration of Research: _____ months Projected Starting Date: _____

Other organizations and/or agencies, if any, involved in the study:

Exempt under code (see definitions on page one – check one) 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐

SUMMARY ABSTRACT: Please supply the following information below: BRIEF description of the participants, the location(s) of the project, the procedures to be used for data collection, whether data will be confidential or anonymous, disposition of the data, who will have access to the data. Attach copy of the Informed Consent Form (if applicable) and/or the measures (questionnaires) to be used in the project.

RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR:

- Any additions or changes in procedures in the protocol will be submitted to the IRB for written approval prior to these changes being implemented

- Any problems connected with the use of human subjects once the project has begun must be communicated to the IRB Chair
- The principal investigator is responsible for retaining informed consent documents for a period of three years after the project.

Principal Investigator Signature _____ Date / / Co-Investigator/Student Signature (if appropriate) _____ Date / /

Signature of IRB Committee Chair:			Date: <u> </u> / <u> </u> / <u> </u>
IRB Chair: Check 1 box:	☐ Approved	☐ Approved with Conditions	☐ Refer to Full Committee Review

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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 Dr. Kathryn Lenth at 307.268.2519.

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