Casper College
Institutional Review Board
EXPEDITED REVIEW OF RESEARCH FORM
(revised 04/12/2017)

Human subject research activities involving no more than minimal risk, defined as the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests to participants in accordance with 45 CFR 46.102(h)(i), may be eligible for expedited review by Casper College's Institutional Review Board (IRB) Chair. The principal investigator (PI) or project director is authorized to make the first determination of eligibility for expedited review; however, the college's IRB has the responsibility for concurring in that determination based on proposed research by the PI.

Research activities eligible for expedited review:

(1) Clinical studies of drugs and medical devices.
(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.
(3) Prospective collection of biological specimens for research purposes by noninvasive means.
(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects according to 45 CFR 46.101(b)(4)).
(6) Collection of data from voice, video, digital, or image recordings made for research purposes.
(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects according to 45 CFR 46.101(b)(2) and (b)(3)).

Expedited review may also be used to review minor changes in previously approved research proposals. Questions regarding if a specific proposed research activity may be appropriate for expedited review can be directed to the IRB Chair.

Date Submitted | **Casper College Institutional Review Board** | **IRB File Number**

Casper College Expedited Review of Research 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

Co-investigator/Student Investigator **Department** **Phone Extension**
Email address

Anticipated Funding Source(s): _____

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

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

Expedited Review Category (see categories on page 1–check one):

1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐

Please respond to the following eight items to allow the college IRB to review this proposal:

1. Brief proposed research description.

2. Proposed human subjects (e.g., age, gender, educational setting, selection method, etc.),

3. Project location(s),

4. Data collection procedure(s),

5. If data will be confidential or anonymous,

6. Disposition of the data,

7. Who will have access to the data, and

8. Participant Informed Consent Form.

RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR:

- Any procedural modifications must be submitted to the IRB Chair for written approval prior to implementing any changes to an approved IRB research proposal.

- 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.

Investigator/Project Director Signature	Date	Co-Investigator/Student Signature (if appropriate)	date

Signature of IRB Committee Member (project reviewer):			**Date:** __/__/__
IRB Chair/Designee: Check 1 box:	☐ **Approved**	☐ **Approved with Conditions**	☐ **Refer for 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