Chadron State College Institutional Review Board IRB Full Board Review Application Form

Submit one original copy with signatures and one digital copy, with signatures, IRB Administrative Chair—allow at least four weeks for review

Research Project Title:		
Principal Investigator (must be a full-time faculty or professional staff member):		
Department:	Telephone:	E-mail:
Co-Principal Investigator (student researcher):		
Department:	Telephone:	E-mail:
Date Project Activity to Begin:		
Site of Research:		
Other institution/Non-institutional Investigators (describe collaboration or use of records):		
Will this project be supported by funds?Yes No.		
If yes, funding agency:		
As the investigator submitting this proposed research and signing below, I agree to conduct the research involving human participants as presented in the protocol as approved by the School Dean/Unit Head and the Institutional Review Board; to obtain and document informed consent and provide a copy of the consent form to each participant unless this is waived by the IRB; to present <u>any</u> proposed modifications in the research to the IRB for review and approval prior to implementation; to retain records for the mandated lengths of time; and to report to the IRB any problems or injuries to subjects.		
Principal Investigator Signature:	:	Date:
Co-PI Signature:		Date:
School Dean/Unit Head Review		Date:

Using the following format and numbering, submit the following:

Principal Researcher Credentials:

- 1. Attach a copy of the Principal Researcher's current curriculum vitae that documents the credentials of the PI to conduct the proposed research.
- 2. Attach copies of current certificate of training in ethical issues involving human subject research for all members of the research team (as noted above in Principal Investigator Responsibilities section).

Overview and Objectives of Research Project:

- 3. Briefly describe the purpose and methods of the proposed research:
 - Research methodology to be used (brief description of research hypotheses should be included; full description will follow below)
 - Participant population
- 4. Include a description of procedures to be conducted.
- 5. Attach all instruments (surveys, recruitment documents, interview protocols, informed consent forms, questionnaires, demographic forms, phone screens, etc.) that will be used.
- 6. Be sure to include appropriate background information needed to assess the participant risk level described in 10 below.

Human Participants description:

- 7. Describe the participant population, including:
 - Source of participant population
 - Number of participants
 - Characteristics of participants (i.e., gender, student, disease conditions, behavioral abnormalities, affiliations, memberships, etc.)
- 8. Describe the selection of participants:
 - What are the characteristics of the participants you are choosing? Offer justification for selecting participants with these characteristics.
 - Describe your recruitment procedures and explain how these procedures will help to increase diversity.
 - If the researcher, or members of the researcher's family, will serve as research participants, explain the rationale for use of these participants in the research project.
 - If your research participants include individuals who are pregnant, economically/educationally disadvantaged, unable to give valid informed consent due to physical or mental condition, or from a targeted specific ethnic/cultural group, address the rationale for such selection, any additional safeguards you will provide for their protection, and why the research is minimal risk for those subjects.
- 9. Will subjects be compensated? How?
 - Note: financial incentives, extra credit, and course grade incentives are <u>not</u> considered a benefit to the participant. If used, these must be used cautiously so as to not coerce participation or to skew participation from the potential population of interest.

- 10. Risks and Benefits to participants:
 - a. Describe potential risks and assess the likelihood, severity, duration, and effects of use. Common risks include physical injury, psychological trauma or stress, social/economic harm, legal risk, and loss of confidentiality.
 - i. Describe methods for minimizing risks. For example, document how potential psychological distress will be addressed, by whom, and with what credentials.
 - ii. Describe other methods, if any, that were considered alternatively and why they will not be used.
 - b. Describe the participant benefits to be gained from participating in this study
 - c. Explain how the risks are reasonable relative to the (i) anticipated benefits to the subjects and (ii) the importance of the knowledge that may reasonably expected to result.
- 11. Other matters pertinent to the human participants.

Procedures to be followed with participants (Methodology):

- 12. Specify location of study.
- 13. List variables to be studied.
- 14. Describe method of data collection (<u>attach</u> copies of surveys, instruments, etc. If using a copyrighted instrument, document authorization of use.).
- 15. Describe activities involving participants, including frequency and duration of each activity (such as experimental stimulus, survey, questions asked in an interview, etc.).
- 16. Describe equipment used with participants, if any.
- 17. Specify factors that will lead to stopping procedures causing physical or emotional stress.
- 18. Describe biological samples to be taken (if any), method, and qualifications of individuals taking samples.
- 19. Provide de-briefing method and materials for participants.
- 20. Describe how attention has been paid to special problems that may arise when research. involves vulnerable populations.
- 21. Other aspects of the procedures.

Consent Procedures:

- 22. Provide a copy of the written informed consent form to be used and signed by participants (see Appendix V). If no consent form will be used, explain how the research meets **each** of the following criteria such that the research qualifies for a waiver of informed consent:
 - Research involves no more than minimal risk to participants;
 - Waiver will not adversely affect the rights and welfare of the participants;
 - Research could not practicably be carried out with the waiver or alteration; and
 - Subjects will be provided with pertinent information in some other format.

Confidentiality:

- 23. Describe the method(s) used to protect the identity of individual participants.
- 24. Describe plans for maintaining data after study is complete. Faculty should keep a complete copy, so the data are auditable.

- 25. Describe how federal requirement will be met for consent forms to be retained for 3 years following the conclusion of the project. (Typically this entails the faculty member storing the documents in locked storage.).
- 26. If audio- or video-taping, specify tape storage, use, and when and how disposition of the tapes will take place.
- 27. Other aspects of confidentiality.

Collaborations and Partnerships:

28. If access to research participants is gained through cooperating institutions not under the control of Chadron State College, provide a letter signed by the authorized individual of that institution, verifying that the research application and collaboration has been approved.