Participant Informed Consent Considerations and Documentation.

The principle investigator is responsible for ensuring that a legally-effective informed consent of the participant (or the participant's legally authorized representative, as appropriate) is obtained. The consent form should clearly communicate sufficient information for the potential participant to consider whether or not they wish to participate in a manner that minimizes the possibility of coercion or undue influence. The language should be clearly understandable, and provide clarification of the ability of the participant to withdraw from the study at any point they deem appropriate.

An informed consent document contains, at minimum, the following information:

- A statement explaining the research, including purposes and expected results, expected duration of the participant's participation, a description of procedures to be followed, and identification of any experimental procedures;
- A description of any reasonably foreseeable risks or discomforts to the participant;
- A description of benefits to the participant or to others which may reasonably be expected from the research;
- A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;
- A clear explanation of the compensation to be give, if any, and conditions under which no or partial payment may occur;
- An explanation of whom to contact for answers to pertinent questions about the research and research participant's rights, including name and contact information for the researcher (and the PI, if the person seeking the information is not the PI);
- Clear communication of whom to contact in the event of research-related injury to the participant (CSC's IRB Chair); and
- A statement that participation is voluntary, refusal to participate will incur no penalty or loss of benefits to which the participant is otherwise entitled, and the ability of the participant to discontinue participation at any time without penalty or loss.

Additional information of informed consent may be required for projects that carry more than minimal risk to the participants.

If the participants' first language is not English, the consent form must be submitted to the IRB in both English and the appropriate first language for the participant.

For further information, see the following:

- Code of Federal Regulations, Title 45, Part 46: Protection of Human Subjects.
    - http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
- Tips on Informed Consent.
    - http://www.hhs.gov/ohrp/policy/ictips.html
- Informed Consent for Non-English Speakers.
    - http://www.hhs.gov/ohrp/policy/ic-non-e.html

The following models of Informed Consent Forms are provided to guide the researcher in developing an appropriate consent form. Inclusion of vulnerable populations may require a more detailed form, as discussed above.

CONSENT FORM for Adult Participants (19 years and older)

Project Title

Invitation to Participate: You are invited to participate in a study of *(describe what is to be studied)* being conducted by (*give names of investigators and their affiliations with Chadron State and other institutions that may be involved*).

Basis for Participant Selection: You have been selected for participation in this study because *(state reasons why. This statement should help the participant assess the nature and importance of participation. Include in here any criteria for subject exclusion, such as age, health restrictions, etc.)*

Overall Purpose of Study: *Provide a clear description, in simple language, of the overall purpose of the research. This should help the participant assess the importance of the study relative to individual values.*

Explanation of Procedures: If you decide to participate, you will be asked to do the following things: *(Describe study design, description of procedures and duration/frequency of occurrence, identification of who will perform the procedures, a statement of where and when the research will be conducted and how much time will be required, etc.*

Potential Risks and Discomforts: (D*escribe physical, psychological, social, legal, and economic risks (both immediate and later), clearly and adequately, including the probability, severity, average duration, and reversibility of any potential injury.)*

Potential Benefits: (*Describe direct benefits, if any. If there are no direct benefits to the participants, explain the benefits that could result to others from this research.)*

Compensation for Participant: (*Describe the amount or nature of compensation, if any, for the participant. The nature and amount of compensation must not constitute undue inducement to participate. If no compensation is to be offered, this section may be deleted.)*

Assurance of Confidentiality: (*State whether or not the information will be kept confidential, and under what conditions the participant's information will be disclosed. Describe the ultimate disposition of data.)*

Withdrawal from the Study: Your participation in this study is voluntary. Your decision whether or not to participate will not affect your (g*rade, treatment, present or future relationship with the College, etc.)*. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time.

Offer to Answer Questions: You should feel free to ask questions now or at any time during the study. If you have questions, you can contact *(your name and contact information, plus that of the PI (if different).* If you have questions about the right of research subjects, contact the Chair of the Chadron State College Institutional Review Board at 1-308-432-6203.

Consent Statement:

You are voluntarily making a decision whether or not to participate. Your signature indicates that, having read and understood the information provided above, you have decided to participate.

You will be given a copy of this consent form to keep.

Signature of Participant	Date
Signature of Investigator	Date

CONSENT FORM for Minor Participants – Parent/Guardian Form

Project Title

Invitation to Participate: Your child is invited to participate in a study of *(describe what is to be studied)* being conducted by (*give names of investigators and their affiliations with Chadron State and other institutions that may be involved*).

Basis for Participant Selection: Your child has been selected for participation in this study because *(state reasons why. This statement should help the participant assess the nature and importance of participation. Include in here any criteria for subject exclusion, such as age, health restrictions, etc.)*

Overall Purpose of Study: (*Provide a clear description, in simple language, of the overall purpose of the research. This should help the participant assess the importance of the study relative to individual values.)*

Explanation of Procedures: If you and your child decide to participate, your child will be asked to do the following things: *(Describe study design, description of procedures and duration/frequency of occurrence, identification of who will perform the procedures, a statement of where and when the research will be conducted and how much time will be required, etc.)*

Potential Risks and Discomforts: (*Describe physical, psychological, social, legal, and economic risks (both immediate and later), clearly and adequately, including the probability, severity, average duration, and reversibility of any potential injury.)*

Potential Benefits: (*Describe direct benefits, if any. If there are no direct benefits to the participants, explain the benefits that could result to others from this research.)*

Compensation for Participant: (*Describe the amount or nature of compensation, if any, for the participant. The nature and amount of compensation must not constitute undue inducement to participate. If no compensation is to be offered, this section may be deleted.)*

Assurance of Confidentiality: (*State whether or not the information will be kept confidential, and under what conditions the participant's information will be disclosed. Describe the ultimate disposition of data.)*

Withdrawal from the Study: Your child's participation in this study is voluntary. Your and your child's decisions whether or not to participate will not affect your child's or your (*grade, treatment, present or future relationship with the College, etc.).* If you or your child decide to participate, you and your child are free to withdraw your consent and discontinue participation at any time.

Offer to Answer Questions: You and your child should feel free to ask questions now or at any time during the study. If you have questions, you or your child can contact *(your name and contact information, plus that of the PI (if different).* If you have questions about the right of research subjects, contact the Chair of the Chadron State College Institutional Review Board at 1-308-432-6203.

You are voluntarily making a decision whether or not to allow your child or legal ward to participate. Your signature indicates that, having read and understood the information provided above, you have decided to permit your child or legal ward to participate in this research.

You will be given a copy of this consent form to keep.

Signature of Participant	Relationship to Participant	Date
Signature of Participant	Relationship to Participant	Date

(Second signature required if participant will be exposed to more than minimal risk)

Signature of Investigator	Date

Note: If the minor is between the ages of eight and nineteen, the minor must complete an "Assent Form" as well. A copy of this assent form will be provided to the parent or legal guardian.

ASSENT FORM for Minor Participants
(ages thirteen to nineteen)

Project Title

Invitation to Participate: You are invited to participate in a study of *(describe what is to be studied)* being conducted by *(give names of investigators and their affiliations with Chadron State and other institutions that may be involved*).

Purpose of the Research: (*Provide a clear description, in simple language, of the overall purpose of the research. This should help the participant assess the importance of the study relative to individual values.)*

Explanation of Procedures: If you decide to participate, you will be asked to do the following things: *(Describe the study design, description of procedures and duration/frequency of occurrence, identification of who will perform the procedures, a statement of where and when the research will be conducted and how much time will be required, etc.)*

Potential Risks and Discomforts: (D*escribe potential risks and discomforts associated with the research.)*

Potential Benefits: (*Describe direct benefits, if an, for the participant. If there are no direct benefits to the participants, explain the benefits that could result to others from this research.)*

Withdrawal from the Study: I am seeking your permission to include you in this research study; you are free to say no at this time. You can also stop your participation at any time, by telling me that you want to stop. Before you agree to be involved, you should discuss whether or not to participate with your parent, prior to signing this form. Your parent will also be asked to agree to your participation.

Offer to Answer Questions: If you have any questions, please feel free to ask questions now or at any time during the study. If you have questions, you can contact *(your name and contact information, plus that of the PI (if different)).*

You are making a decision whether or not to participate in this study. By signing this form you indicate that you have read and understood the information, and you have decided to be involved in this study

Your parent/legal guardian will be given a copy of this assent form to keep.

_____ _____
Signature of Participant Date

_____ _____
Signature of Investigator Date

ASSENT FORM for Minor Participants
(ages eight to thirteen)

Project Title

I am *(name and that you are from Chadron State College.)*

I am doing a study on *(describe clearly what you are studying, in an appropriate level of language).* I hope to discover (*describe).*

I invite you to participate in a study of *(describe what is to be studied)*

If you decide to participate, this is what I will ask you to do: (*clearly describe, in appropriate level of language.)*

You may feel some discomfort, such as **(***describe risks and discomforts)*

(Also describe any benefit).

You are being asked to participate in this study, but you do not have to. You should talk over with your parent or guardian whether or not you should participate. Your parent/guardian will also be asked for permission for you to participate in this study.

If you decide to participate and then change your mind, you can tell me and you can stop at that point.

If you have any questions, please do ask me.

You are making a decision whether or not to participate in this study. Please read and understand the information above. If you agree to participate, please sign the form below to show that you have decided to be involved in this study.

Your parent/legal guardian will be given a copy of this assent form to keep.

_____ _____
Signature of Participant Date

_____ _____
Signature of Investigator Date
(*Include contact information for Investigator)*