**Institutional Review Board for Protection of Human Subjects**

Office of Research and Economic Development

University of Wyoming

## Elements of Informed Consent and Assent Forms

**The following are the basic required elements of informed consent (a sample** [**consent form**](#Consentformoutline) **follows):**

[ ]  Statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

[ ]  A description of any reasonably foreseeable risks or discomforts to the subject;

[ ]  A description of any benefits to the subject or to persons that may reasonably be expected from the research;

[ ]  A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

[ ]  A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

[ ]  For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

[ ]  An explanation of whom to contact about research subjects' rights using the following language: “*If you have questions about your rights as a research subject, please contact the University of Wyoming IRB Administrator at 307-766-5322*.”

[ ]  An explanation of whom to contact for answers to pertinent questions about the research; **and**

[ ]  A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

**Whenever appropriate, one or more of the following elements of information shall also be provided to each subject:**

[ ]  If the risks of any research procedure are not well known, for example because of limited experience in humans, a statement that the particular treatment or procedure may involve risks to the participant which are currently unforeseeable.

[ ]  If the research includes women of child bearing potential or pregnant women, and the effects of any research procedures on embryos and fetuses is not well known, a statement that the particular treatment or procedure may involve risks to the embryo or fetus, if the participant is or may become pregnant, which are currently unforeseeable.

[ ]  If there are anticipated circumstances under which the participant’s participation will be terminated by the investigator without regard to the participant’s consent, a list of anticipated circumstances under which participation may be terminated by the investigator without the participant’s consent.

[ ]  If there are costs to the participant that may result from participation in the research, a list of additional costs associated with study participation.

[ ]  If there are adverse consequences (e.g., physical, social, economic, legal, and/or psychological) of a participant’s decision to withdraw from the research, a list of consequences of a participant’s decision to withdraw from the research and procedures for an orderly termination of participation.

[ ]  If significant new findings during the course of the research that may relate to the participant’s willingness to continue participation are possible, a statement will be provided to the participant stating such.

[ ]  If the approximate number of participants involved in the study might be relevant to a decision to take part in the research, an approximate number of participants involved in the study.

Informed consent forms should be written in **plain language** at a reading level appropriate for the age or maturity-level of the participants. The informed consent form should be written in second person for clarity and readability (i.e., there is minimal risk to you; you will be required to perform a certain procedure; etc.).

**Requirements for Consent and Assent Involving Children**

The IRB must determine that adequate provisions have been made for soliciting the assent of children, when in the judgment of the IRB the children are capable of providing assent. The IRB recommends that assent be sought for children ages seven and older, but may be appropriate for younger children depending on their aptitude.

The IRB may determine that assent is not a necessary condition for proceeding with the research if:

1. The aptitude of some or all of the children is so limited that they cannot reasonably be assented (determinations of capacity to assent will be assessed by age, maturity, and psychological state, and may be made for one, some, or all children in the research as the IRB deems appropriate);
2. The intervention or procedure involved holds out a prospect of direct benefit that is important to the health or well being of the children and is available only in the context of research; or
3. The research meets the required criteria for waiver of consent stated in [45 C.F.R. 46.116(d)](http://www.hhs.gov/ohrp/documents/OHRPRegulations.pdf).

When assent is required, the child will sign the assent form for documentation.

In addition to the children’s assent, the PI is required to solicit consent of each child’s parents or adoptive parents. If there is any other person who claims to be the child’s guardian (grandparents, foster parents, etc.), the PI must contact the Office of Research and Economic Development and IRB legal counsel will be consulted to determine whether the individual has the legal authority to make health care decisions on behalf of the child and therefore is the guardian as defined in federal regulations.

Parents must be consented following the criteria outlined above and any additional elements the IRB deems necessary. One parent’s signature is sufficient for research that is minimal risk or greater than minimal risk with the prospect of direct benefit to the participant.

**University of Wyoming Consent Form Outline**

**I. General purpose of the study:**

 Why are you conducting this study? What do you hope to gain from this study? Why should subjects participate?

**II. Procedure:**

 **How and where** will the study be conducted? **Who** will be conducting the study? **What** will the subject be expected to do? **How much** of the subject's **time** is needed?

**III. Disclosure of risks**

State why risks involved in participation are minimal, or if the project involves more than minimal risk, **describe in detail all potential risks of the study, and procedures to minimize risks.**

**Liability for injury statement**

**The University of Wyoming, the** **principal investigator, and the research team are not liable for any injury participants might sustain while participating in this study and are not able to offer financial compensation or absorb the costs of medical treatment should the participant sustain such an injury. By agreeing to participate you do not waive any of your legal rights; however, no funds have been set aside to compensate you in the event of injury.**

Also, please be sure to include the following statement in this section:

*COVID-19*

*The University has put in place reasonable physical safeguards relative to the COVID-19 virus. However, an inherent risk of exposure to COVID-19 exists in any public place where people are present. While on University property, you agree to follow all posted rules and verbal instructions from staff members, and you voluntarily assume all risks related to exposure to COVID-19.*

**IV. Description of benefits:**

 List any direct/indirect benefits to the subject, including compensation or incentive, if any.

**V. Confidentiality:**

 What level of confidentiality will be afforded to subjects? **How will confidentiality be protected? Who will have access to the data, how will the data be protected, and how long will the data be kept?** Will the data be used for research purposes at any time other than the purpose(s) stated above? Please note that confidentiality cannot be guaranteed, but you can describe the methods you will use to protect confidentiality. Confidential and anonymous are not the same, please use the applicable terminology for your study.

**VI. Freedom of consent:**

**Include a statement such as:** “Participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you may discontinue participation at any time.” This statement should be written in language appropriate for the age and level of education of the subjects. Also include **procedures to withdraw** from study.

**VII. Questions about the research:**

 Include name, address and phone number where principal investigator/faculty advisor can be reached during normal business hours. Also include the statement “If you have questions about your rights as a research subject, please contact the University of Wyoming IRB Administrator at 307-766-5322.”

**VIII. Consent to participate**:

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Printed name of participant

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Participant signature Date

**IX. If any part of the study is audio or video recorded include**: a check-box or signature line for consent to be audio and/or video recorded.

**University of Wyoming Parent Consent Form Outline**

**I. General purpose of the study:**

 Why are you conducting this study? What do you hope to gain from this study? Why should children participate?

 **Include a statement such as:** You are being asked to allow your child to take part in a research study. This document has important information about the reason for the study, what your child will do if you in this research study, and the way we would like to use your child’s information

**II. Procedure:**

 **How and where** will the study be conducted? **Who** will be conducting the study? **What** will the child be expected to do? **How much** of the child's **time** is needed?

**III. Disclosure of risks**

State why risks involved in participation are minimal, or if the project involves more than minimal risk, **describe in detail all potential risks of the study, and procedures to minimize risks.**

**Liability for injury statement**

**The University of Wyoming, the principal investigator, and the research team are not liable for any injury participants might sustain while participating in this study and are not able to offer financial compensation or absorb the costs of medical treatment should the participant sustain such an injury. By agreeing to participate you do not waive any of your legal rights; however, no funds have been set aside to compensate you in the event of injury.**

Also, please be sure to include the following statement in this section:

*COVID-19*

*The University has put in place reasonable physical safeguards relative to the COVID-19 virus. However, an inherent risk of exposure to COVID-19 exists in any public place where people are present. While on University property, you agree to follow all posted rules and verbal instructions from staff members, and you voluntarily assume all risks related to exposure to COVID-19.*

**IV. Description of benefits:**

 List any direct/indirect benefits to the child, including compensation or incentive, if any.

**V. Confidentiality:**

 What level of confidentiality will be afforded to subjects? **How will confidentiality be protected? Who will have access to the data, how will the data be protected, and how long will the data be kept?** Will the data be used for research purposes at any time other than the purpose(s) stated above? Please note that confidentiality cannot be guaranteed, but you can describe the methods you will use to protect confidentiality. Confidential and anonymous are not the same, please use the applicable terminology for your study.

**VI. Freedom of consent:**

 **Include a statement such as:** "Your child's participation is voluntary and your child's refusal to participate will not involve penalty or loss of benefits to which your child is otherwise entitled, and your child may discontinue participation at any time without penalty or loss of benefits to which your child is otherwise entitled."

 **For studies involving classroom students:** "Your child's refusal to participate or your child's withdrawal at any point will not affect your child's course grade or class standing." **Include procedures** for the child, or parent/guardian on behalf of the child, **to withdraw** from study.

**VII. Questions about the research:**

 Include name, address and phone number where principal investigator/faculty advisor can be reached during normal business hours. Also include the statement “If you have questions about your rights as a research subject, please contact the University of Wyoming IRB Administrator at 307-766-5322.”

**VIII. Parental consent required for all subjects under 18 years of age.**

Parental consent must include all the elements of a normal consent form and must be **SEPARATE** from the minor’s assent (the minor and parent need to consider participation independently).

 *PARENTAL SIGNATURE EXAMPLE*:

As parent or legal guardian, I hereby give my permission for (child’s name) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ to participate in the research described above.

 (printed name of participant)

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Printed name of parent/legal guardian

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Parent/legal guardian signature Date

**IX. If any part of the study is audio or video recorded include**: a check-box or signature line for consent to be audio and/or video recorded.

**University of Wyoming Assent Form Outline**

**I. General purpose of the study:**

 My name is (insert the name of the person that will approach the child during the assent process) I want to tell you about a research study I am doing. A research study is usually done to find a better way to treat people or to understand how things work. In this study, I want to find out more about (insert purpose of study in simple language).

**II. Procedure:**

 **How and where** will the study be conducted? **Who** will be conducting the study? **What** will the subject be expected to do? **How much** of the subject's **time** is needed? Describe procedures in words a child in this age group would know and understand.

**III. Disclosure of risks**

State why risks involved in participation are minimal, or if the project involves more than minimal risk, **describe in detail all potential risks of the study, and procedures to minimize risks.**

**IV. Description of benefits:**

 List any direct/indirect benefits to the subject, including compensation or incentive, if any.

**V. Confidentiality:**

 What level of confidentiality will be afforded to subjects? **How will confidentiality be protected? Who will have access to the data, how will the data be protected, and how long will the data be kept?** Will the data be used for research purposes at any time other than the purpose(s) stated above? Please note that confidentiality cannot be guaranteed, but you can describe the methods you will use to protect confidentiality. Confidential and anonymous are not the same, please use the applicable terminology for your study.

**VI. Freedom of consent:**

 **Include a statement such as:** "My participation (my child's participation) is voluntary and my (my child's) refusal to participate will not involve penalty or loss of benefits to which I am (my child is) otherwise entitled, and I (my child) may discontinue participation at any time without penalty or loss of benefits to which I am (my child is) otherwise entitled."

 **For studies involving classroom students:** "I understand that my refusal to participate or my withdrawal at any point will not affect my course grade or class standing." This statement should be written in language appropriate for the age and level of education of the subjects.

 **Include procedures for the child to withdraw from the study.**

**VII. Questions about the research:**

 Include name, address and phone number where principal investigator/faculty advisor can be reached during normal business hours. Also include the statement “If you have questions about your rights as a research subject, please contact the University of Wyoming IRB Administrator at 307-766-5322.”

**VIII. Assent to participate**:

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Printed name of participant

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Participant signature Date

**IX. If any part of the study is audio or video recorded include**: a check-box or signature line for consent to be audio and/or video recorded.