Informed Consent Requirements and Template

The required elements for informed consent

- Title of the study, exactly as it appears on the application.
- Investigator's affiliation with Colorado Mountain College.
- Contact information of the investigator.
- Purpose of the study and the procedure to be followed.
- Level of risk or discomfort for research subjects (if none, please mention that).
- Benefits of the study to the subjects and community.
- Duration of subjects' participation in the study.
- Compensation for participation in the study.
- A statement of voluntary participation by research subjects.
- Option to withdraw from study or decline answering specific question at any point during the study.
- Statement that subject must be 18years or older to participate.
- In case of minors, include legally authorized representative consent and minor assent.
- Signatures and date (unless using passive consent).

1. Pagination: 1 OF 2, 2 OF 2, etc.

2. Duplicate on both sides to eliminate page separation; try to keep consent to 2 pages if possible. If 3 pages, first page is single sided, pages 2 and 3 are duplicated back to back.

3. Language level commensurate with participant reading level (guideline 8^{th} grade or lower).

4. NO language must be used that asks participants to waive legal rights or releases investigators from negligence.

5. Minor Assent forms can follow the same template but language is simplified and understandable to the young child.

6. Legally Authorized Representative Consent form can also follow the same template but should include a statement where investigator asks for the permission of the parent or guardian to allow the child to participate in the study.

Institutional Review Board (IRB) Informed Consent Form (Template)

[TITLE OF THE STUDY]

INTRODUCTION

You are invited to be in a research study of [*insert general statement about study*]. You were selected as a possible participant because [*explain how participant was identified*]. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

This study is being conducted by: [*Indicate all pertinent information*].

BACKGROUND

The purpose of this study is [*explain research question and purpose in lay language*].

Procedures: If you agree to be in this study, we would ask you to do the following things. [*Explain the tasks and procedures; participants should be told about assignment to study groups, length of time for participation, frequency of procedures, etc.*.]

RISKS/BENEFITS

This study has no known risks OR The study has [*insert #*] risks. First, [*explain first risk*]. Second, [*explain second risk*]. [*Each risk must be explained, including the likelihood of the risk.*]

In the event of injury, [*insert what actions will be taken to prevent/minimize injury or assist participant with seeking appropriate care*].

[*If there are significant physical or psychological risks to participation, the participant should be told under what circumstances the researcher will terminate the study.*]

The benefits of participation are [*explain the benefits, or, if there are none, state that fact here.*]

CONFIDENTIALITY

The records of this study will be kept private. In any sort of report I/we might publish, I/we will not include any information that will made it possible to identify a participant. Research records will be kept in a locked file; only the researchers will have access to the records. [*If audio or videotapes are made, explain who will have access, if the will be used for educational purposes, and when they will be erased.*]

VOLUNTARY NATURE OF THE STUDY
Your decision whether or not to participate will not affect your current or future relations with Colorado Mountain College [*or specify any other institutions involved*].

FUNDING SOURCES (if applicable)
[Identify external funding sources that are supporting this study].

CONTACTS AND QUESTIONS
The researchers conducting this study are [*provide names*]. You may ask any questions you have now. If you have questions later, you may contact them at [*provide phone numbers including that of IRB chair*]. [*If the researcher is a student, provide the faculty moderator's or advisor's name and telephone here*.]
You will be given a copy of this form to keep for your records.

STATEMENT OF CONSENT
I have read the above information. I have asked questions and have received answers. I consent to participate in the research.

Participant's Signature_____ Date _____

Parent/Guardian Signature_____ Date _____
(if applicable)

Child's Signature_____ Date _____
(if applicable)

Printed name _____

Investigator's Signature _____ Date _____