INFORMED CONSENT REQUIREMENTS AND EXAMPLES

No investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.

No informed consent, whether oral or written, may include any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence, http://www.hhs.gov/ohrp/policy/exculp.html**.**

Examples of Exculpatory Language:

- By agreeing to this use, you should understand that you will give up all claim to personal benefit from commercial or other use of these substances.
- I voluntarily and freely donate any and all blood, urine, and tissue samples to the U.S. Government and hereby relinquish all right, title, and interest to said items.
- By consent to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research.
- I waive any possibility of compensation for injuries that I may receive as a result of participation in this research.

Examples of Acceptable Language:

- Tissue obtained from you in this research may be used to establish a cell line that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.
- By consenting to participate, you authorize the use of your bodily fluids and tissue samples for the research described above.
- This hospital is not able to offer financial compensation nor to absorb the costs of medical treatment should you be injured as a result of participating in this research.
- This hospital makes no commitment to provide free medical care or payment for any unfavorable outcomes resulting from participation in this research. Medical services will be offered at the usual charge.

Consent documents are more understandable if they are written just as the investigator would give an oral explanation to the subject, that is, the subject is addressed as "you" and the investigator(s) as "I/we." This second person writing style also helps to communicate that there is a choice to be made by the prospective subject.

Subjects are not in a position to judge whether the information provided is complete. Subjects may certify that they understand the statements in the consent document and are satisfied with the explanation provided by the consent process (e.g., "I understand the statements in this informed consent document)." They should not be required to certify completeness of disclosure (e.g., "This study has been fully explained to me," or, "I fully understand the study."). Furthermore, consent documents should not contain unproven claims of effectiveness or certainty of benefit, either explicit or implicit, that may unduly influence potential subjects.

For more information refer to the FDA's *A Guide to Informed Consent – Information Sheet* http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm.

BASIC ELEMENTS OF INFORMED CONSENT

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental
2. A description of any reasonably foreseeable risks or discomforts to the subject
3. A description of any benefits to the subject or to others which may reasonably be expected from the research
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
6. 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
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
8. 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

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

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject
6. The approximate number of subjects involved in the study.
7. The source of funding if there is external funding for the research.
8. Use of information and/or specimens:
    a. Returning Results: If the study will produce any clinically relevant research results, describe whether these results will be given to the subjects, and if so, under what conditions. Describe whether and how subjects can opt out of receiving results.
    b. Using Data in Future Research: Describe whether or not there will be plans to use this research in the future. Most studies will use the information gathered for further research. If the information will never be used for future research, let the subjects know that as well. ***If there are plans to store or share data for future research, for example the data will be submitted to a repository, describe those plans here, including whether or not the data will be shared with identifying information and the purposes for which the data will be used.*

TEMPLATE

Introduction

Title of study, name of investigator(s), contact information for investigators, etc.

Signing this form indicates that you voluntarily agree to participate in a research study entitled: *<title>* to be carried out by *<student name>* under the supervision of *<faculty sponsor>*, Principal Investigator.

<Student name> can be contacted at *<phone, email, mailing address>* and *<faculty sponsor>* can be contacted at *<phone, email, mailing address>*. Also provide contact information for the MSUB IRB and a statement that the research project has been approved by the IRB.

Confidentiality

Anonymity if provided needs to be stated, otherwise, access to records and similar information needs to be explained clearly. For Instance: if names are associated with data, will numbers replace names with code that matches names and numbers maintained in only one file under supervision, secured, and locked? Will members of research team have access to numbered code, will administrators of entity supporting research have access, etc.? IRB has the right to inspect records only for reasons of maintaining research integrity.

Whom to Contact for Questions

You can call the supervisor of this study, identified at the beginning of this consent document if you have any questions related to this project, about your rights, or about any other aspect of your involvement in this study.

Study Specifics

PURPOSE
Without disclosing information that would likely bias results, inform prospective participants of the reason for the study.

PROCEDURES
Clearly delineate the types of activities participants will be asked to do, the circumstances under which their involvement would occur, the number of times they will be asked for involvement, and any potentially strenuous, unusual, embarrassing, or unexpected activities if such are involved.

RISKS/COSTS
No one can ever truly guarantee a condition of no risks, though none beyond those of normal daily activities may be anticipated. An example of risk would be exposure to discomfort, social embarrassment, legal action, financial harm, etc. If participation will involve costs for participants, those must be disclosed.

BENEFITS
If participants are compensated specify how much, when, etc. If no direct compensation is planned but participants can be reasonably expected to benefit from the activities, from the knowledge of results that will be shared with them once the study is completed and interpreted, then state such. A benefit might be helping create knowledge that will possibly benefit others.

USE OF INFORMATION
If the study will produce any clinically relevant research results, describe whether these results will be given to the subjects, and if so, under what conditions. Describe whether and how subjects can opt out of receiving results.

If there are plans to store or share data for future research describe those plans here. If no one will ever

use information from this student for future research, let the subjects know this as well.

VOLUNTARY NATURE OF PARTICIPATION/FREEDOM FROM COERCION/FREEDOM TO WITHDRAW
Participation must be voluntary and participants have to know that they can withdraw from the study at any time, without penalty, prejudice, or negative consequence. They have to know that future services, considerations, etc. will not be affected by their participation or refusal.

If there are appropriate alternative procedures or courses of treatment that might be advantageous to the potential subject, list them here.

SUMMARY
In a brief overview, state that the information has been explained, discussed, and any questions answered. Also offer a copy of the consent document if they desire one, whether or not they have agreed to participate.

Participant Signature	Participant (printed)	Date
Witness (person obtaining consent)	Witness (printed)	Date

EXAMPLE

CONSENT FORM FOR PARTICIPATION IN HUMAN RESEARCH AT
MONTANA STATE UNIVERSITY BILLINGS

Project Title: [ENTER HERE]

Project Leads: [NAME(s), CONTACT INFORMATION (make sure both student and faculty are included)]

We would like to include you in this research project. If you participate…
- You will be interviewed for approximately 20 minutes.
- We will collect this consent form at the same place where the interview will occur.

Audio Recording: Your interview will be recorded via audio only to ensure that the researchers can maintain the fidelity of your response. Your responses will be transcribed and then the audio files will be deleted. You can choose to not have your interview audio recorded or you can request for recording to stop at any time.

Confidentiality: The investigator will keep your identity private. If you agree to being interviewed, your survey responses will be linked with your interview and these results will no longer be anonymous. Even though what we learn from this study could be used in a research report or journal article, all information will remain totally private.

Risks and Benefits: Possible adverse effects could include stress, discomfort, or invasion of privacy. However, should you feel discomfort you may choose to ask the observation to cease, or you may choose to stop answering any of the questions. There are no benefits to you related to your participation. And it will not cost you anything to participate.

Optional Consent: Your consent is optional, and your decision whether or not to participate will not impact your relations with MSUB or [ANY OTHER ASSOCIATIONS WITH PI].

***Questions or Concerns*:** You should contact us if you have any questions about the study. If you do have questions that may help you decide to participate, please call or email [PI NAME AND CONTACT HERE]. If you would like to talk to someone else, you can call the Institutional Review Board at 406-657-2364 or email at irb@msubillings.edu.

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AUTHORIZATION: I have read the above and understand the discomforts, inconvenience and risk of this study. I agree to participate in this research. I understand that I may later choose not to participate and that I may withdraw from the study at any time.

☐ Check the box to indicate that you agree to be audio recorded.

Printed name: _____ Date: _____

Signature: _____

TEMPLATE

[Title of Project]
Child Assent to Research Participation
[Date]

You are being asked to join a research study by [PI and other researcher name(s)], from the [department name] at MSU Billings. A research study is a way to learn more about people. With this research study, [briefly describe the purpose of the project].

If you decide that you want to be part of this study, you will be asked to [briefly describe what will happen to the participant in the project, where it will take place, the duration of the study, etc.].

You should know that there are some risks, or bad things, that could happen, including [describe the risks]. There might also be some good thing that happen, [describe the benefits].

If you do not want to join the project, you can [alternative choice to participation].

When we are done with our research study, we will write a report about what was learned. Any information about you will not include your name and will be kept secure by the researchers by [describe confidentiality plan].

If you want to be part of this study, we will also ask your parents if they want you to be in this study.

If you have any questions at any time, please call or email [PI name] at [contact information]. If you would like to talk to someone else, you can call the Office of Grants and Sponsored Programs at 406-657-2364 or email at grants@msubillings.edu.

You do not have to be in this study. If you do choose to be in the study, you can change your mind at any time. The researcher won't care if you change your mind or if you don't want to join this study.

Signing this form means you have read this form and all of your questions have been answered. You and your parents will be given a copy of this form.

I agree to join this study. I know I can quit at any time.

_____ _____ _____
Name of Child Participant Signature of Child Participant Date

Researcher Signature (to be completed at time of informed consent)

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information described in this consent form and freely consents to participate.

_____ _____ _____
Name of Researcher Signature of Researcher Date

TEMPLATE

Survey Landing Page
(Electronic Survey, Low Risk)

You are invited to participate in a research study given by [STUDENT NAME] at Montana State University Billings. The purpose of this study is to [DESCRIBE HERE].

Responses will be confidential, and findings will be presented only in summary form—your name and individual data will not be used in any report.

The benefits of this survey are [LIST HERE]. The risks are [LIST HERE].

Participation is voluntary, and you can leave the survey at any time. Your participation will not affect your relationships with the researchers, [ANY OTHER INVOLVED ROUPS/INDIVIDUALS, example: your professors, a certain MSUB department, etc.].

Questions about this study should be directed to Student Name (studentname@email.com or 406-555-0000) or Faculty Name (facultyname@email.com or 406-555-5555). If you have questions about your rights as a research participant please contact the MSUB IRB at irb@msubillings.edu.

By clicking continue, I acknowledge that:

- I have read and understand the information presented and am choosing to participate.
- I understand that my participation is voluntary, and that I may quit the survey at any time.
- I am at least 18 years old.

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Montana State University Billings
1500 University Drive
Billings, MT 59101
irb@msubillings.edu
406-657-2364