

<http://www.fda.gov/oc/ohrt/irbs/informedconsent.html>

21 CFR 50.20 General requirements for informed consent

Except as provided in §50.23, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

The IRB should ensure that technical and scientific terms are adequately explained or that common terms are substituted. The IRB should ensure that the informed consent document properly translates complex scientific concepts into simple concepts that the typical subject can read and comprehend.

Although not prohibited by the FDA regulations, use of the wording, "I understand..." in informed consent documents may be inappropriate as many prospective subjects will not "understand" the scientific and medical significance of all the statements. Consent documents are more understandable if they are written just as the clinical investigator would give an oral explanation to the subject, that is, the subject is addressed as "you" and the clinical investigator as "I/we." This second person writing style also helps to communicate that there is a choice to be made by the prospective subject. Use of first person may be interpreted as presumption of subject consent, i.e., the subject has no choice. Also, the tone of the first person "I understand" style seems to misplace emphasis on legal statements rather than on explanatory wording enhancing the subject's comprehension.

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.")

Consent documents should not contain unproven claims of effectiveness or certainty of benefit, either explicit or implicit, that may unduly influence potential subjects. Overly optimistic representations are misleading and violate FDA regulations concerning the promotion of investigational drugs [21 CFR 312.7] or investigational devices [21 CFR 812.7(d)] as well as the requirement to minimize the possibility of coercion or undue influence [21 CFR 50.20].

Informed Consent (and Young Adult Assent if applicable) for Participation in Research

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 <ph. #, e-mail, mailing address> and <faculty sponsor> can be contacted at <ph. #, e-mail, mailing address>. Also provide contact information for the MSU-B 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 may have 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

1. PURPOSE:

Without disclosing information that would likely bias results, inform prospective participants of the reason for the study, i.e. to investigate factors thought to influence health, activities considered to be important in training, etc.

2. 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.

3. 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, i.e. bus fare, childcare, etc.

4. BENEFITS:

If participants are compensated, i.e. money, grocery script, etc. 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.

5. 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.

6. 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 (Parent) Signature

Participant (Parent) Name (printed)

Date

Witness (person obtaining consent)

Name (printed)

Date

Minor Child Assent Signature

Minor Child Name (printed)

Date

Template for Consent Form for Participation in Research
(Source: paraphrased from Clemson University form)

Title of Study: (matching the title of the research protocol submitted to the IRB)

Description of the Research and Participant's Activities:

Invite the person to participate in a research study conducted by (insert the Principal Investigator's name here, along with the student's name if the research is being performed by a student under the direction of the Principal Investigator). Briefly explain the purpose of the study in easily understood language, without introducing bias by creating expectations for outcomes, and cite the approximate number of participants expected.

In easily understood language, describe the procedures that will be followed, the activities in which a participant will engage, and any assessments that will be conducted. Note the amount of time required of participants and an estimate of the expected duration of study. Describe any pertinent inclusion/exclusion criteria, i.e. age, level of health, ACSM guidelines for exercise, etc.

Disclosure of Risks and Discomfort:

If there are no known risks associated with the study, or the activities present no discomfort beyond routine, daily activities, state that. Describe any reasonably foreseeable risks or discomforts as well as the measures you will take to minimize those risks and discomforts. If unforeseen events such as becoming pregnant would change risks, note such conditions.

Potential Benefits:

Describe any benefits to the participant and to others that may reasonably be expected from the research. If there are no known benefits to the participant as a result of participating, but the research may increase knowledge that will help others, state that.

Protection of Confidentiality: (If anonymity cannot be provided)

Describe the manner (the procedures that will be followed) by which confidentiality of data that could identify a participant will be maintained. Provide enough detail so participants know how their data are protected and clarify that individual identities will not be revealed in any publication that might result from the study. If applicable, explain that medical emergencies could occur that would necessitate suspending a participant's confidentiality. Note that, in rare cases, the IRB or the federal Office for Human Research Protections might review confidential records to assure that the study was conducted properly with respect to protecting participant rights.

Voluntary Nature of Participation

Explain that participation is voluntary, that participants may choose not to participate and may withdraw consent at any time, without any prejudice or penalty of any sort. If conditions can be anticipated that would lead to the researcher terminating participant engagement without respect to consent, note those here.

Contact information

Explain that any questions or concerns about this study or any problems can be directed to (insert the Principal Investigator's name here) at (insert phone number, campus address, e-mail). Note that any questions or concerns about their rights as a participant should be directed to the MSU-Billings Institutional Review Board at 406.657.2046 and that the project has been approved by the IRB.

Consent

I have read this consent form and have been given the opportunity to ask questions. I give my consent to participate in this study.

Participant's signature: _____ Date: _____

Witness (person obtaining consent) signature: _____ Date: _____

Multi-Generational Planning Process for Senior Housing in Billings, Montana

INFORMED CONSENT DOCUMENT

The goal of the project is to evaluate whether or not a multi-generational task force can successfully design a 3-D Concept Model of a senior housing alternative for Billings. The project is also designed to measure how the task force members respond to the process. At least 15-20 people from this area will participate.

1. My participation in this project is completely **voluntary**.
2. I **may refuse** to answer any question that makes me or my child uncomfortable.
3. I **may end participation** in the project, the surveys or the interviews at any time.
4. The researcher will ask me questions (**surveys and/or interviews**) about:
 - Senior adults
 - Young adults
 - Environmental Safety Concerns for Seniors
 - Environmentally Friendly Cities
5. I understand that I will **not be asked to self-identify** in any survey questions (my input will be both anonymous and confidential).
6. I understand that the **task force meetings will be recorded**. Later, those tapes will be transcribed, providing the researcher with a verbatim text of the conversations. The drafting and design students will have access to the tapes in order to proceed with developing the project. Participation in the task force meetings requires that I agree to allow myself to be recorded.
7. I understand that I may be asked to participate in a one-on-one interview with the researcher. **Initial One:**
 - a. _____ I agree that I will participate in the one-on-one interview and that the **interview may be recorded**. I understand that the audio-tape will be transcribed, providing the researcher with a verbatim text of the conversation, but any reporting of the conversation will be done by pseudonym.
 - b. _____ I choose to **not allow myself to be recorded**, however a one-on-one interview can still be conducted. In this case, the researcher will take **handwritten notes only**. Any reporting of the conversation will be done by pseudonym. I may participate in any or all other aspects of the project even if I do not allow the interview to be recorded.
 - c. _____ I choose to **not allow myself to be interviewed**, however I may still participate in any or all other aspects of the project.

8. All surveys, notes, and recordings will be kept on the campuses of MSU-Billings (Dr. Gilbertz; 211 LA Building and Tim Urbaniak's office at the COT).
9. I understand that **I will not be identified** in any publication or report. The researcher will only use the comments under a fictitious name assigned by her. My identity will be protected and confidential.

This research has been reviewed and approved by the Human Subjects Research Committee (HSRS) at MSU-Billings. For research-related problems or questions regarding subject's rights, the HRSC may be contacted through Dr. George White, in the Office of Graduate Studies & Research, MSU-Billings, Billings, MT 59101 or by calling (406) 657-2238.

I have read and understand the explanation provided to me. I have had all of my questions answered to my satisfaction, and I voluntarily agree to participate. I have been given a copy of this form.

(Printed) Name of Participant

Signature of Participant

Signature of Investigator

Date

Susan J. Gilbertz, Ph.D.
211 LA Building
1500 University Drive
MSU-Billings
Billings MT 59101
(406) 657-2183

Example

Informed Consent

Dear Participant:

You have the right to know that your participation in this study is entirely voluntary. You have the right to not participate, and may withdraw at any time. There will be no adverse consequences if you do decide not to participate or to withdraw. No identifying information will be collected and there is no way in which the researcher will be able to tell which responses are yours. Your participation will be completely confidential.

This study involves your reading the list of requirements that Boy Scouts and/or Girl Scouts complete in order to earn badges. You will be shown the requirements for pairs of badges and be asked to compare the difficulty level of the requirements for the badges in each pair. All references to gender have been removed from the requirements, so you will not be able to tell which badges are for boys and which are for girls. After you have completed the study, that information will be available, if you would like to see it.

To indicate that you understand that your participation is voluntary and will be kept confidential, please sign below.

signature

name (please print)

date

Example

INFORMED CONSENT FORM

INFORMED CONSENT STATEMENT

Master's thesis of Kyle Ellefson

INTRODUCTION

You are being invited to participate in a research study. The purpose of this study is to evaluate apologies as an image restoration strategy for use in public relations.

INFORMATION ABOUT PARTICIPANTS' INVOLVEMENT IN THE STUDY

This study asks that you read a short scenario and then respond to seven statements/questions that follow.

This survey will take approximately ten minutes to complete.

RISKS

There are no foreseeable risks to any of the subjects involved in this survey.

BENEFITS

Participation in this survey will contribute to the body of knowledge on image restoration theories in the field of public relations.

CONFIDENTIALITY

The information in the study records will be kept confidential. Data will be stored securely and will be made available only to persons conducting the study unless participants specifically give permission in writing to do otherwise. No reference will be made in oral or written reports which could link participants to the study.

COMPENSATION

There is no compensation for participating in this study.

CONTACT INFORMATION

If you have questions at any time about the study or the procedures, you may contact the researcher, Kyle Ellefson, at 406-670-6715 or kellefson@msubillings.edu. If you have questions about your rights as a participant, you may contact the office of Research Compliance at (406) 657-2238.

Participant's initials _____

PARTICIPATION

Your participation in this study is voluntary; you may decline to participate without penalty. If you decide to participate, you may withdraw from the study at anytime without penalty and without loss of benefits to which you are otherwise entitled. If you withdraw from the study before data collection is completed you data will be returned to you or destroyed.

CONSENT

I have read the above information. I have received a copy of this form. I agree to participate in this study.

Participant's signature _____ Date _____

Investigator's signature _____ Date _____

Example

Consent Form

To appropriately evaluate the current Performance Management System particularly the Performance Appraisal System (job design and process) of Frances Marion Deaconess Hospital, I agree to participate in a one-on-one taped interview and may also be asked to participate in focus group administered by the researcher.

This study is intended to gather information and understanding of the performance appraisal process, not a device to control or direct the work environment. All of the information shared will be treated confidentially and compiled anonymously. This research is for informational purposes only and will not reflect on the performance of any manager choosing to participate. I may also choose to decline participation in this research at any time, without penalty.

I also understand I may be asked to participate in a focus group to discuss the results of the data after all information has been compiled by the researcher.

Signature

Date

Example

Script

My name is _____. I am a student at Montana State University – Billings. I am conducting a survey to determine the feasibility of a Montana based night hawk teleradiology company. All personal information in this survey will remain anonymous and confidential. Once the data is summarized, all information will be destroyed. The data collected will not be used for any other purpose either than for night hawk teleradiology feasibility.

Thank you for your time. Once again, the information you provided will remain anonymous and confidential.

Survey Consent

I voluntarily consent to a survey regarding my motivations to serve on the hospital Board of Directors. I understand that I may end the survey at any time, or may refuse to answer questions if I so choose. This survey is conducted under the auspices of Montana State University Billings and Danielle D. Emery, MD. All survey responses are confidential.

This survey is administered with the permission of, but not sponsored by, the Sisters of Charity of Leavenworth Health System.

Example