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.

Use of the wording, "I understand..." in informed consent documents is inappropriate as many prospective subjects will not "understand" the significance of all the statements. 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. Use of first person may be interpreted as presumption of subject consent; i.e., the subject has no choice.

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.

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

TEMPLATES

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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.

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.

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) (printed)                      Date
Witness (person obtaining consent)                                     Witness (printed)                               Date
Minor Child Assent Signature                                           Minor Child (printed)                           Date
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.

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.

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 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.

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.

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, and 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 ________________

Investigator _______________________________ Date ________________
The project is 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.
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 IRB at MSU Billings. For research-related questions regarding subject’s rights, contact the Office of Research Compliance at 406-657-2364 or irb@msubillings.edu.

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

Name (print) ____________________________________________
Participant Signature _____________________________ Date ________________
Investigator Signature _______________________________ Date ________________
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 you’re 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.

Name (print) ________________________________
Signature ________________________________ Date __________________

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 study 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 ______. If you have questions about your rights as a participant, you may contact the Office of Research Compliance at (406) 657-2364.

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 any time 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 ________________

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To appropriately evaluate the current Performance Management System, particularly the Performance Appraisal System (job design and process) of 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____________________

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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 other than for night hawk teleradiology feasibility.

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

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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______. All survey responses are confidential.

This survey is administered with the permission of, but not sponsored by _____.

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Montana State University Billings
1500 University Drive
Billings, MT 59101
sponsoredprograms@msubillings.edu
406-657-2046