Millikin University IRB Consent Form Instructions

The purpose of obtaining informed consent is to provide participants with information they can easily understand to allow them to accurately weigh the risks and benefits of participating in a research study. Whenever possible, documentation of participant consent is strongly recommended though not required for research that meets the "Exempt from Review" criteria. For "Expedited and Full IRB Review" categories, written or oral (using a verbatim written script, detached signature page, and witness) consent is required, unless the researcher can provide a compelling argument explaining how foregoing the consent process reduces participant risk or harm.

Types of Consent

1. Written Consent: Except as described below, informed consent must be documented on a written consent form submitted with the Review Request for Research form and approved by the IRB. A copy of the consent form must be provided to the participants.

2. Oral Consent: A researcher may present an oral summary (script) to the participants including all the required information about the research. Participants sign only a short form written consent document stating that the elements of informed consent were presented orally to the subject or the subject's legally authorized representative and including the information required by Millikin University. When this method is used, there must be a witness to the oral presentation who will sign both the shortened consent form and a summary of the script. Participants will be given a copy of the oral summary as well as a copy of the shortened consent form. The IRB must approve the oral script submitted with the Review Request for Research form.

3. Waiver of Consent: The IRB may waive the requirement for written informed consent under the following conditions:
   a. The only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
   b. The research presents no more than minimal risk of harm to subjects, and involves no procedures for which written consent is normally required outside of the research context.

Assent: Assent is a participant's voluntarily agreement to participate in research. The IRB will approve research that presents no more than minimal risk to children or persons with diminished autonomy provided that parent/legal guardian consent and the assent of the participant is also obtained.

- Children under age 8 may assent either orally or passively, depending on their level of maturity (e.g. an infant may not be able to assent).
- Children 8-17 years old should sign a written assent form unless the Millikin IRB approves of a different process.

Consent and Assent Form Elements

All consent and assent forms must adhere to the requirements stipulated in the Common Rule (45 CFR 46.116). Required elements are listed below, followed by samples.

Required Consent and Assent Form Elements

1. Use language that is age/reading level appropriate for someone without research training or scientific expertise.

2. Provide a general description of the research that clearly enables participants to know that they are participating in a research study. The researcher need not provide hypothesis or design details that would compromise the validity of the research design, but should provide enough information to give participants a general idea of the study's purpose (e.g., You will be asked to answer an online survey about your attitudes on gender by selecting your response from a list of alternatives provided with each question).

3. Provide participants with any relevant study details that may affect their decision whether or not to participate:

    a. Explain what data will be collected and how confidentiality of the data will be maintained. Millikin University requires some version of the following statement in all consent and assent forms: *"I understand that the responses I give will be considered confidential, reported only as group data, and that every possible effort will be made to preserve my confidentiality regarding these data."*

    b. Describe any risks or discomfort the participant may experience as a consequence of participation. Also, provide the potential benefits that could result from participation, if applicable.

    c. Provide information on any inducements participants will receive for participation (e.g., gift card, # of course points).

    d. Provide a statement detailing the responsibility for and coverage of treatment costs should an injury or health condition arise due to participation in the study.

    e. Provide the name, title, phone number, and email address for the Principal Investigator, the faculty or staff Project Supervisor, and the IRB Chair so that participants may contact those responsible for providing participant safeguards and answering study questions. Millikin University requires that this statement be included in all consent / assent forms: *"I understand that if I have any questions regarding the study, I can contact… [Researcher contacts]. If I have any questions about my rights as a participant, I can contact… [IRB contacts]."*

f. Inform participants that participation is completely voluntary and that they have the right to end their participation at any time without penalty. Millikin University requires some version of this statement to be a part of all consent / assent forms*: "I understand that my participation is voluntary and that I am free to end my participation at any time, or refuse to answer any question, without penalty. I understand that none of my legal rights regarding negligence and the liability of Millikin University or its agents have been waived."*

4. A written copy of the consent form, verbatim written consent script, or consent disclosure (e.g., survey research) must be provided to the IRB with the Review Request for Research and approved before the research begins.

5. Signed consent forms or group consent signature sheets (oral consent) must have the participant's or parent/ legal guardian's printed name, signature, date, and the signature and title of the research staff member obtaining the consent (e.g., Jane Smith, PI) on the signed form. For oral consent, the witness must also sign the consent form and script.

6. Participants should receive a copy of the consent form or consent information sheet that provides contact information as required by the IRB. For online surveys, the participant should be able to record the researcher and IRB contact information.

7. If research is being conducted at another site and uses a consent form specific to that site, the researcher must ensure that some version of all the Millikin required information is included in the consent form used in the study.

A. **Additional Consent and Assent Form Elements (when applicable)**

The researcher must inform the participant if more than minimal risk is probable, if confidentiality may be limited, if participants will receive rewards or incur costs, and if medical, biological or other invasive procedures are to be used as a part of the study's procedures.

1. An explanation that the participant may be removed from the study based on the researcher's judgment, despite the participant's consent to continue participating.
2. For biomedical research, if there are available treatment alternatives to those being offered in the study, participants must be made aware of these options.
3. An estimate of the number of participants being recruited to provide a context for the ability of the researcher to detect real differences and or generalize the data.
4. Indication of whether or not participants will be debriefed or provided with an opportunity to ask questions at the conclusion of their participation.
5. If you may have participants with limited intellectual capacity (e.g., due to cognitive disability or a disease which decreases cognitive capacity over time), you may want to add a few questions to the end of your consent form to ensure that those you solicit understand what you are asking and can knowledgeably consent to participate. The following are an example of the types of questions you might add to your consent form. You may use these same questions and simply edit them to

reflect the purpose, benefits, and requirements of your particular study. Do not hesitate to contact the IRB should you have any questions or would like assistance with this or any other aspects of your submission.

1. *What is the purpose of the study that you have been asked to take part in?*
   (1) Understand how couples navigate the potentially difficult circumstances that Accompany health issues.
   (0) Examine the effect of television exposure on children's attentiveness.
2. *Do you have to be in this study if you do not want to participate?*
   (1) No.
   (0) Yes.
3. *If you participate in this study, what are some things you will be asked to do?*
   (1) Answer survey questions about my health and relationship
   (0) Conduct an interview with a coworker
4. *Are you allowed to skip questions that make you upset or feel uncomfortable?*
   (1) Yes.
   (0) No.
5. What are some of the possible benefits of this study?
   (1) You may not get personal benefit from taking part in this research study, your responses may help us understand more about how romantic partners cope with health issues.
   (0) You are not allowed to benefit from this study.

Sample Forms

Sample 1

UNIVERSITY OF WISCONSIN-MADISON
Research Participant Information and Consent Form

Title of the Study: Communication about money allocation decisions

Principal Investigator: XXXXXXXX (phone: (XXX) XXX-XXXX or (email: x@wisc.edu)
Student Researcher: XXXXXXXX (phone: (XXX) XXX-XXXX or (email: s@wisc.edu)

DESCRIPTION OF THE RESEARCH
You are invited to participate in a research study about how people communicate about money allocation decisions.

You have been asked to participate because you are taking a Communication Arts or Journalism class that offers extra credit for participation in this study.

The purpose of the research is to examine how people both communicate about the allocation of money and perceive an interaction with another person in which they discuss the allocation of money. The research will examine differences in communication when people deceive versus do not deceive.

This study will include undergraduates taking Journalism and Communication Arts classes.

Research will be conducted in the Communication Science lab in 4000V Vilas Hall. Video tapes will be made of your participation. Research personnel will view the videotapes. The tapes will be kept until the research is published in a scientific journal; once the research has been published, the tapes will be destroyed.

WHAT WILL MY PARTICIPATION INVOLVE?
If you decide to participate in this research you will be asked to either allocate a small amount of money between yourself and your partner (role of allocator) or receive an allocation of money from your partner (role of recipient). You will discuss the allocation of money face-to-face with your partner for a few minutes. This interaction will be videotaped. After the interaction, the recipient will make a decision whether or not to accept the money from the allocator. The recipient will not be told the amount of money given to the allocator. Afterwards, you will be asked to fill out a questionnaire about the interaction.

You will be asked to complete two interactions with two different partners.

Your total participation will require approximately 25 minutes.

ARE THERE ANY RISKS TO ME?
We don't anticipate any risks to you from participation in this study.

ARE THERE ANY BENEFITS TO ME?
We don't expect any direct benefits to you from participation in this study.

WILL I BE COMPENSATED FOR MY PARTICIPATION?
You will receive 1 extra credit point in your Communication Arts or Journalism class for participating in this study. You may also receive a small amount of money in the money allocation interaction.

HOW WILL MY CONFIDENTIALITY BE PROTECTED?
While there will probably be publications as a result of this study, your name will not be used. Only group characteristics will be published.

If you participate in this study, we would like to be able to quote you directly without using your name. If you agree to allow us to quote you in publications, please initial the statement at the bottom of this form.

WHOM SHOULD I CONTACT IF I HAVE QUESTIONS?
You may ask any questions about the research at any time. If you have questions about the research after you leave today you should contact the Principal Investigator XXXXXXXX (phone: (XXX) XXX-XXXX or (email: x@wisc.edu)

If you are not satisfied with response of research team, have more questions, or want to talk with someone about your rights as a research participant, you should contact the Education Research and Social & Behavioral Science IRB Office at xxx-xxxx.

Your participation is completely voluntary. If you decide not to participate or to withdraw from the study it will have no effect on your grade in this class.

Your signature indicates that you have read this consent form, had an opportunity to ask any questions about your participation in this research and voluntarily consent to participate. You will receive a copy of this form for your records.

Name of Participant (please print):_____

_____ _____
Signature Date

_____ I give my permission to be quoted directly in publications without using my name.

Sample 2

Sleep Apnea & Heart Failure Project Consent

I understand that I have been invited to participate in a research study at the Heart Institute - Heart Failure Clinic that is enrolling approximately 200 current patients. This study will evaluate the effectiveness of education provided on sleep apnea, heart failure, and continuous positive airway pressure therapy.

I agree to participate in this study by providing answers to questions about my feelings and expectations regarding the use of a continuous positive airway pressure machine (CPAP). The survey takes 30 minutes or less to complete. The survey must be completed at the Heart Institute - Heart Failure Clinic before or after your clinic visit, or by scheduling an appointment (call 333-333-3333 for an appointment). I understand that my participation in this study is completely voluntary, and has no impact on the care and treatment I receive from the Heart Institute - Heart Failure Clinic. I understand that I can refuse to answer any question or end my participation at any time without any penalty.

I understand that my responses are anonymous and that no identifying information will be linked to my survey responses. The responses I provide will only be reported as aggregated or group data, and only used for educational and/or scientific purposes. I understand that the information gained from the study will help provide insight to the understanding CPAP barriers and compliance and will help inform those providing education and treatment to better help others with sleep apnea and heart problems.

There are no known risks associated with participating in this study, and I understand that if injury from the research study occurs, I will not automatically be compensated by the Heart Institute. I understand that none of my legal rights regarding negligence and the liability of Millikin University or its agents have been waived. I understand that if I have any questions regarding the study, I can contact the lead researcher at Dr. XXX at 222-222-222 or via email at x@hihfc.org. If I have any questions about my rights as a subject, I may contact Dr. XXXX, Millikin University IRB Chair at xxx-xxx-xxxx or via email at x@millikin.edu. I understand that I will be given a copy of this consent form to keep for later reference.

I understand that sealing my survey answer sheet in envelope provided and placing it in the survey return box demonstrates my consent to participate.

Participant's Signature: _____ Date: _____

Printed Name: _____ Date: _____

Sample 3

Cornell University
Sample Child Assent Form

http://www.irb.cornell.edu/forms/assent.htm

We are doing a study to learn about people who tell the truth and people who lie. We are asking you to help because we don't know very much about whether kids your age expect people to lie or tell the truth.

If you agree to be in our study, we are going to ask you some questions about types of people. We want to know if you think they usually tell the truth or if they usually lie. For example, we will ask you if a teacher, parent, or other people usually lie or usually tell the truth.

You can ask questions about this study at any time. If you decide at any time not to finish, you can ask us to stop.

The questions we will ask are only about what you think. There are no right or wrong answers because this is not a test.

If you sign this paper, it means that you have read this and that you want to be in the study. If you don't want to be in the study, don't sign this paper. Being in the study is up to you, and no one will be upset if you don't sign this paper or if you change your mind later.

Your signature: _____ Date _____

Your printed name: _____ Date _____

Signature of person obtaining consent: _____ Date _____

Printed name of person obtaining consent: _____ Date _____