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

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

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,

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.

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.

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 studl