Version 05/2006

Example
(At least) 12-point font

INFORMED CONSENT DOCUMENT

Insert title of study

You are being asked to participate in a research study about *insert general statement about study*. You were selected as a possible participant because *explain how participant was identified*. Please read this form and ask any questions that you may have before agreeing to be in the research.

Researchers at Case Western Reserve University are conducting this study.

Background Information
The purpose of this research is *explain research question and purpose in lay language*.

Only if you answered YES to item #14 of the new protocol application, add the following: Please note that the responsible investigator and/or other members of the research team have a significant financial interest in *choose one: the sponsor of this research* ***OR*** *the product being investigated in this study.*

Procedures
If you agree to be a participant in this research, we would ask you to do the following things:
[*Describe the procedures to be followed (including audio/videorecording); indicate expected frequency and duration of participation; identify any procedures that are experimental. When writing the procedures for the study, please keep the following points in mind: (a) how and from whom the potential subjects will receive the consent information/document; (b) who would be approached for consent/assent/permission (c) where the informed consent interaction will occur; (d) the timing of presentation of the informed consent document and consideration of a waiting period; (e) steps taken to minimize the possibility of coercion or undue influence; (f) the language used by those obtaining consent; (g) the language understood by the prospective participant or the representative.*]

Risks and Benefits to Being in the Study
This research has the following risks: First, *explain first risk, including the likelihood of the risk.* Second, *explain second risk, including the likelihood of the risk.* Third, *if there are no foreseeable risks, state as such. If there are significant physical or psychological risks to participation, the participants should be told under what conditions the researcher will terminate the study without regard to the participant's consent*

To investigators: If the study involves more than minimal risk, then some or all additional elements must be included in your informed consent document as described in the Case IRB Guidebook

The benefits of participation are [*explain benefits of participation that will be gained by the participants or others (Note: monetary compensation is not considered a benefit)*]
[*If there are no benefits, state as such*]

To investigators: No informed consent, whether oral or written, may include any exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the investigator or the institution or its agents from liability for negligence.

Compensation
You will receive the following payment/reimbursement: [*explain amount of payment or other reimbursement information (i.e., class credits, tokens, etc.), as well as when payment and/or reimbursement will occur*]
Explain how such withdrawal will be pro-rated (i.e., half of the money or extra credit if discontinue participation half-way through)]

Confidentiality
The records of this research will be kept private. In any sort of report we might publish, we will not include any information that will make it possible to identify a participant. Research records will be kept in a locked file, and access will be limited to the researchers, the University review board responsible for protecting human participants, regulatory agencies, and *[add only if applicable]* sponsors and funding agencies.
[*If tape or video recordings are made, explain who will have access to them, and when they will be erased/destroyed*]

Voluntary Nature of the Study

Your participation is voluntary. If you choose not to participate, it will not affect your current or future relations with the University [*or with other cooperating institutions (insert names)*]. There is no penalty or loss of benefits for not participating or for discontinuing your participation.
[*Explain any consequences (i.e., adjusted monetary benefits or loss of course credit) due to early withdrawal. Explain how such withdrawal will be pro-rated (i.e., half of the money or extra credit if discontinue participation half-way through)*]

You will be provided with any significant new findings that develop during the course of the research that may make you decide that you want to stop participating. [*We understand that this statement is part of our template, but if it does not or cannot apply to your study, please delete it or justify how you plan to share findings to participants.*]

Contacts and Questions
The researchers conducting this study are *[Responsible Investigator]* and *[Co-Investigator(s)]*. You may ask any questions you have now. If you have any additional questions, concerns or complaints about the study, you may contact them at [*contact information*].

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; (1) questions, concerns or complaints regarding this study, (2) research participant rights, (3) research-related injuries, or (4) other human subjects issues, please contact Case Western Reserve University's Institutional Review Board at (216) 368-6925 or write: Case Western Reserve University; Institutional Review Board; 10900 Euclid Ave.; Cleveland, OH 44106-7230.

You will be given a copy of this form for your records.

Statement of Consent

I have read the above information. I have received answers to the questions I have asked. I consent to participate in this research. I am at least 18 years of age.

To investigators: If this form is used as a parental permission and assent form (usually appropriate for teenage participants), please omit "I am at least 18 years of age."]

To investigators:
If audio or video recording, indicate that recording is an integral part of the study and that if the participants do not wish, they should not participate in the study.
OR
Insert yes/no checkboxes. The informed consent documents must have audio and video checkboxes, if applicable. In the procedures paragraph of the consent forms, state that you will take notes if they refuse to be recorded, if that is an option for this study. Include yes/no checkboxes for audio and video recording at the end of each consent form.

"☐ YES, I CONSENT to being audio/video recorded.
I also understand that I reserve the right to change my mind;"

"☐ NO, I DO NOT CONSENT to being audio/video recorded."

Print Name of Participant: _____

Signature of Participant: _____ Date: _____

Signature of Parent or Guardian [*omit if not applicable*]: _____ Date: _____

Signature of Person Obtaining Consent [*omit if not applicable*]: _____ Date: _____