Institutional Review Board

## Research Consent Form Instructions and Template

Informed consent is required to provide potential subjects or their legally authorized representatives with the information necessary for them to make a decision about participating in research.

Consent documents should be written in plain language, generally at the 8th grade reading level. The reading level can be higher if the target population tends to have a higher literacy rate than the general population.

We recommend the use of this template to create the informed consent document(s) for your study. Carefully read the following important directions:

1. Blue text in [brackets] represents information about your study that you must add (in plain text).
2. Additional instructions or sample text are provided in boxes.
3. Carefully proofread your final document. Use the same font and type size throughout. The finished document should reflect what you will give to the subject.
4. You and your subject should sign a copy of the consent form. Keep it with your research records. Give an unsigned copy to the subject.
5. Use a file name for each consent document that clearly identifies type of consent and for which subjects it is intended (e.g. child assent, parental permission, adult consent, etc.). Include the last name of the principal investigator (e.g., Smith Adult Consent.docx).

For questions about informed consent, please contact the CU-IRB at 262-243-2721 or janessa.doucette@cuw.edu. For more information about plain language go to http://www.plainlanguage.gov/

**Before you upload your completed consent document to Cayuse, delete this cover page, blue words in brackets, and boxes.**

Rev. March 2019

# Consent to Be Part of a Research Study

[Title of the project.]

**Who is conducting this study?**

[Give the name of the principal investigator (PI), credentials, and institutional affiliation. Give the name of any co-investigators, credentials, and institutional affiliation. If you are a student PI, give the name of your faculty advisor, credentials, and institutional affiliation. State the name of the study sponsor, if any.]

**Who can take part?**

You are invited to participate in a research study. In order to participate, you must be [include eligibility criteria: e.g., age, gender, language, etc.] Your consent is being sought for participation in this research study. Your participation in this study is voluntary.

**Briefly, what is this research about?**

**Delete this section if your consent form is 3 pages or less.**

For research projects that involve more than a three-page consent document, provide a summary of key information that is most likely to help potential subjects understand why they might or might not want to participate in the study. Organize information to facilitate comprehension. For guidance on the informed consent summary, see http://www.irb.pitt.edu/GuidanceKeyInformation.

Required elements of this key information are:

a. Identification of the project as a research study and that participation is voluntary
b. Purpose of the research, duration of participation, and a description of research procedures
c. Foreseeable risks or discomforts, if any
d. Expected benefits to subjects or others, if any
e. Alternative procedures or treatments that might benefit the subject (Note: applies primarily to clinical research)

**What is the purpose of this study? (Why would you want to participate?)**

[Briefly state the purpose of your study.]

**What will you be expected to do?**

If you agree to take part in this study, you will be asked to [If your consent form is more than three pages and you included the research summary (see box above), use this section to provide a more comprehensive description about the research procedures. Describe what the subject will be asked to do in chronological order (what, when, where, how). Use short sentences and easy words.]. We expect this to take about [indicate duration and number of interactions].

**What are the risks to you?**
You might face some risks from being in this study. They are [All research carries some degree of risk, however minimal (such as loss of time, mental fatigue, boredom, etc.). Describe specific risks, and indicate what the study team will do to minimize those risks.].

Primary risks include physical, psychological, or informational risks. For informational risks (e.g., those involving breach of confidentiality), describe what you will do to protect the data during collection, while stored or during transmission of the data. Psychological risks (e.g., those associated with the completion of a particularly sensitive survey or interview) could be mitigated by providing subjects with contact information for counseling resources. If you are conducting your research at Concordia University, see counseling information specific to your campus on the last page of this consent form template.

For biomedical research posing more than minimal risk to subjects include the following text: "Please tell the researchers if you have any injuries or other problems related to your participation in the study. If you are injured as a result of the experimental parts of this study, the principal investigator will arrange for the provision of or will instruct you on where to go to receive necessary medical services. The cost of treating complications may or may not be covered by your insurance, and if not, you may be held responsible for costs depending on where you receive treatment. By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study."

**What are the benefits to you?**
Although you may not directly benefit from being in this study, others might benefit because [insert details; you could state potential benefits to society, the advancement of science, or theory.]. You may benefit from being in this study because [insert details or delete this sentence if the subject will likely not benefit].

**Do you have to participate?**
It is totally up to you to decide to be in this research study. Participating in this study is voluntary. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer.

**What are your options if you do not participate in this study?**
[State other possible activities, procedures, or courses of treatment which the subject might take part. If there are no alternatives, just state "none."]

**How will we protect your personal information?**
The records of this study will be kept private. In any sort of published report we will not include information that will make it possible to identify you. Your record for the study may, however, be reviewed by a member of the research team, the Institutional Review Board, [the study sponsor, if any], or the federal Office of Human Research Protections (OHRP), and to that extent, confidentiality is not absolute.

**Will your personal information be used for future research?** ***Yes*****_____** ***No*** **_____**

**If you have checked "yes," include the following wording. If you have checked "no," delete this box.**

*I agree that my information may be shared with other researchers for future research studies that may be similar to this study or may be completely different. The information shared with other researchers will not include any information that can directly identify me. Researchers will not contact me for additional permission to use this information.* [Note: This separate consent is not necessary if you will only store and share deidentified data.]

***YES*****_____** ***NO*****_____**

_____

Signature Date

**Will you be paid for being in this study?** ***Yes*****_____** ***No*** **_____**

**If you have checked "yes," include the following wording applicable to your study. If you have checked "no," delete this box.**

You will receive [nature and total amount of incentive/compensation] for your participation in this study. [Describe how compensation will be determined (prorated) if the subject withdraws from the research before the end of the study.]

If compensation is more than $100 in a calendar year, include the following text:

"Because this study pays more than $100, Concordia University will collect your name, address, social security number, and payment amount. This information will be safely stored and used for income tax reporting purposes only if your total payments from the University are greater than $600 in a calendar year (January through December). If you receive more than $600 in payments from the Concordia University in a calendar year, this information will be submitted to the Internal Revenue Service (IRS) for tax reporting purposes and an extra tax form (Form 1099) will be sent to your home."

**Whom can you contact with questions?**
If you have questions about this research, you may contact [PI name, email, phone (and faculty advisor if the PI is a student)].

If you have any questions or concerns about the way you were treated as a participant in this research study, please contact Dr. Stacy Stolzman, Chair of the Concordia University Institutional Review Board, at 262-243-2176, stacy.stolzman@cuw.edu. Even though Dr. Stolzman may ask your name, information will be kept confidential.

If you have any questions or concerns about your mental well-being as a result of participation in this study, please contact David Enters at Concordia University Wisconsin Counseling Center at 262-243-4211, dave.enters@cuw.edu; or Aysha Abiade at Concordia University Ann Arbor Counseling and Psychological Services at 734-995-7316, aysha.abiade@cuaa.edu.

**Delete this wording if there are no mental health risks associated with your study.**

**Your Consent:**
The information about the proposed research study and consent has been explained to you by:

| _____ | _____ | _____ |
|---|---|---|
| *Name of Principal Investigator (print)* | *Signature of Principal Investigator* | *Date* |

When you sign this form, you agree that you understand the above description of this research. You also agree that your questions have been answered, and that you want to take part in this research study. I have received a copy of this form to keep for my records.

| _____ | _____ | _____ |
|---|---|---|
| *Name of Participant (print)* | *Signature of Participant* | *Date* |

You may also need to obtain dated consent for specific activities when those activities are ***optional.*** Whether an activity is required or optional must be clearly described in the main body of the consent above. Insert these words in the section of the consent form that describes what the subject will be expected to do. A common optional research activity is included below:

**Your Consent to Be Audio [or Video] Recorded**

*I agree to be audio [or video] recorded.*

***YES*_____ *NO*_____**

_____
Signature Date

**Delete this box if this optional wording does not apply to your study.**