City University of Seattle Informed Consent Guide

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.

Information in the consent document must be organized to facilitate comprehension. 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. For child assent documents, the reading level and complexity of the information provided should be appropriate for the age level of the child.

Please note:

1. Regulations now require that federally-sponsored research projects contain a concise and focused presentation of the key information that is most likely to help potential subjects understand why they might or might not want to participate in the study. The key information must be presented first and must include the following:
    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

    Foreseeable risks or discomforts, if any
    c. Expected benefits to subjects or others, if any
    d. Alternative procedures or treatments that might benefit the subject

(Note: applies primarily to clinical research)

The following Informed Consent Templates are required for your Ethical Review Protocol submission. Please follow the informed consent process outlined and include all the required information highlighted in red type.

All correspondence and transmission of research documents between the researcher and the participant is required to be conducted via City U email and all documents (Informed Consent Forms, research data collection instruments) must be encrypted/password protected. The email to research participants that contains encrypted/password protected research documents is required to contain directions to the participant describing the process of returning signed encrypted/password protected documents.

School/Division of _____

CITYU RESEARCH PARTICIPANT INFORMED CONSENT

Title of Study:

_____

Name and Title of Researcher(s):

_____

For Faculty Researcher(s):
Department: _____
Telephone: _____
City U Email: _____
Immediate Supervisor: _____

For Student Researcher(s):
Faculty Supervisor: _____
Department: _____
Telephone: _____
City U E-mail: _____

Program Coordinator (or Program Director):

_____

Sponsor, if any:

_____

Key Information about this Research Study

You are being invited to participate in a research study.

The researcher will explain this research study to you before you will be asked to participate in the study and before you sign this consent form.

Follow the informed consent process:

1. ***Potential participant responds to recruitment letter/poster or email invitation to join the study as a participant.***
2. ***Schedule a meeting with the potential participant to describe the research study and to explain the process of informed consent. Emphasize that their participation is voluntary, that they can withdraw from being a participant in the study at any time with out penalty or negative consequences.***
3. ***Allow the potential participant time to consider whether they wish to volunteer as a participant in the research study before you ask them to sign the Informed Consent Form.***

4. ***Ask participant verbally if they understand the purpose of the research, what they are being asked to do and what the potential risks and benefits of being a participant may be.***
5. ***Ask the participant if they have any questions.***

- You do not have to participate in this research.
- It is your choice whether or not you want to participate in this research.
- Your participation is voluntary and you can decide not to participate or withdraw your participation at any time without penalty or negative consequences.
- You should talk to the researcher(s) about the study and ask them as many questions you need to help you make your decision.

What should I know about being a participant in this research study?

This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information.

You are eligible to participate in this study because you _____.

State the eligibility criteria as cited in our Ethical Review Protocol. For example, age, gender, language, member of population sample, etc).

You will be in this research study for approximately _____.

State the approximate length of time your study will be open. What is the estimated termination date of your study?

About __ individuals will participate in this study.

State how many participants will be recruited into the study.

To make your decision, you must consider all the information below:

- The purpose of the research
- The procedures of the research. That is, what you will be asked to do and how much of your time will be required.
- The risks of participating in the research.
- The benefits of participating in the research and whether participation is worth the risk.

If you decide to join the study, you will be asked to sign this form before you can start study-related activities.

Why is this research being done?
Provide a clear, concise explanation in lay language of the purposes of the research, including prominent use of the term "research."

Purpose of Study:

_____

Research Participation.
You will be asked to participate in the following procedures:

In the space provided explain in simple, non-scientific language what will happen to the participant or what s/he will be asked to do in the study. Describe the participant time commitment for each component.

For studies involving the collection of sensitive information or the inclusion of questions that might be upsetting, include examples of the types of questions that will be asked or describe the sensitive topic areas that the questions will be asked about.

Have participant initial the procedure below that are described as the data collection method in your Ethical Review Protocol.

I understand I am being asked to participate in this study in one or more of the following ways (initial options below that apply):

☐ Respond to in-person and/or telephone Interview questions; Approximate time _____

☐ Answer written questionnaire(s); Approximate time _____

☐ Participate in other data gathering activities, specifically, _____; Approximate time _____

☐ Other, specifically, _____. Approximate time _____

Audio/Video Recording
If audio and/or video recording devices will be used, explain why these are needed and what will be done with them upon completion of the research (kept indefinitely, archived after transcription, destroyed after X years).

If data is gathered through observation of behavior, explain what information will be observed how it will be recorded and what will be done with the data upon completion of the research.

You may refuse to answer any question or any item in verbal interviews, written questionnaires or surveys, and, you can stop or withdraw from any audio or visual recording at any time without any penalty or negative consequences.

Are there any risks, stress or discomforts that I will experience as a result of being a participant in this study?

In simple, non-scientific language, describe any reasonably foreseeable risks or discomforts:

- ***Legal risks (e.g., possibility of discovering activities that may require reporting to authorities, possibility of being arrested)***
- ***Physical risks (e.g., nausea, muscle aches, rashes, infection, discomfort)***
- ***Social or economic risks (e.g., loss of confidentiality; effect on financial standing, employability, or insurability)***
- ***Emotional risks (e.g., feelings of sadness or anxiety)***

If there are no known risks, state: I/We do not anticipate any risks from participating in this research.

Taking part in this research involves certain risks: This could include:

Will being a participant in this study benefit me in any way?

Describe any probable benefits of participation. Be sure to distinguish between a likely direct benefit (e.g., from therapeutic or intervention research) and a possible indirect benefit (e.g., reflecting on an experience may lead to a better understanding of oneself). If there are no direct benefits, indicate that there are none.

Describe the expected benefits to society or scientific knowledge: e.g., "…information from this study may benefit other people now or in the future…" or "…we hope to learn more about _____ …"

We cannot promise any benefits to you or others from your participation in this research. However, possible benefits may include _____.

Indicate whether the participant will receive compensation or extra credit for being in the study. If participants will not receive any compensation, state this.

You will receive ____ for your participation in this research.

You will not receive any payment for participation in this study.

Confidentiality

I understand that participation is confidential to the limits of applicable privacy laws. No one except the faculty researcher or student researcher, his/her supervisor and Program Coordinator (or Program Director) will be allowed to view any information or data collected whether by questionnaire, interview and/or other means.

If the student researcher's cooperating classroom teacher will also have access to raw data, the following box will be initialed by the researcher. ☐

Steps will be taken to protect your identity, however, information collected about you can never be 100% secure. Your name and any other identifying information that can directly identify you will be stored separately from data collected as part of the research study. The results of this study will be published as a thesis and potentially published in an academic book or journal, or presented at a academic conference. To protect your privacy no information that could directly identify you will be included.
All data (the questionnaires, audio/video tapes, typed records of the interview, interview notes, informed consent forms, computer discs, any backup of computer discs and any other storage devices) are kept locked and computer files will be encrypted and password protected by the researcher. The research data will be stored for years (5 years). At the end of that time all data of whatever nature will be permanently destroyed. The published results of the study will contain data from which no individual participant can be identified.

Signatures

I have carefully reviewed and understand this consent form. I understand the description of the research protocol and consent process provided to me by the researcher. My signature on this form indicates that I understand to my satisfaction the information provided to me about my participation in this research project. My signature also indicates that I have been apprised of the potential risks involved in my participation. Lastly, my signature indicates that I agree to participate as a research subject.

My consent to participate does not waive my legal rights nor release the researchers, sponsors, and/or City University of Seattle from their legal and professional responsibilities with respect to this research. I understand I am free to withdraw from this research study at any time. I further understand that I may ask for clarification or new information throughout my participation at any time during this research.

I have been advised that I may request a copy of the final research study report. Should I request a copy, I understand that I will be asked to pay the costs of photocopy and mailing.

Participant's Name: _____
Please Print

Participant's Signature: _____ Date: _____

Researcher's Name: _____
Please Print

Researcher's Signature: _____ Date: _____

If I have any questions about this research, I have been advised to contact the researcher and/or his/her supervisor, as listed on page one of this consent form.

Should I have any concerns about the way I have been treated or think that I have been harmed as a research participant, I may contact the following individual(s):

_____, Program Coordinator (and/or Program Director), City University of Seattle, at _____ (address, direct phone line and CityU email address).

This study has been reviewed and has been approved by the Institutional Review Board (IRB) of City University of Seattle. If you have questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the IRB at:
City University of Seattle
521 Wall Street, Suite 100.
Seattle, WA, 98121
IRB@Cityu.edu.

Please apply the above information in the respective Informed Consent Forms below.

School/Division of _____

CITYU RESEARCH INFORMED CONSENT
FOR PARENT-LEGAL GUARDIAN OF PARTICIPANT

Title of Study:
_____

Name and Title of Researcher(s):
_____

For Faculty Researcher(s):
Department: _____
Telephone: _____
City U Email: _____
Immediate Supervisor: _____

For Student Researcher(s):
Faculty Supervisor: _____
Department: _____
Telephone: _____
City U E-mail: _____

Program Coordinator (or Program Director):
_____

Sponsor, if any:
_____

Why is my child being invited to participate in this research?
You, or your child, may be eligible to participate in this research study.

- Your child is eligible to participate in this study if he/she is _____.
- Your child will be in this research study for about _____.
- About __ individuals will participate in this study.

What should I know about being in a research study?

This form contains important information that will help you decide whether to consent to your child's participation in this research. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. If you decide to join the study, you will be asked to sign this form before you can start study-related activities.

To make your decision, you must consider all the information below:

- The purpose of the research.
- The procedures of the research. What you will be asked to do.
- The risks of participating in the research.

- The benefits of participating in the research and whether participation is worth the risk.

The researcher will explain this research study to you:

- You do not have to give permission for your child to participate in this research.
- It is your choice whether or not you want your child to participate in this research.
- Your child's participation is voluntary and you can withdraw your child's participation at any time without negative consequences.
- You should talk to the researchers about the study and ask them any questions you have.

Why is this research being done?

Purpose of Study:

_____

Research Participation:
Your child will be asked to participate in the following procedures:

I understand I am being asked to participate in this study in one or more of the following ways (the checked options below apply):

☐ Respond to in-person and/or telephone Interview questions; Approximate time _____.

☐ Answer written questionnaire(s); Approximate time _____.

.

☐ Participate in other data gathering activities, specifically, _____; Approximate time _____.

☐ Other, specifically, _____. Approximate time _____.

Is there any way being in this study could be bad for me or my child?

Taking part in this research involves certain risks: This could include:

Will being in this study help me or my child in any way?

We cannot promise any benefits to you, your child or others from your and your child's participation in this research. However, possible benefits may include _____.

You will receive ____ for your participation in this research.

You will not receive any payment for participation in this study.

I have been advised that I may request a copy of the final research study report. Should I request a copy, I understand I may be asked to pay the costs of photocopying and mailing.

Confidentiality

I understand that participation is confidential to the limits of applicable privacy laws. No one except the faculty researcher or student researcher, his/her supervisor and Program Coordinator (or Program Director) will be allowed to view any information or data collected whether by questionnaire, interview and/or other means. If the student researcher's cooperating classroom teacher will also have access to raw data, the following box will be checked. ☐

Steps will be taken to protect your identity, however, information collected about you can never be 100% secure. All data (the questionnaires, audio/video tapes, typed records of the interview,

interview notes, informed consent forms, computer discs, any backup of computer discs and any other storage devices) are kept locked and computer files will be encrypted and password protected by the researcher. The research data will be stored for years (5 years or more if required by local regulations). At the end of that time all data of whatever nature will be permanently destroyed. The published results of the study will contain data from which no individual participant can be identified.

Signatures

I have carefully reviewed and understand this consent form. I understand the description of the research protocol and consent process provided to me by the researcher. My signature on this form indicates that I understand to my satisfaction the information provided to me about my participation in this research project. My signature also indicates that I have been apprised of the potential risks involved in my participation. Lastly, my signature indicates that I agree to participate as a research subject.

My consent to participate does not waive my legal rights nor release the researchers, sponsors, and/or City University of Seattle from their legal and professional responsibilities with respect to this research. I understand I am free to withdraw from this research project at any time. I further understand that I may ask for clarification or new information throughout my participation at any time during this research.

I, _____, the parent and/or legal guardian of _____ (hereafter referred to as "Participant") agree to allow him/her to participate in the following research project to be conducted by _____, ☐ faculty member or ☐ student, in the _____ Program. I understand this research study has been approved by the City University of Seattle Institutional Review Board.

I acknowledge that I have received a copy of this consent form, signed by all persons involved. I further acknowledge that I have been provided an overview of the research protocol as well as a detailed explanation of the informed consent process.

Participant's Name: _____
Please Print

Participant's Signature: _____ Date: _____

Researcher's Name: _____
Please Print

Researcher's Signature: _____ Date: _____

If I have any questions about this research, I have been advised to contact the researcher and/or his/her supervisor, as listed on page one of this consent form.

Should I have any concerns about the way I have been treated as a research participant, I may contact the following individual(s):

_____, Program Coordinator (and/or Program Director), City University of Seattle, at _____ (address, direct phone line and City U email address).

CityUniversity of Seattle

CITYU RESEARCH PARTICIPANT INFORMED CONSENT
FOR ON-LINE SURVEYS AND INTERNET DATA COLLECTION

Title of Study:

_____

Name and Title of Researcher(s):

_____

For Faculty Researcher(s):
Department: _____
Telephone: _____
City U Email: _____
Immediate Supervisor: _____

For Student Researcher(s):
Faculty Supervisor: _____
Department: _____
Telephone: _____
City U E-mail: _____

Program Coordinator (or Program Director):

_____

Sponsor, if any:

_____

Why am I being invited to participate in this research?

You are eligible to participate in this study if you _____.

You will be in this research study for about _____.

About __ individuals will participate in this study.

What should I know about being in a research study?

This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information.

To make your decision, you must consider all the information below:

- The purpose of the research
- The procedures of the research. That is, what you will be asked to do.
- The risks of participating in the research.
- The benefits of participating in the research and whether participation is worth the risk.

The researcher will explain this research study to you.

- You do not have to participate in this research.
- It is your choice whether or not you want to participate in this research.
- Your participation is voluntary and you can decide not to participate or withdraw your participation at any time without negative consequences.

- You should talk to the researchers about the study and ask them any questions you have.

If you decide to join the study, you will be asked to electronically sign this form before you can start study-related activities.

Why is this research being done?

You are being invited to participate in an on-line survey that is part of a research study that has been approved by City University of Seattle Institutional Review Board.

This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. To make your decision, you must consider all the information below:

The purpose of the research
The procedures of the research. What you will be asked to do.
The risks of participating in the research.
The benefits of participating in the research and whether participation is worth the risk.

You do not have to participate in this research. It is your choice whether or not you want to participate in this research. Your participation is voluntary and you can decide not to participate or withdraw your participation at any time without negative consequences.

Purpose of Study:

_____

Research Participation.
You will be asked to participate in the following procedures:

I understand I am being asked to participate in this study by completing an on-line survey. The survey consists of _____ questions and is expected to take approximately _____ to complete. You may choose to answer as many questions as you decide and each question will have a "no response" choice.

Is there any way being in this study could be bad for me?

Taking part in this research involves certain risks: This could include:

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your participation in this research. However, possible benefits may include _____.

You will receive ____ for your participation in this research.

You will not receive any payment for participation in this study.

Your involvement is completely voluntary and you may refuse to participate or withdraw from participation at any time without negative consequences, by refusing to answer any further questions or exiting from the survey entirely. You may request a copy of the final research study report. Should you request a copy, you may be asked to pay the costs of photocopying and mailing.

I have been advised that I may request a copy of the final research study report. Should I request a copy, I understand I may be asked to pay the costs of photocopying and mailing.

Confidentiality

I understand that participation is confidential to the limits of applicable privacy laws. No one except the faculty researcher or student researcher, his/her supervisor and Program Coordinator (or Program Director) will be allowed to view any information or data collected whether by questionnaire, interview and/or other means. If the student researcher's cooperating classroom teacher will also have access to raw data, the following box will be checked. ☐

Steps will be taken to protect your identity, however, information collected about you can never be 100% secure. All data (the questionnaires, audio/video tapes, typed records of the interview, interview notes, informed consent forms, computer discs, any backup of computer discs and any other storage devices) are kept locked and computer files will be encrypted and password protected by the researcher. The research data will be stored for years (5 years or more if required by local regulations). At the end of that time all data of whatever nature will be permanently destroyed. The published results of the study will contain data from which no individual participant can be identified.

[Include if survey company server is in the United States]
You are advised that the company hosting this survey is located in the United States and as such is subject to U.S. laws, including the US Patriot Act which allows authorities access to the records of internet service providers. Therefore, anonymity and confidentiality cannot be guaranteed. If you choose to participate in this survey, you understand that your responses to the survey questions will be stored and may be accessed in the USA.

Signatures

I have carefully reviewed and understand this consent form. I understand the description of the research protocol and consent process provided to me by the researcher. My signature on this form indicates that I understand to my satisfaction the information provided to me about my participation in this research project. My signature also indicates that I have been apprised of the potential risks involved in my participation. Lastly, my signature indicates that I agree to participate as a research subject.

My consent to participate does not waive my legal rights nor release the researchers, sponsors, and/or City University of Seattle from their legal and professional responsibilities with respect to this research. I understand I am free to withdraw from this research project at any time. I further understand that I may ask for clarification or new information throughout my participation at any time during this research.

ELECTRONIC CONSENT: Please select your choice below.

Clicking on the **"agree"** button below indicates that:

-you have read and understand all of the above information, and
-you voluntarily agree to participate, and
-you are at least 18 years of age.

If you **do not wish to participate** in the research study, please decline participation by clicking on the **"disagree"** button.

☐ Agree

☐ Disagree

Thank you,

_____
Name of Researcher

CITY UNIVERSITY OF SEATTLE

General Statement of Confidentiality by Transcribers
Name of the Transcriber:

_____

Title of Research Study:

Researcher Name:
Research Supervisor Name:

An important part of conducting research is having respect for privacy and confidentiality. In signing below, you are agreeing to respect the participant's right to privacy and that of the people and organizations that may be included in the information collected. Such information may include interviews, questionnaires, diaries, audiotapes, and
videotapes. As part of your role in the above research study, you are required to respect people's right to confidentially by not discussing the information collected in public, with friends or family members. The study and its participants are to be discussed only during research meetings with the Principal Investigators, Co-Investigators, Program Manager, and/or others identified by the Investigators.

By signing below, you are indicating that you understand the following:

- I understand the importance of providing anonymity (if relevant) and confidentiality to research participants.
- I understand that the research information may contain references to individuals or organizations in the community, other than the participant. I understand that this information is to be kept confidential.
- I understand that the information collected is not to be discussed or communicated outside of research meetings with the Principal Investigators, Co-Investigators or others specifically identified by the Investigators.
- When transcribing audio or videotapes (where applicable), I will be the only one to hear the tapes and I will store these tapes and transcripts in a secure location at all times.
- I understand that the data files (electronic and hard copy) are to be secured at all times (e.g., not left unattended) and returned to the Principal Investigator when the transcription process or research study, whichever is earlier, is complete.

By signing my name below, I agree to the above statements and promise to guarantee the anonymity (if relevant) and confidentiality of the research participants

Signature of Transcriber: _____

Printed Name:_____

Date: _____