Adult Consent to Participate in a Research Study

Research Project Title:
Principal Investigator:
Graduate Student, if applicable:
Co-investigator from an external institution, if applicable:
IRB Protocol #:

I. Purpose of Research Study  (Required Element of Consent)
The form must acknowledge the word “research” in the context of the specific study. This section should open with a statement that explains in plain-language the purpose of the study and why the potential participant is being asked to participate.

Include key information and goals of the study in order for a potential participant to make an informed decision about whether to participate. Explain how research data will be used and why a person may or may not want to participate including any possible controversial research if some participants would find the research objectionable.

Explain how the prospective participant was identified and briefly describe inclusion criteria of study population(s).

II. Participation Procedures and Activities  (Required Element of Consent)
Describe what participants will be asked to do during their participation.

Study procedures should be listed in chronological order, and broken down by duration and frequency for each procedure or activity, and location.

Explain and describe any groups into which participants are randomized into treatments, sessions or arms of an intervention. When applicable, provide a clear description of any experimental procedures or untested interventions.

Provide samples of questions that will be asked of research participants. When applicable, describe who will be in focus group discussions.

When applicable, disclose any appropriate alternative activity or procedure as a substitute to research participation; particularly, those other procedures or activities that might be advantageous to the participant instead of the procedures or activities that are part of the research study or when the population is a captive audience (e.g., student or detained populations).

If the study combines non-research activities with research activities, then distinguish between the non-research activities and research activities or describe only the types of information needed for the voluntary research aspect of the project.
When applicable, explain why the research team may audio or video record the participant. If audio/video recording are not optional as a separate consent, then clearly state that it is required for participation.

III. Risks/Discomforts of Being in Study  (Required Element of Consent)
This section should include risks that are most likely to occur, foreseeable risks and discomforts that may occur as a result of research participation.

The primary risk in social, education or behavioral science research is a confidentiality breach; therefore, describe if responses outside the research would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation.

A statement about the approximate number of participants enrolled in the study if the number of participants would be important to a participant’s decision to participate. If the population sample is low, there may be a higher possibility of a privacy breach.

For example, a statement describing the limits of privacy should be made, such as, "It is possible that someone at (name of organization) may be able to associate information included in the publications from this research study to you, especially since you are among the few staff at (name of organization). The researchers will take measures to minimize the risk of you being recognized in the study to the extent possible through reporting aggregate themes or overall summaries that emerge; however, the risk of identification remains.”

Or

“There are a … (number of participants in study), which may compromise confidentiality since researchers are studying (a particular program or organization) and there is a higher probability of someone being able to decipher the identity of your participation in this study. The researchers will take measures to minimize the risk of you being recognized in the study to the extent possible through reporting aggregate themes or overall summaries that emerge; however, the risk of identification remains.”

If there is the possible risk of emotional discomfort, distressful feelings, or embarrassment from sharing sensitive issues, then this risk must be included. Risks may not always be immediate – damage to reputation, employability harm, social status, criminal liability, emotional upset, or stress may appear later.

Explain how the research team will mitigate risks. Inform potential participants that they may take breaks, skip questions they do not want to answer, or stop participation.

For experimental procedures, provide a statement that significant new findings developed during the course of the research that may relate to a participant’s willingness to continue participation will be shared with the participant.

For research involving more than minimal risk, there must be a statement on compensation and treatment, if any, for research-related injuries

IV. Benefits of Being in the Study  (Required Element of Consent)
This section should include a description of reasonably expected benefits for participants and/or others (e.g., society, field of study, community social services, family and community strategies, legal systems, programs, public policy). If no benefits are anticipated for the study either directly or to society, then that should be stated.
Note: Compensation/reimbursement is not a research benefit.

V. Confidentiality of Data and Limits to Confidentiality (Required Element of Consent)
If there is a promise to keep data confidential or researchers have collected sensitive, confidential information, there needs to be a description of data protections while in the field and during storage. The descriptions can be short but concise. There should also be a description of who will have access to data records.

This section should include a description of the retention period for both identifiable and de-identifiable data.

Describe how research data will be used. For example, inform potential participants that the results will be published, presented at scientific meetings, used for future studies, presented to program or employer stakeholders, or individual research results will be returned to the participant.

If appropriate, add information about plans to quote participants.

Limits to data confidentiality and participation privacy must be described to potential participants in regards to mandated reporting, when applicable.

For example, a statement describing the limits of confidentiality should be made, such as, “If during your participation of this study, we are concerned that you may be suicidal or at immediate risk of seriously harming other, we are required to take the necessary actions. This may include notifying your doctor, your therapist, police or other individuals. If this were to occur, we would not be able to assure confidentiality.” OR

“The researcher will make every reasonable effort to protect the confidentiality of your research information; however, if during your participation in this study, we have reasonable cause to believe that child abuse or neglect is occurring, we must report this to the Department of Children and Family Services as required by law.”

VI. Use of Research Data (Required Element of Consent)

Confidential data that will be used for secondary, future studies must be disclosed to participants.

One of the following two statements must be included for any research consent form that involves the collection of identifiable private information (or identifiable biospecimens):

1. A statement that identifiers will be removed and that after such removal the information data could be used for future research studies or distributed to another investigator for future research studies including other researchers or institutions without additional informed consent from the data subject (if this might be a possibility); Or

2. A statement that the subject’s information collected as part of the research, even if identifiers are removed during or after study, will not be used or distributed for future research studies.

If data is shared that potentially could be identifiable, then that should be clear to potential participants, including audio and video recordings (e.g., scientific publications, professional presentations, future studies).

VII. Voluntary Participation and Right to Withdraw (Required Element of Consent)
This section must include a statement that participation is voluntary. When applicable, it should distinguish between research activities and non-research activities that the participant
may already or will be enrolled. There must be statement that participants can withdraw from the research aspect of an activity or study at any time, and a statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.

When applicable, provide a statement about what researchers will do with data collected from a participant who withdraws prior to completion of research activities.

If prospective participants are in a subordinate relationship with people at study location, then the consent form should emphasize that withdraw of study or non-participation will have no effect on their current standing with, for example, a program organization, employer, supervisor, classroom instructor, relationship with program counselor, etc.

VIII. Use of Clinical Research Results Required Statements (When applicable, Required Element)
One or more of the following statements must be included for any research that involves applicable use of data from clinical research:

• The participant’s bio-specimens (even if identifiers are removed) may be used for commercial profit and you will (or will not) share in this commercial profit;
• The participant’s clinically relevant results from study will be disclosed to participant under xxxx conditions;
• The participant’s data will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

IX. Contact Information for Research Questions and Rights (Required Element of Consent)
Questions from potential participants about the research study are directed to the principal investigator (and graduate student or primary contact). The consent form must include their name, title(s), phone number and/or email.

Question about participant’s rights or research-related injury should be directed to the Institutional Review Board (IRB):
School of Social Service Administration, Urban Education Institute, and Chapin Hall IRB
University of Chicago
969 East 60th Street
Chicago, Illinois 60637
Telephone: 773-834-0402
Email ssairb@uchicago.edu

Note: If study will be conducted outside the United States, include a local contact advocate for questions about research study and participants’ rights, if possible.

X. Consent Documentation
Encourage participants to ask questions prior to consenting such as informing the potential participants that their signatures below indicate that they have decided to volunteer as a research participant for research study, and if they have any questions to be sure to the person obtaining consent.

Offer a copy of the consent form to participants.
**Participant’s Name and Signature**

*Date*

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**For Waiver of Documented (SIGNED) Consent, substitute signature lines for checkboxes**

☐ Yes, I agree to participate in the research study

☐ No, I do not agree to participate in the research study.

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**Options:**

☐ Yes, I agree to have my data used for secondary purposes.

☐ No, I do not agree to have my data used for secondary purposes.

☐ Yes, I agree to be video/audio recorded for this study.

☐ No, I do not want to be video/audio recorded for this study.

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**Additional Elements of Consent When Applicable or Required by the IRB:**

1. The approximate number of subjects involved in the study;
2. An option for the subject or the representative to consent, or refuse to consent, to investigators re-contacting the subject to seek additional information or to discuss participation in another research study;
3. A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject;
4. A statement that the subject’s bio-specimens may be used for commercial profit and whether the subject will or will not share in this commercial profit;
5. A statement whether biospecimens might be used for whole genome sequencing;
6. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions;
7. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
8. Any additional costs to the subject that may result from participation in the research;
9. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject; or
10. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable.

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**Federal Certificate of Confidentiality has been obtained**

“We have a Certificate of Confidentiality from the (federal agency) for this study. This certificate adds special protection for research information that identifies you. This Certificate does not mean that the DHHS approves or disapproves of this study. With this Certificate, we cannot be forced (for example by
court order or subpoena) to release any identifying research information about you. You should understand that the Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your participation in this research study. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. The Certificate does not prevent the researchers from voluntarily disclosing information that would identify you as a subject in this research study if we: 1) are concerned that you may be suicidal or at immediate risk of seriously harming others, or 2) learn about child abuse/neglect or elder abuse. Under these circumstances, we will notify the appropriate people. This CoC expires (xx/xx/xxxx).”

Payments over $100
If payment to the research participant per occurrence is over $100, researchers need to include the following paragraph: “You will need to provide the researchers your name, address and Social Security number for an IRS W-9 form.“

Conflict of Interest Statement
Include the language outlined in investigator’s COI Management Plan if it is applicable to this research study