Adult Consent to Participate in a Research Study (Template)

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

The form must begin with a "concise and focused" presentation of "key information" to facilitate comprehension in understanding the reasons why one might or might not want to participate in a research study including any possible controversial research that some participants would find objectionable.

I. Purpose of Research Study (Required Element of Consent)

This section must explain in plain-language the purpose of the study and acknowledge the word "research" in the context of the specific study.

Include a statement why the potential participant is being asked to participate, and briefly describe inclusion criteria of study population(s).

II. Participation Procedures and Activities (Required Element of Consent)

List study procedures in chronological order, explaining what participation entails, the duration and frequency for each procedure or activity. Include expected location of participation.

When applicable, provide a description of any experimental procedures or untested interventions. When applicable, researchers must inform potential participants that they may randomized into treatments, sessions or arms of an intervention.

If the study combines non-research activities with research activities, then researchers must distinguish between the non-research activities and research activities to distinguish that opting out of research does not mean opting out of non-research activities. When applicable, disclose any appropriate alternative activity or procedure as a substitute to research participation, such as, standard of care or other procedures that might be advantageous to the participant instead of the procedures or activities that are part of the research.

When the population is a captive audience (e.g., students in a classroom), researchers must provide a non-research activity for individuals who do not want to participate but are unable to leave the area where the research is underway.

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. When applicable, describe the type of participants who will be included in focus group discussions.

III. Risks/Discomforts of Being in Study (Required Element of Consent)

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.

The two primary foreseeable risks in social, education or behavioral science research is a breach in confidential data and an invasion of privacy. When applicable, participants must be informed that any breach in their research data or being linked to a sensitive research study could place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or may cause discomfort, embarrassment or harm to their reputation.

For sensitive topics, provide samples of questions that will be asked of research participants. Risks may not always be immediate, such as stress may appear later, and should be recognized in consent form when applicable.

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. Researchers must disclose how they will try to prevent unintentional disclosure of individual's identity. If the population sample is low, a statement about the approximate number of participants enrolled in the study may be important to participants.

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)

Include a description of expected benefits for participants and/or others (such as, society, field of study, family and community services, legal systems, social programs, and public policy). If there are no anticipated benefits to participants or to society, then that information would be stated in this section.

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, researchers must provide a brief but concise description of how they will maintain data protections while in the field and during storage, and how publications will report data. If applicable, add information about plans to quote participants.

There should also be a description of who will have access to data and private information, and the length of time that identifiable information and identifiable research data will be stored.

Participants must be informed that the researchers are mandated reporters (such as imminent intention to harm self or others, or suspected child abuse or neglect) as required by the University or Chapin Hall. Reporting may include notifying a social service agency (such as Department of Children, Family Services) or participant's medical caregiver.

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

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

1. *A statement that identifiers will be removed and that after such removal the information data could be used for secondary or future research or distributed to another investigator for secondary/future research 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 or data 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., professional presentations, transcriptionists).

V. 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 potential 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.

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.

VII. 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:

1. *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;*
2. *The participant's clinically relevant results from study will be disclosed to participant under xxx conditions;*
3. *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).*

VIII. 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/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):
Crown Family School of Social Work, Policy, and Practice
University of Chicago
969 East 60th Street
Chicago, Illinois 60637
Telephone: 773-834-0402
Email irb@crownschool.uchicago.edu

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Encourage potential participants to ask questions prior to consenting. Inform 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.

Provide or 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, you may use confirmed checkboxes or record verbal consent

☐ *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 / future purposes (must align with "***Use of Research Data"** as stated *above.*
☐ *No, I do not agree to have my data used for secondary / future 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.