

INFORMED CONSENT GUIDANCE

GENERAL RECOMMENDATIONS:

1. The consent information should be written at a 6th Grade literacy level. Technical terms should be explained. Highlighted section titles, lists using bullets and/or numbers, and underlining should be used to facilitate readability.
2. Paginate each page (Page 1 of _____)
3. Indicate the date and version number on the first page of each consent form/assent form. This will help keep track of changes.
4. Leave 1 1/2 inches at the bottom of each page for IRB stamping
5. Assent– in general, an Assent will be required for participants between the ages of 8 and 17. This may be further broken down into 8-11 and 12-17 or other age groups, as appropriate for the specific study.
6. Review consent/assent forms against protocol to assure there are no discrepancies.

CONTENTS OF INFORMED CONSENT:

Title of Research: Must be identical to sponsor's protocol or grant application

Investigator's Name:

Research Entity:

A Statement that the study involves research: If you sign this form, you are agreeing to participate in this research study. You should not sign this form until you are sure you wish to participate, and all of your questions about this study have been answered.

Purpose of Research:

Be sure to include:

- information on any sponsor(s)
- How/why participants are selected(inclusion & exclusion criteria)
- Number of participants at this site and total, if multiple sites.
- What conduct or conditions might end the participation in the study

Procedures:

Be sure to include:

- A full description of the procedures to be followed, identifying what part is research
- Expected duration of the subject's participation, length of visits, number, total months, etc.

- Explain what procedures may be declined by the participant without withdrawing from the study.
- Explain what procedures may not be declined.

Risks:

Be sure to include:

- All possible risks, both physical and psychological, due to the study condition, including probability and severity, if indicated
- Any additional risks if the participant has certain conditions
- All possible risks due to breach of confidentiality
- If group therapy or focus group is utilized, include potential breach of confidentiality from other participants
- If there are any risks that may require treatment or counseling, address what services will be provided by the research study or other providers.
- If there are any risks that might need medical attention, include emergency contact information, and, if appropriate indicate that participant should feel free to contact their own primary care physician or go to the emergency room.
- If appropriate for the research condition, include a statement that there may be risks which are currently unforeseeable.

Benefits:

Be sure to include:

- **Do not include** unproven benefits of the study condition
- Any benefit that the participant can reasonably anticipate from participation in the study. If none, state that there may be no direct benefits from participating in this study.
- Any benefit that may accrue to others by participating in the research.

Alternatives:

Be sure to include:

- All reasonable alternatives to participating in the research
- The choice to not participate.
- If research therapy/medication, etc. is available without participation in the study

Confidentiality:

Be sure to include:

- How the patient's confidentiality will be secured (e.g. locked file cabinet, password protected data base)
- When data will be destroyed
- All bodies that may have access to study data – be sure to include Philadelphia Department of Public Health Institutional Review Board
- Notice to participant that any information about child abuse or intent to harm self or others **will** be reported to authorities, as required by law.
- Information on any Certificate of Confidentiality, and what protection that provides.

Compensation:

Include a comprehensive description of any compensation, transportation costs, meals, vouchers, etc., which the participant can expect. If several payments, be sure to sum the maximum compensation.

Participant Rights:

Be sure to include:

- A statement that participation is voluntary and refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled. Withdrawal from the study will also not involve any penalty or loss of benefits to which the participant would otherwise be entitled.
- Provide full contact name and procedure for withdrawing from the study, including if the participant may request disposal of data collected prior to withdrawal of consent, or if that information will remain in the study.
- Include an explanation of whom to contact for answers to questions about the research. This should be someone relatively easy to reach, who is well versed in the study (Principal Investigator, Research Coordinator, etc.)
- Include a statement on whom to contact if the participant has questions about research participants’ rights. While a home site office of research administration or institutional review board may be sited, the information should include, “Judith Samans-Dunn, Administrator, Philadelphia Department of Public Health Institutional Review Board, 215-685-2411.”

ADDITIONAL ELEMENTS TO INCLUDE, AS APPROPRIATE:

Removal from study: A statement of reasons that the researcher may remove a participant from the study.

New information: A statement that if new relevant information becomes available, the investigator will inform the participant.

Specific procedure consent line or form: If it is important to highlight a specific procedure or requirement to the participant, a separate line for participant initials should be considered. This might be for participant consent to be audiotaped, or for participant acknowledgement that she has been warned not to become pregnant, etc.

DOCUMENTATION OF CONSENT

Participant’s Signature

Date

Parent/Guardian’s Signature (If a minor)

Date

Investigator or Individual Obtaining this Consent/Permission

Date

Optional, depending on circumstances:

Witness to Signature

Date

List of Individuals Authorized to Obtain Consent/Permission

Name	Title	Day Phone #	24 Hr Phone #
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