

	Children's Hospital of Philadelphia Committees for the Protection of Human Subjects Policies and Procedures	SOP 701 Page: 1 of 13 Effective Date: 9/8/2006 Revision Date: 1/22/2019
	Title: Required Elements of Consent and Documentation of Consent	

I. PURPOSE

The purpose of this standard operating procedure is to describe the required elements of consent and the general requirements for documentation of informed consent.

Within pediatrics the concept of informed consent shifts from that of a competent adult who grants informed consent to participate in research, to that of parents who grant permission to involve their children in research. This document uses the term informed consent for simplicity; however, it should be recognized that, in the case of children, it is actually parental permission that is being documented and granted.

II. POLICY STATEMENT

Legally effective informed consent of the subject or of the subject's parents or guardian is required before an investigator can involve the person in research. Consent must be documented in writing in accordance with applicable federal regulations unless the IRB finds that the conditions for a waiver of consent or a waiver of documentation of consent are met.

III. SCOPE

These policies and procedures apply to all research submitted to the IRB.

IV. DEFINITIONS

Guardian: Any person designated by Court Order as the Minor's legal guardian or as a person who can otherwise make medical decisions on behalf of the Minor.

Interpreter (for consent interviews involving subjects with Limited English Proficiency): A person who (a) understands both English and the subject's preferred language and (b) is not part of the study team or otherwise involved with the study. This individual may also serve as the witness when the Short Form Consent process is used. The interpreter must comply with the CHOP Language Services Policy.

Legally Authorized Representative (LAR): The individual or judicial or other body with the legal authority to provide proxy consent for a person who lacks the capacity or legal status to function autonomously. In Pennsylvania, PA Act 169 (Advance Directives) establishes the priority order of individuals who may serve as the LAR in situations where the incompetent individual has not designated an LAR. If the research takes place outside of Pennsylvania, and/or there is no applicable law, this is the representative designated by the appropriate institutional policy as acceptable for providing consent in the non-research context.

Parent: A child's biological or adoptive parent.

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Individuals with Impaired Decision-Making Capacity: An individual who possesses a limited capacity for self-determination.

Short Form Consent Document: A brief document, written in the subject's preferred language. The short form consent document must contain the following:

- A description of the required elements of informed consent; and
- An explanation that the purpose of the research, the study procedures and the other required elements in the consent form will be presented to the subject, or legally authorized representative in their preferred language.
- A statement that the key information was presented first to the subject, before other information, if any, was provided.

Summary Document: A document used in the consent process with Limited English Proficiency subjects when the short form process is implemented. The IRB-approved English version of the informed consent form can be used to create the summary document (e.g. by attaching additional signature pages).

Translator: A person who translates written documents from one language into another. The translator must be approved by the Hospital in accordance with the Language Services Policy.

Witness: A third party present during the oral presentation of the consent form and the consent interview. The IRB may require a witness to the consent process based on the nature and risks of research.

For consent interviews involving subjects with Limited English Proficiency: A person that (a) understands both English and the subject's preferred language and (b) is not part of the study team or otherwise involved with the study, and witnesses the consent process. This can be an interpreter assisting the person obtaining consent.

For illiterate subjects the witness must be impartial.

Written Consent Form: The written consent form is a formalization of the agreement to participate, and it is used to document the informed consent process.

V. PROCEDURES

A. Review of the Informed Consent Document

1. The Investigator submits informed consent documents or requests an alteration in the consent process for review by the IRB (SOP 706).
2. The IRB reviews the description of the proposed consent process and documentation to ensure that:

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- (a) The informed consent document is consistent with the protocol and the investigator's brochure regarding the purpose, risks, and benefits of the research;
 - (b) The document contains all of the required elements of informed consent as defined by applicable federal regulations unless waived by the IRB (**SOP 706**);
 - (c) All additional elements are appropriate to the research and are incorporated into the document;
 - (d) The document minimizes the use of scientific language and contains the appropriate statements regarding safety and effectiveness for FDA regulated research.
 - (e) The circumstances of the consent process minimize the possibility of coercion and undue influence;
 - (f) The information must be presented to the subject or the legally authorized representative in language understandable to the subject or the representative;
 - (g) The information being communicated during the consent process will not include exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or release or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.
 - (h) The document begins with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research.
3. When the consent document includes a written authorization (a combined consent/authorization), the IRB ensures that the document satisfies the requirements of HIPAA at 45 CFR 164.508(c)(1) - (2) (**SOP 707**).
 4. The Investigator documents the consent and authorization as required by the IRB.

B. Required Elements of Consent

1. The Investigator and IRB ensure that all of the following elements are included as part of the informed consent document unless a waiver or alteration is granted by the IRB.
 - (a) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

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- (b) A description of any reasonably foreseeable risks or discomforts to the subject or others.
- (c) A description of any benefits to either the subject or others which may reasonably be expected from the research. The description within the consent process or document must also be clear if no direct benefit is expected.
- (d) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject or affect the subject's willingness to participate in the research.
- (e) A statement describing the extent to which, if any, the confidentiality of records identifying the subject will be maintained and that notes the possibility that representatives of the institution (such as the IRB) or any of the federal regulatory agencies may inspect the records.
- (f) For research involving more than minimal risk, an explanation as to whether any compensation or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained. The informed consent document must not contain any exculpatory language and must not waive or appear to waive the rights of the participant or release or appear to release those conducting the study from liability for negligence.
- (g) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights and whom to contact in the event of a research-related injury to the subject.
- (h) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- (i) For FDA-regulated research, the following statement must be included as part of the consent document:

 A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.
- (j) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
 - (1) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the

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information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

- (2) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

C. Additional Elements

1. The IRB will ensure that, when appropriate, one or more of the following elements of information shall also be provided to each subject:
 - (a) 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.
 - (b) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or legally authorized representative's consent.
 - (c) Any additional costs to the subject that may result from participation in the research.
 - (d) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
 - (e) A statement that 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.
 - (f) The approximate number of subjects involved in the study.
 - (g) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.
 - (h) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions;
 - (i) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or

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somatic specimen with the intent to generate the genome or exome sequence of that specimen).

D. Methods of Documenting Consent

During the review of the research the IRB considers the requirements for documentation of consent that may include any of the following:

1. **Written informed consent form** that embodies the elements of informed consent and the required elements of HIPAA authorization (or a separate HIPAA Authorization is used);
 - (a) This form may be read to the subject or the subject's legally authorized representative.
 - (b) The investigator shall give either the subject or the subject's legally authorized representative adequate opportunity to read the informed consent form before it is signed.
 - (c) The form must be signed and dated by the subject or the subject's legally authorized representative.
 - (d) Each participant shall be provided a copy of the consent document.
 - (e) When the informed consent is combined with a written authorization, the subject must be provided a signed copy of the consent/authorization.
2. **Short form written consent document** must be used in combination with an oral and written presentation of the informed consent information.
 - (a) When this method is used, there shall be an impartial witness to the oral presentation. An interpreter who is not part of the study team may serve as a witness.
 - (1) The witness must attest to the adequacy of the consent process and the subject's voluntary consent.
 - (2) The witness shall be conversant in both English and the preferred language of the participant.
 - (b) The written summary must embody the basic elements and required additional elements of informed consent. The summary can either be:
 - (1) The IRB-approved consent document that includes the appropriate signature sections for the interpreter and the witness; or
 - (2) An IRB-approved written summary document of what will be shared with the

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subject. When a study summary document is used the content must be consistent with the information contained in the IRB-approved English version of consent document.

- (c) The subject and witness sign and date the short form.
- (d) The witness and study team member sign and date a copy of the consent document/summary document.
- (e) A copy of the consent document/summary document and short form shall be provided to the subject.

3. Waiver of documentation of consent

- (a) The IRB may waive the requirement for the investigator to obtain a signed consent form from some or all subjects if it finds either:
 - (1) That the only record linking the subject and the research would be the informed consent form, the principal risk would be potential harm resulting from a breach of confidentiality, and the research is not regulated by the FDA. In this case, each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
 - (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or
 - (3) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.
- (b) In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.
- (c) The waiver of written documentation does not change the requirement for including the required and applicable additional elements of informed consent in the consent process.
- (d) The subject's agreement to participate can be either captured on the consent form or in the study records. When consent is waived under 46.117(c)(1)(i) there will be no documentation.

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E. Other General Requirements:

1. Written in language understandable to the subject: For consent to be valid, the subject must be able to comprehend the information presented in the consent document. When possible, the target grade level should be written in the subject's native language at a 6 – 8th grade level.
2. FDA-Regulated Test Articles: For all research involving test articles regulated by the U.S. Food and Drug Administration (FDA), informed consent documents must include a statement that the purpose of the study includes evaluation, whether for safety and/or effectiveness of the test article. The consent form must also include a statement that the FDA has access to the subject's medical records.
3. Other Sponsor or Funder Requirements: When the funding agency requires additional language, this will be included in the consent document.

F. Requirement for Informed Consent for Screening, Recruiting, or Determining the Eligibility of Subjects (45 CFR 46.116(g))

The IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

1. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

If the information or biospecimens used for the purpose of screening, recruiting, or determining the eligibility of prospective subjects include protected health information (PHI), the investigators must obtain written HIPAA Authorization from all participants in the research study prior to the use or disclosure of the PHI for any research-related purpose, unless the IRB has issued a waiver or alteration.

This exception from obtaining informed consent does not apply to screening procedures that include creating/obtaining new information through means other than oral or written communication with, or obtaining new biospecimens (e.g. blood, stool, saliva samples) from, the subject as part of the research. Obtaining information or using stored biospecimens for reasons other than establishing eligibility requires prior consent.

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G. Special Considerations

1. Subjects with Limited English Proficiency
 - (a) Investigators indicate in the research submission if subjects with Limited English Proficiency may be enrolled. The submission includes the Investigator's plans for the enrollment of this potentially vulnerable population.
 - (b) Investigators engage an interpreter who is fluent in English and the subject's preferred language during the consent process.
 - (c) Investigators provide the IRB-approved translated consent document or the Short Form along with the consent document/summary document.
 - (1) When the investigator plans to use a translated consent document, they provide the IRB-approved English version of the consent document to an appropriate translator approved by the Hospital.
 - (a) The Investigator submits the translated document to the IRB for review and approval. This must be accompanied by a statement from the translator indicating that the document is a true representation of the English version and provides the qualifications of the person providing the translation.
 - (2) When the investigator plans to use the Short Form process they use a short form consent document and the consent document/summary document approved by the IRB.
 - (i) The IRB maintains an English version of the Short Form as well as certified translations for other languages.
 - (ii) Translations in languages other than those available on the IRB website may be submitted to the IRB for approval. These translated documents must be accompanied by a statement from the translator indicating that the document is a true representation of the English version of the Short Form and provide qualifications of the person providing the translation.
 - (d) When the IRB has approved a waiver of documentation of consent, the investigator may propose and the IRB may permit subjects with Limited English Proficiency to consent with a waiver of documentation from either or both the subject and the interpreter/witness.
 - (e) The IRB determines if the Investigator's plan for the enrollment of subjects with Limited English Proficiency provides sufficient protections.

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2. Illiterate Subjects

- (a) Investigators indicate in the research submission when potential subjects may be illiterate. The submission includes the Investigator's plans for the enrollment of this potentially vulnerable population.
- (1) Before asking a subject to review and sign an informed consent form, the Investigator ensures that the potential research subject is capable of reading the form. (Children under a certain age are presumed to be unable to read; this policy is not intended for this population.)
 - (2) Investigators do not assume that subjects are able to read and, when appropriate, inquire in a sensitive way whether the subject is able to do so. If a subject is not able to read the investigator makes special arrangements without causing embarrassment to the subject.
 - (3) Illiterate subjects are not to be excluded from the research because they are unable to read unless there is an overriding scientific or safety concern.
 - (4) If illiterate (in whatever the language of the consent process) but cognitively competent, the Investigator may plan for the consent process to proceed as usual. The informed consent will be read to the subject and the subject should be encouraged to ask questions.
 - (5) This process must be conducted with a witness present. In this case, the witness is to observe the consent process.
 - (6) If able, the subject will affix a signature to or make an "X" on the consent document.
 - (7) The witness is to sign and date the consent document, and is to document, in writing, that the process took place and that the subject voluntarily consented to participate.
- (b) The IRB determines if the Investigator's plan for the enrollment of subjects who are not able to read provides sufficient protections.

3. CHOP Requirement for Written Consent When Recording or Filming Patients

CHOP legal counsel has concluded that if the consent process for a CHOP patient/subject is taped and then retained as evidence of the consent, then this recording will meet CHOP's requirement for documentation of consent. Under this circumstance, the IRB may waive the requirement for written consent

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VI. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.117	21 CFR 56.117
45 CFR 46.111	21 CFR 56.109
45 CFR 46.116	21 CFR 50.25
45 CFR 164.508	

VII. REFERENCES TO OTHER APPLICABLE SOPS

SOP 702: Assent and Parental Permission	SOP 704: Payment to Subjects
SOP 703: Review of Recruitment Materials	SOP 705: Waiver of Informed Consent for Planned Research Conducted in Emergency Settings
SOP 706: Waiver of Elements of Consent and Waiver of Written Authorization	SOP 707: Requirements and Documentation of HIPAA Authorization in Research
CHOP Language Services Patient Care Manual	

VIII. RESPONSIBILITIES

Title	Responsibility
Director, HSR	Responsible for establishing and periodically reviewing and modifying (as appropriate) IRB standard operating policies and procedures involving the consent process.
Chair, CPHS	Responsible for establishing and periodically reviewing and modifying (as appropriate) IRB and Investigator responsibilities pertaining to obtaining and documenting consent.
Investigator	Responsible for obtaining consent from research subjects, their parent/guardian(s) or the legally authorized representative of the subject as required by this SOP.

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IRB Reviewer	Responsible for ensuring that all informed consent documents include the required and applicable optional elements and for ensuring that the documents and process of obtaining consent comply with the requirements of this policy.
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IX. ATTACHMENTS

The following documents are available on the IRB website:

- Consent Templates with and without Written Authorization
- A CHOP-approved stand-alone HIPAA Authorization
- Short Form document in English and with translations

Additional guidance for constructing consent documents as well as links to other resources are available on the IRB's website

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X. REVISIONS:

- 3-11-09: Revised to include investigator responsibility A.1 and editorial updates for consistency with other SOPs. The requirements for waiver of elements of informed consent are now in IRB SOP 706 and the requirements for HIPAA Authorization are in IRB SOP 707.
- 6-10-10: Revised to include the short form process for non-English speaking subjects and modified for clarity and links to the resources on the IRB's website were added.
- 6-29-10: Revised to clarify the elements of the consent process and documentation that the IRB must review based on AAHRPP recommendations.
- 7-8-10: Revised, based on AAHRPP recommendations, to specify that the consent document must be signed and dated by the subject or the legally authorized representative of the subject and to clarify that condition D (3)(a)(1) under the criteria for waiver of documentation does not apply if the research is regulated by the FDA.
- 2-28-13: Revised to include the FDA required language regarding registration on clinicaltrials.gov and removal of the requirement for a witness when the consent form is translated by a member of the study team.
- 11-11-13: Revised requirements for interpreters in accordance with CHOP policy RI-4-01 (Effective Date: 5/14/09).
- 1-22-19: Revised to reflect the 2018 common rule revisions, current use of Limited English Proficiency language, updated definitions, added provisions for legally blind and hearing impaired individuals, and other minor edits.

XI. APPROVAL:

 Director, Human Subjects Research

 Date

 Chair, Committees for the Protection of Human Subjects

 Date