Documentation of Informed Consent/Parental Permission/Assent

Procedures

1. General

Parents and guardians are asked to document their permission to allow their children to participate in research by signing an Informed Consent Form. The consent of both parents is required unless the determination has been made that the consent of one parent is sufficient. The CCI will advise investigators as to whether the signature of one or both parents is required.

Informed consent must be documented on a written consent form approved by the CCI and signed by the subject or the subject's legally authorized representative. A copy is to be given to the person signing the form. Unless otherwise approved by the CCI, a copy of the signed consent form is to be placed in the medical record if the study involves medical interventions, to ensure the safety of the patients who participate in research. Informed consent must be obtained before the initiation of any screening processes performed solely for the Purpose of research.

The study investigator or designee is also required to sign the consent document to attest to the fact that all the elements of informed consent have been explained to the subject/legally authorized representative (parent/guardian) and all questions have been answered to the best of the investigator's ability.

2. Required Elements:

The following elements are required in all informed consent/parental permission documents:

- A statement that the study involves research
- An explanation of the Purposes of the research
- The expected duration of the subject's participation
- A description of the procedures to be followed and identify any that are experimental
- A description of drugs or devices, if applicable, state whether any are investigational
- Description of study design
- A description of any potential risks or discomforts to the subject
- A description of any direct or potential benefits to the subject or to others that may reasonably be expected from the research
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject. Indicate if none
- A statement that describes how confidentiality will be protected and maintained and who has access to the data

- For research that involves more than minimal risk, explanations as to whether any compensation and any medical treatments are available if injury occurs and, if so, what this consists of, or where further information may be obtained or who to call
- An explanation of whom to contact for answers to pertinent questions about the research and the research subject's rights,
- An explanation of whom to contact in the event of a research-related injury to the subject
- A statement that participation is voluntary, that refusal to participate involves no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which he or she is otherwise entitled
- Compensation or study reimbursement for participants
- The number of subjects in the trial
- Description as to where research data and consent documents will be stored
- A phone number to call
    - If participants had questions regarding the research
    - If participants wanted to voice concerns or complaints to the research staff, investigator or CCI office
    - If participants feel their rights or welfare as a research subject have been violated

3. Additional Elements that May be Required As Appropriate

- A statement that the particular treatment or procedure may involve risks to the subject that is currently unforeseeable. The statements should be included for all research involving investigational drugs and medical devices, and for all research in which the risk profile of the research interventions in the participant population are not well known.
- The possibility that participation would be terminated including by the investigator without regard to the subject's consent and plans for discontinuation. This statement should be included whenever there are anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subjects' consent. (.i.e sponsor may stop trial before completion)
- Any additional costs to the subject that may result from participation in the research. This should be disclosed when there is a possibility the study will add additional costs
- A statement that any 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. This should be disclosed in all studies
- The consequences of a subject's decision to withdraw from the research, and the procedures for orderly termination of participation by the subject. This should be disclosed whenever a subject's decision to withdraw from the research may result in adverse consequences.
- Statement that treatment or procedure may involve risks to the embryo or fetus if the subject is or becomes pregnant. This statement should be included for all research that included pregnant women or women of child bearing potential in which the risk profile of the research interventions on the embryo and fetuses are not well known
- FDA may inspect the records for any research that involves any drug or device that is either being administered as part of the research study or is not approved for marketing. This statement should be included in all consents for research that will be

submitted to or held for inspection by the FDA in support of a marketing application. All uses of drugs and devices are subject to this unless it is the use of a marketed drug or device in the practice of medicine. investigational drug or device, or is under their jurisdiction

- Any conflict of interest disclosure. This should be included in any protocol that the CCI determines it is necessary to disclose a real or potential COI for the investigator or institution
- Risk of determining unreported sexual abuse, neglect or suicidality
- Requirement for pregnancy testing

No informed consent, whether oral or written, may include exculpatory language whereby a subject or representative is made to waive or appear to waive any of his or her rights, or to release or appear to release the investigator, sponsor, institution, or its agents from liability or negligence.

4. Signatures

A. Subject or Legally Authorized Representative

The CCI requires the signature of the subject or legally authorized representatives (parent/guardian) on informed consent documents unless a waiver or alteration of consent is approved. During the review process, the CCI determines the signatures required and incorporates these requirements in the final approved consent/assent forms.

All consent documents must contain the date signed by the participant, the participant's parents/guardians or the participant's legally authorized representative. Please see the policy for *Informed Consent/Parental Permission/Assent Process* for further guidance as to whether one or both parents/guardians should sign the documents

A variety of legally recognized arrangements exist, including those that involve custody of children, guardians for children, wards, and children in foster home situations. However, not all guardians have the legal right to consent to research for a child. In many instances, biological parents maintain this right. Moreover, differences exist in consent procedures related to clinical care versus research. For these reasons it is important that investigators contact the Clinical Investigation Office or the Office of General Counsel if questions arise as to who constitutes a legally authorized representative for a child.

If the CCI reviews research that is conducted in another state or country, the determination as to who may sign the consent and who is a legally authorized representative must be determined by the locality where the research takes place.

B. Assent from the Child / Adolescent

Child/adolescent assent is to be documented, and may be done so by several methods. In most situations, the CCI indicates its approval on the parental permission form, which the child/adolescent signs to indicate his or her willingness to participate. Consent documents contain a separate section where investigators are required to document the reason(s) why it is not feasible or appropriate to obtain assent from a particular child/adolescent.

In other situations, determined by the CCI on a case-by-case basis, the Committee requires a separate assent form. This may apply in non-therapeutic studies that involve older children and adolescents. These assent forms must be simple and easy to understand. Investigators may choose to utilize a separate assent form, even when not required by the CCI.

The CCI is to determine whether adequate provisions are made for soliciting the assent of a child/adolescent when, in the judgment of the Committee, the child/adolescent is capable of providing assent. If the CCI determines that the capability of a child/adolescent is so limited that he or she cannot reasonably be consulted, or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the child/adolescent and is available only in the context of the research, the assent of the child/adolescent is not a necessary condition for proceeding with the research.

Additional steps in the child/adolescent assent documentation process include:

The investigator is to indicate on the protocol application his or her initial determination as to whether assent may be obtained.

During the review process, the CCI is to review the investigator's justification and determine whether assent is required.

The investigator is to be advised in the approval notification whether assent is required.

The CCI minutes are to document the Committee's determination

C. Signature of Individual Obtaining Informed consent/Assent/Parental Permission

The signature of the individual responsible for obtaining informed consent must be included on all consent documents, along with the date of the signature. Individuals other than the investigator may obtain consent; however, any individual who obtains consent must be listed on the protocol application as having this role. It is also the investigator's responsibility to train, oversee, and monitor all individuals who obtain consent on his or her protocol. The individual who obtains consent is not required to be present to witness the family/subject sign the consent. Only after a subject signs the consent is the individual who obtained consent to sign the document. The signature of the person who obtains consent is not to be "back dated" to coincide with the date of the research subject's signature.

D. Witness Signature

A witness signature is required only in the following circumstances:

- If the committee approves the use of the " short form" (see policy on Waivers and *Alterations of Documentation of Informed Consent/Parental permission Assent)* . In this situation the witness signature only attests to the fact that the information was explained in the subjects native language and the subject/family had opportunities to ask questions
- When the subject cannot read and the consent document must be read to him or her.
- When communication impairments limit a subject's ability to unambiguously register consent. In such cases, it is important that there be an independent observer of the communication.
- When, given the nature of the research and the anticipated condition of a subject, the CCI is concerned that questions may arise as to whether consent/assent is being given knowingly and voluntarily. In these situations, verification of the consent may help to protect subjects, who may be temporarily sick or too upset to provide meaningful consent/assent under the anticipated circumstances.

In the last three bullets the witness signature confirms that the information in the consent form and other written documents was accurately explained to, and ostensibly understood by,

the subject or the subject's legally authorized representative, and that the informed consent was given freely

E. Obtaining consent/Parental Permission if Parent/Guardian is not present

Federal regulatory agencies do not regard verbal telephone consent as constituting the documentation of informed consent that is required by federal regulations. Although verbal telephone consent is accepted and frequently obtained for clinical care, this practice does not automatically apply to consent for research protocols. The guidelines, below, are provided to assist investigators in obtaining informed consent when a parent/guardian is not present to sign the informed consent document within a time frame specified by a research protocol (e.g., when a newborn is transferred to the Children's Hospital NICU while the parents remain at the birth hospital, and enrollment in the study is required within the first 12 hours of life).

Guidelines for obtaining informed consent for an approved research protocol when the parent/guardian is not present with the subject are as follows

All reasonable efforts must be made to obtain written informed consent from the parents/guardians of children who are eligible for a research protocol. If a parent is present at the hospital or will be present within the time frame for recruitment, the CCI-approved informed consent must be signed prior to enrollment. If a parent is at a birth hospital adjacent to Children's Hospital or another location, investigators may speak with the parent by phone, and send an appropriate designated individual to the parent to obtain written consent. Alternatively, the investigator may speak with the parent by phone, and fax or send by messenger a copy of the consent for signature prior to enrollment. Once the consent form is received by the parent or guardian, it must immediately be signed and sent back to the investigator. If it is not feasible to return the signed fax within the required period of time, the investigator must be advised, by telephone, by an individual who witnessed the consent being signed, that it had, in fact, been signed by the parent or guardian. The witness must also sign the consent document. The signed consent must then be returned as soon as possible to the investigator by fax or mail. Once the investigator either receives the signed consent or is notified by the witness that the consent was signed, the patient may be enrolled.

F. Informed Consent in other Languages

The Committee on Clinical Investigation prohibits the exclusion of non-English speaking individuals from research protocols unless there is a sufficient justification for the exclusion. In particular, if a research protocols offers a potential for direct benefit that may only be available within the context of the research, the exclusion of non-English speaking individuals becomes ethically problematic. Investigators are obliged to consider the potential that study populations may include non-English speaking individuals and plan for this while developing the protocol. Investigators need to plan for the inclusion of non-English speaking subjects. Informed consent must be obtained in a language that is understandable to the subject. Investigators may be required to translate informed consent documents and other study documents. In addition an interpreter may be required during the informed consent process and ongoing interactions with the subject.

Justifications for excluding non-English speaking participants usually include scientific and methodological limitations based on the lack of appropriate validated instruments, surveys or assessments. In some situations use of another language may confound the research results or not permit appropriate analysis of the data especially when protocols are designed with a

small sample size. These concerns are usually limited to behavioral and social research. It is an investigators' obligation to determine whether there are appropriate alternate assessments, instruments or surveys that could be utilized for non-English speaking participants prior to excluding them.

In order to ensure the inclusion of non-English speaking individuals in research, the following guidelines are provided.

1. Corporate Sponsored Research: When research is sponsored by a corporate entity, the clinical trial agreement negotiated between the company and Children's Hospital should include a provision for the sponsor to cover the costs of translating consents and other important research documents. This cost could be included as a line item within a budget or if there is uncertainty as to whether non-English speakers will be eligible, it may be included as a provision, if needed, in the agreement.

2. Federally Funded Research: When research is federally funded it is permissible to include the translation of research documents and the potential use of an interpreter as direct expense in a budget. Investigators should include these costs in their budgets.

3, Use of Short Forms: The CCI allow the use of short forms when the research has been determined by the IRB to represent minimal risk. For greater than minimal risk research when the research has potential for benefit that is not available outside the context of the research and there is insufficient time to obtain a translated version of the consent, the IRB will consider whether the short form is appropriate for use on a case by case basis, however investigators must get permission from the IRB. (for further information about the use of short forms see the c policy "*Use of Short Forms for Informed Consent"*

4. Interpreter Services is available to assist when recruiting and interacting with a non-English speaking individual; however, while a translator may be helpful in facilitating conversations with non-English speaking families. Investigators need to contact interpreter services as soon as they anticipate a need for an interpreter. This will permit planning for appropriate staffing.

5. Hospital Funds: The Committee on Clinical Investigation realizes that not all research is sponsored or some research has limited funding. For this reason the Hospital has established a fund to assist in paying for translation of research informed consent documents. There is a limited amount of funding; therefore the funding is limited to the translation of informed consent documents only. The Director of Clinical Research Compliance in consultation with the Committee on Clinical Investigation Chairperson is responsible for allocating the funds.

G. Illiterate Subjects

Before asking a subject/family to review and sign an informed consent form, every investigator is responsible, under the informed consent process, for ensuring that potential research subjects/families are 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.) Investigators are not to assume that subjects/families are able to read and, when appropriate, are to inquire in a sensitive way as to whether the subjects/families are able to do so. If not, investigators are to make special arrangements without causing embarrassment to the subjects/families. 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.

The following CCI recommendations are to be implemented if, when asked to provide permission, a research subject or family member is determined to be illiterate:

- If illiterate (in whatever the language of the consent process) but cognitively competent, the consent process proceeds as usual. The informed consent is to be read to the subject/family, and the subject/family is to be encouraged to ask questions.
- This process must be conducted with a witness present. In this case, the witness is to observe the entire process, not just the signature.
- If able, the subject/family is to affix a signature to or make an "X" on the consent document.
- 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/family member voluntarily consents to participate.

Document Attributes

Title	Required Elements for All Informed Consent/Parental Permission		
Author	**Susan Kornetsky**	**Dates Reviewed/ Revised**	04/01/07 04/05/07
Reviewed/ Revised by	Susan Kornetsky		
Copyright	©Children's Hospital Boston, 2012	**Last Modified**	03/26/2010
Approved	Susan Kornetsky Director of Clinical Research Compliance Carleen Brunelli, MBA, PhD Vice President for Research Administration		