CONSIDERATIONS REGARDING THE PROCESS FOR INFORMED CONSENT

A regulatory criterion for IRB approval is that informed consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with and to the extent required by the regulations. This cannot be accomplished solely by evaluation of a written consent document, since the consent process is a discussion that should be culturally and linguistically appropriate to the research population, and not simply a consent form. Instead, the IRB should know the nature and circumstances of the consent process, and judge whether the consent process meets the required attributes described in the regulatory criteria for approval. The investigator may not involve a human being as a participant in research unless the investigator has obtained the legally effective informed consent of the participant or the
Participant's legally authorized representative. Under the regulatory requirements the consent process should fulfill these attributes:

- The consent process provides sufficient opportunity to consider whether to participate.
- The consent process minimizes the possibility of coercion or undue influence.
- The consent discussion is in language understandable to the participant or the representative.
- The consent discussion is free of exculpatory language.

Evaluation of the circumstances of consent may require the IRB to know who will conduct the consent interview, the timing of obtaining informed consent, and any waiting period between informing the participant and obtaining the consent.

When some or all of the participants are likely to be vulnerable to coercion or undue influence, the IRB should consider additional safeguards to provide for appropriate informed consent. If the IRB reviews research that involves children, pregnant women, fetuses, neonates, prisoners, or adults who lack the ability to consent, non-English speakers, the IRB consider the regulations as well as any local policies and procedures for these vulnerable individuals.

Assent from Adults who cannot give Consent

The Partners IRBs have developed policies and procedures for considering studies in which adult subjects will not be able to give consent due to their diseases or disorders. In some circumstances surrogate consent, based upon the substituted judgment provided by a close family member of health care

proxy may be acceptable. The IRB will carefully consider the risks and benefits of studies where surrogate consent is proposed. Guidance for these vulnerable subjects is found here:
http://intranet.massgeneral.org/phrc/surrogate_consent_memo.pdf

Assent from Children
The IRB must determine that adequate provisions are made for soliciting the assent of the children when in the judgment of the IRB the children are capable of providing assent.

In determining whether children are capable of providing assent, the IRB must take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate.

The assent of the children is not a necessary condition for proceeding with the research if the IRB determines that either of the following is true:

- That the capability of some or all of the children is so limited that they cannot reasonably be consulted.
- 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 children and is available only in the context of the research.

Even where the IRB determines that the participants are capable of giving assent, the IRB may still waive the assent requirement if it finds and documents that:

- The research involves no more than minimal risk to the participants;
- The waiver will not adversely affect the rights and welfare of the participants;
- The research could not practicably be carried out without the waiver; and
- Whenever appropriate, the participants will be provided with additional pertinent information after participation.

In addition the IRB must determine, in accordance with and to the extent that consent is required by the regulations, that adequate provisions are made for soliciting the permission of each child's parents or guardian.

Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient, {FDA: if consistent with State law,} for research that is found to be of minimal risk to the children, or research

that involves greater than minimal risk but presents the prospect of direct benefit to the individual subjects. Either way, the IRB needs to determine whether both parents are a necessary part of the permissions process or, when the research meets one of the two categories above, it is sufficient to include only one parent.

Where research involves greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition; or research found to be not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children; both parents must give their permission for their child to participate in the research unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child {FDA: if consistent with State law}.

Permission by parents or guardians shall be documented in accordance with and to the extent required by the regulations.

When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

Observing the Consent Process

According to the federal regulations, IRBs have the authority to observe or have a third party observe the consent process. The IRB should have policies and procedures that describe how the IRB considers and implements such monitoring. Specifically, IRBs should consider monitoring of the informed consent a method that can be used to provide for an appropriate consent process in special situations, and have a mechanism by which observation of the consent process might be implemented. For example, observation of the consent process might provide additional protections when research involves adults with potentially limited decision-making capacity. Observation of the consent process might be performed by the IRB, research review unit staff, other individuals in the organization, or by a third party hired by the organization, investigator, or sponsor.

References:

AAHRPP Evaluation Tool
OHRP Guidebook