Surrogate Consent

The IRB must assess the individuals or populations being recruited for potential vulnerability to coercion or undue influence, lack of decision-making capacity, or increased susceptibility to harm from the research under review. If vulnerability is determined to exist, the IRB must ensure that additional safeguards have been included in the study to protect the rights and welfare of these subjects. (For more information, see Section 20 of VHA Handbook 1200.05.)

When planning to enter subjects with impaired decision-making capacity, investigators must address in the protocol how they will determine when surrogate consent will be required. In general, the research staff must perform or obtain and document a clinical assessment of decision-making capacity for any subject suspected of lacking decision-making capacity. The IRB must review and approve the plan to ensure that it is appropriate given the population and setting of the research.

Investigators may only obtain ***informed consent*** from the Legally Authorized Representative (LAR) of a subject if the IRB has approved the participation of persons who lack decision-making capacity. The following persons are authorized to consent on behalf of persons who lack decision-making capacity in the following order of priority:

1st. Health care agent (i.e., an individual named by the individual in a Durable Power of Attorney for Health Care)

2nd. Legal guardian or special guardian

3rd. A close relative of the patient 18 years of age or older, in the following priority: spouse, child, parent, sibling, grandparent, or grandchild

4th. Close friend

An individual who is qualified as a LAR to provide informed consent on behalf of a prospective research subject may not always qualify as a Personal Representative for purposes of consent to use or disclose a human subject's PHI. Personal Representatives who sign a ***HIPAA Authorization*** must have:

- Power of Attorney (POA) which includes decisions related to health care, or
- Legal Guardian designation by a court of competent jurisdiction to take care of and to manage the rights of the individual, or
- Authority to Act on behalf of a living individual under other Federal, State, Local, or Tribal Law.

In circumstances involving authorization for use or disclosure of a human subject's PHI, the investigator must ensure the LAR meets the requirements of a Personal Representative in HIPAA and the Privacy Act of 1974 ***prior to the LAR's signing a HIPAA Authorization*** (See Paragraph 5b of VHA Handbook 1605.1).

DISSENT OR ASSENT: If feasible, the investigator must explain the proposed research to the prospective research subject even when the surrogate gives consent. Although unable to provide informed consent, some persons may resist participating in a research protocol approved by their representatives. Under no circumstances may a subject be forced or coerced to participate in a research study even if the LAR has provided consent.

FLUCTUATING CAPACITY: Investigators, IRB members, and LARs must be aware that decision-making capacity may fluctuate in some subjects. For subjects with fluctuating decision-making capacity or those with decreasing capacity to give consent, a re-consenting process with surrogate consent may be necessary.

References:

1. *Ethical Aspects of the Relationship Between Clinicians and Surrogate Decision Makers: A Report by the National Ethics Committee of the Veterans Health Administration*, April 2007
2. VHA Handbook 1200.05
3. VHA Handbook 1605.1
4. HIPAA and the Privacy Act of 1974