Ensuring Effective and Legal Informed Consent in Clinical Research

Clinical research has contributed significantly to the quality of healthcare in recent years. Key to the ethical and legal conduct of these studies is fully informed and voluntary consent from the research subject. In other words, the research subject must understand what they are agreeing to, including the purpose of the study as well as the benefits and risks of participating. Informed consent is documented by the use of a written informed consent form that meets several criteria established by federal regulations.

While proper documentation of informed consent is essential to compliance with federal regulations, improving the effectiveness of informed consent should be directed toward focusing on the consent process rather than the document itself. The process of informed consent begins with the researcher’s first contact with the prospective subject and continues throughout their participation in the study. Research staff are responsible for ensuring an effective consent process.

Adhering to the following guidelines will help ensure the consent process is effective and that ethical and legal requirements are met.

- Obtain consent only if you have been trained in human subject research regulations and are knowledgeable about the research study.
- Explain the study (orally and via the written consent form) to the subject in a language understandable to the subject. Avoid technical language and complex medical terminology. As a general rule, try to use language equivalent to 8th grade reading level.
- Allow sufficient time for the consent discussion to take place. Assess understanding by open-ended questions. Give the subject the opportunity to discuss the study with family and friends.
- If appropriate, use IRB-approved supplemental information sheets or other to aide in study comprehension.
- Continually assess the subject’s understanding of the study and willingness to continue throughout participation in the study. Inform the subject if new information becomes available that may affect his or her willingness to participate.
- If the subject is unable to read, ensure an impartial third party witness is present during the entire consent process and signs the informed consent form.
- Give special consideration to subjects whose capacity to understand or make decisions may be temporarily or permanently impaired (such as non-English speaking subjects, children, the elderly, or subjects with cognitive deficits.)