Simplifying, Strengthening the Informed Consent Process

After years of struggling with the informed consent process (ICP), the research protection community is working diligently to achieve consensus on how best to help research participants understand the purpose, risks, and benefits of a study before enrolling.

The Clinical Trials Transformation Initiative (CTTI) is expected to release evidence-based recommendations this year on ways to shorten consent documents, gauge participants’ comprehension, and train research staff in best ICP practices. A primary goal is to design ICPs that can be easily adapted depending on the needs of research participants.

“It’s no secret that informed consent has long been an issue. Our goal was to identify and tackle a few key areas where change not only was possible but also could effect a difference,” says Michele Kennett, J.D., M.S.N., LL.M., Assistant Vice Chancellor for Research at the University of Missouri-Columbia. Ms. Kennett is a member of the CTTI Informed Consent Project team and AAHRPP’s Council on Accreditation.

“Our hope is that our recommendations will encourage people to look outside the box,” Ms. Kennett adds, “to ease the process for obtaining consent and reduce barriers to participants’ understanding.”

CTTI is a public-private partnership that identifies and promotes practices designed to increase the quality and efficiency of clinical trials. Members come from government agencies, industry, patient advocacy groups, professional societies, investigator groups, academic institutions, and other interested groups. Past CTTI recommendations have addressed reporting serious adverse effects, use of central institutional review boards (IRBs) for multicenter clinical trials, and good clinical practice training for investigators.

Members of the CTTI Informed Consent Project Team presented their findings and sought input and consensus on proposed recommendations during a two-day experts meeting in March. PDFs of the presentations can be viewed and downloaded online.

Key messages include:

- **ICP should be an ongoing, interactive, participant-focused process.** Although the informed consent document is important, it should not be the primary means of obtaining consent. Instead, it should serve as the basis of an interactive discussion. Furthermore, research staff should reach out to participants throughout the course of the study to make sure they continue to consent.

The CTTI team developed a checklist to help document the consent process and, perhaps even more important, provide reminders about obtaining consent in a nonthreatening environment, including family and friends as appropriate, tailoring the conversation to the participant’s level of interest and understanding, evaluating the participant’s comprehension, and other key considerations.

AAHRPP Conference Features Sessions on Informed Consent

Informed consent will be the subject of three different sessions at the 2015 AAHRPP conference May 19-21:

- “Demystifying Consent Requirements”
- “Just Do It: Waivers and Flexibility in Informed Consent”
- “Valid Informed Consent Education (VoICE) Project”
- **Training is essential for those involved in obtaining consent.** The proposed recommendations call for formal ICP training that covers federal requirements for obtaining and documenting informed consent, effective health communications, and writing an easily understood consent document. Training should recognize that informed consent is not a one-size-fits-all scenario and should identify opportunities to keep refining the ICP.

- **New formats can enhance participants’ understanding.** CTTI team members presented alternatives to today’s typical consent forms, which tend to be too long and difficult for laypeople to understand. Among the options are e-consent technology and a tiered-consent model that summarizes major points, written in plain language, followed by a lengthier explanation for those who want more information.

**AAHRPP accreditation and informed consent**

The final CTTI recommendations are expected to be consistent with AAHRPP standards, which require organizations to have policies and procedures that comply with informed consent regulations and promote an ICP that protects and informs research participants. AAHRPP standards include three references to informed consent:

- **Element II.3.F.** The IRB or ethics committee (EC) has and follows written policies and procedures to evaluate the consent process and to require that the researcher appropriately document the consent process.

- **Element II.3.G.** The IRB or EC has and follows written policies and procedures for approving waivers or alterations of the consent process and waivers of consent documentation.

- **Element III.1.F.** Researchers employ consent processes and methods of documentation appropriate to the type of research and the study population, emphasizing the importance of comprehension and voluntary participation to foster informed decision-making by participants.

Elyse I. Summers, J.D., AAHRPP President and CEO, and Sarah Kiskaddon, J.D., AAHRPP Director, Global Business Development and Public Affairs, attended the experts meeting and found much to support. “The proposed recommendations go a long way in addressing concerns about the informed consent process and ensuring that the emphasis is in the right place, which is protecting participants,” Ms. Summers says.

For Ms. Kiskaddon, many of the presentations drove home the importance of training, observation, and continuous quality improvement activities that often are the purview of the IRB.

“So much depends on the individual who is obtaining the consent. That’s why training is essential,” she says. Ms. Kiskaddon encourages IRBs to take advantage of opportunities to observe the consent process and provide immediate feedback. “That’s a very good training tool,” she says.