Are You Securing (Truly) Informed Consent? Part 2 – The Form

Our previous Hot Issue looked at the importance of a complete consent conversation between the provider and the patient, in order to ensure that the consent given by the patient is truly ‘informed’. While that conversation effectively creates the informed consent, it is also necessary to review the documentation that follows the conversation.

The format of the form should follow that of the conversation, so that it becomes a facilitation tool rather than a piece of paper given to the patient. To that end the format of the document should follow our previous outline:

- **Treatment Explained** – the actual test or treatment as explained to the patient, in simple language rather than in technical jargon;
- **Risks and Alternatives Explained** – any material risks identified for the patient, as well as alternatives to the test or treatment recommended;
- **Acknowledgement of Questions Answered** – confirmation that the patient was given the opportunity to ask questions and that answers were given to their satisfaction and understanding;
- **Confirmation of Comprehension Achieved** – the patient’s agreement that they understand the information presented and choose to proceed with the recommended procedure;
- **Placement of Signatures** – signature of the patient (or legal guardian) as well as a statement by the provider that they confirm that the patient was given a chance to ask questions, did so, and wishes to proceed with the treatment.

The form should also be reviewed for simple grammar rules, including the tense of the wording. The proper tense should be present time and first person, so that the patient is reading and signing “I agree” as opposed to the third person use of “You agree”. If the provider or practice wishes to provide educational materials separate from the actual consent form, these can be worded in third person.

The reading level recommended for average comprehension is 6th grade, eliminating large medical words and substituting them with simple, common phrases. The font should be as clear as possible (such as Arial), and in at least 10 point type. It is better to have several pages in large print than to try to compress text to fit a single page, and risk the patient not having the ability to fully see the text.

This guarantees that most patients will understand what they read, and that if the form ever has to be presented to a jury, that they will be able to read it as well.

For more information on this topic, plan to attend the Informed Consent CME program on March 5 at the OrthoForum Mid Year Meeting in Scottsdale, Arizona. Registration is available on the [www.theOrthoForum.com](http://www.theOrthoForum.com) website.