Informed Consent Guidelines

In today’s volatile professional liability environment, litigation involving informed consent issues is more common than ever. Corresponding to the increase in litigation is a similar increase in the rate of malpractice premiums.

While the endodontist may conform to applicable standards of care in the performance of his or her procedures, that alone will not prevent him or her from being subjected to a claim by the patient for an untoward result. Failure to inform the patient of the risk of an untoward result prior to the performance of that procedure will just as likely result in a claim by the patient for failing to obtain his or her consent. As a general rule, informed consent is satisfied after the endodontist has discussed with his or her patient all relevant information so as to assist the patient in making an informed decision with respect to undergoing that proposed procedure.

History
Informed consent originally developed from common law principles of negligent non-disclosure. It has since evolved from repeated interpretations by the courts and state legislatures into the patient’s right to participate in the decision-making process regarding the type of treatment he or she is about to undergo. Because of the confusion created by various interpretations of the doctrine of informed consent by the courts and state legislatures, it is difficult to formulate a single, simple statement on the legal requirements of informed consent.

General Guidelines
Despite these various interpretations of informed consent, it is generally accepted that to obtain the informed consent of the patient, the endodontist needs to:

1. Disclose the following information in understandable lay language:
   • Diagnosis of the existing problem
   • Nature of the proposed treatment or procedure
   • Inherent risks associated with the proposed treatment or procedure
   • Prognosis
   • Feasible alternatives to the proposed treatment or procedure
   • Inherent risks associated with the alternative treatments or procedures
   • Prognosis of alternative treatments or procedures
2. Provide a generalized opportunity to question the doctor about any of the above.

Diagnosis
It is required before treatment is rendered that there be a diagnosis of the existing condition and that this diagnosis be given in a manner that is readily understood by the patient.

No Treatment
Keep in mind that choosing no treatment at all is always an alternative to every treatment or procedure. However, the likely results of no treatment must also be explained.

Lay Language
It is important to note that the discussion regarding the proposed procedure and alternatives and their prognoses must be presented in language and terms understandable by each individual patient.

Doctor Must Discuss
The practitioner who is to perform the procedure must personally present the details of the case, and the patient must be able to question the provider regarding treatment or alternatives. The office staff does not have the power to obtain consent. A written consent form, while imperative for accurate record keeping, CANNOT be used as a substitute for the doctor’s discussion with each individual patient.

A thoughtful, well documented dialogue between the doctor and the patient can reduce misunderstandings and incidence of claims and suits alleging a lack of informed consent.

Signatures
Your consent form must be signed and dated by the patient (legal guardian if under 18 years of age) and should be signed and dated by the practitioner as testimony to the fact that the endodontist did discuss the elements of the consent form. The signature of a witness is also recommended.

Consent is Limited to Procedures Discussed
It is important to note that consent is limited to the procedures discussed and is not open ended. Therefore, informed consent should be thought of as an ongoing process that may have to be modified if procedures change (i.e., nonsurgical to surgical, unexpected results, or procedural mishaps).

Designing a Form
The form should:

• Document the date and time of the consent process
• Include a statement that the patient was given the opportunity to question the provider regarding treatment or alternatives
• Provide space for signatures by the patient, parent or guardian, the provider, and a witness.

It should be clearly understood that no particular form could possibly be suggested for use on a uniform basis. The form provided is a sample and should not be considered a standard form.

Consult with an Attorney and Check Your State Statutes
These guidelines are not to be considered legal advice. Members should consider their own particular needs and on the basis of those needs, draft forms and procedures for use in their own offices.

Recognizing that state statutes regarding informed consent vary, it is recommended that members consult their state statutes when developing their own informed consent forms. A copy of your state statute can be obtained from your attorney or by writing to the local county bar association where you practice or reside.
1. I hereby authorize Dr. ____________________________ and any other agents or employees of ____________________________ and such assistants as may be selected by any of them to treat the condition(s) described below:

2. The procedure(s) necessary to treat the condition(s) have been explained to me, and I understand the nature of the procedure(s) to be:

3. The prognosis for this(these) procedure(s) was described as:

4. I have been informed of possible alternative methods of treatment including no treatment at all.

5. The doctor has explained to me that there are certain inherent and potential risks in any treatment plan or procedure. I understand that the following may be inherent or potential risks for the treatment I will receive:
   swelling; sensitivity; bleeding; pain; infection; numbness and/or tingling sensation in the lip, tongue, chin, gums, cheeks, and teeth, which is transient but on infrequent occasions may be permanent; reactions to injections; changes in occlusion (biting); jaw muscle cramps and spasm; temporomandibular joint difficulty; loosening of teeth, crowns or bridges; referred pain to ear, neck and head; delayed healing; sinus perforations; treatment failure; complications resulting from the use of dental instruments (broken instruments—perforation of tooth, root, sinus), medications, anesthetics and injections; discoloration of the face; reactions to medications causing drowsiness and lack of coordination; and antibiotics may inhibit the effectiveness of birth control pills.

6. It has been explained to me and I understand that a perfect result is not guaranteed or warranted and cannot be guaranteed or warranted.

7. I have been given the opportunity to question the doctor concerning the nature of treatment, the inherent risks of the treatment, and the alternatives to this treatment.

8. This consent form does not encompass the entire discussion I had with the doctor regarding the proposed treatment.

Patient’s Signature ____________________________ Date/Time _________________

Doctor’s Signature ____________________________ Date/Time _________________

Witness’ Signature ____________________________ Date/Time _________________