INFORMED CONSENT AND THE LAW

SAMPLE EXCERPT

1999-2000 Informed Consent Tool Kit
Task Force

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TABLE OF CONTENTS

TOOL KIT INSTRUCTIONS

The **Informed Consent Tool Kit** is intended to be instructional and informative. It is meant to be generic in nature, so that you can customize the contents to the needs of your organization. **NOTE: This sample is a PDF, although the actual tool kit includes a Word document and PowerPoint files for use as visual aids.**

Some suggested uses for this tool kit include, but are not limited to, the following:

- Staff, board, and physician education
- Self-study
- Talking points for a consistent message about informed consent
- Resource for further information on the subject

Each section of the tool kit is divided by an outline, followed by speakers' notes/study guide and corresponding visual aids. The disk that is included in your tool kit will allow you to customize and update the contents as desired. ASHRM will not be responsible for tool kit content that is changed or modified by the user.

The tool kit is neither intended to provide legal advice nor to serve as a professional standard. The contents are only for purposes of information and education. It is recommended that consultation be obtained with legal counsel for advice on particular issues or concerns. In addition, consideration of all state laws and statutes is beyond the scope of this product.

Once you have had an opportunity to use the tool kit, we would appreciate your feedback. Please complete the evaluation form and return to ASHRM with your suggestions and comments.

We hope you will enjoy your tool kit. Look for these other ASHRM tool:

- **Physician Office Risk Management Tool Kit**
- **Risk Management Program Development Tool Kit**
- **Confidentiality Tool Kit**

INFORMED CONSENT TOOL KIT
TRAINING OBJECTIVES

Upon completion of this informed consent training program, you will learn:

1) Principles of informed consent

2) Disclosure requirements

3) Elements of disclosure

4) Aspects of documentation of consent

5) Exceptions to the consent process

6) Additional considerations pertaining to informed consent

INFORMED CONSENT: AN OVERVIEW

A. Informed Consent

1. Legal doctrine
2. Process
3. Duty

B. Disclosure Requirements

1. Professional standard
2. Layperson standard

C. Elements of Disclosure

1. Nature of procedure/treatment
2. Reason for procedure/treatment
3. Benefits of procedure/treatment
4. Risks and complications
5. Alternatives to procedure/treatment

D. Documentation of Consent

1. Evidence of the consent process
2. Procedure/treatment specific forms
3. Notation in patient record
4. Witnesses
5. Tape recordings/videotapes
6. Refusal of consent

E. Exceptions to Consent Process

1. Emergency
2. Incompetence
3. Therapeutic privilege
4. Waiver
5. Legal mandate

F. Consent for Minors

1. State law
2. Capacity to consent
3. Treatment of specific conditions

SPEAKER'S NOTES/STUDY GUIDE

Informed Consent and the Law

Informed consent is a legal doctrine that requires a physician to obtain consent for treatment rendered, an operation that is performed, and many diagnostic procedures. *It is a process not a form*.

Consent is the dialogue between the patient and the physician in which information is shared about the proposed procedure/treatment, questions are asked and answered to the patient's satisfaction and the ultimate goal of an informed consent is achieved. It is the transfer of information to a patient before any invasive procedure or treatment so that an informed decision can be made. Consent must be obtained whenever the patient is going to be touched by a care provider. Failure to obtain consent constitutes battery.

For the informed consent process to be effective, the physician and patient must actively participate. The law of informed consent varies from state to state. However, the law in most states mandates that informed consent is a duty of the physician, which cannot be delegated.

The doctrine of informed consent has become an explicitly legal process in almost all aspects of medical treatment. Although the application of informed consent varies considerably, most links in the medical treatment chain have an interest in the proper use of informed consent principles.

The heart of the informed consent process is disclosure. The disclosure requirements as defined legally are of two basic types. The first type is the "reasonable physician" or "professional standard" of disclosure and is used in the majority of jurisdictions. This standard of disclosure is based on what is customary practice or what a reasonable practitioner in the medical community would disclose under the same or similar circumstances.

The second type is the "reasonable person" or "layperson" disclosure standard, which is being accepted by the courts with much more frequency. This standard provides that disclosure of information should be based on what a reasonable person in the same situation as the patient would want to know under similar circumstances. This standard is based on the patient's perception rather than on the professional perception of the physician of what the patient should know or needs to know.

In order to achieve these standards, certain elements of disclosure must be met. These include:

- The nature of the procedure/treatment
- The reason for the procedure/treatment
- The benefits of the procedure/treatment
- The risks, side effects and complications of the procedure/treatment (including the frequency with which complications occur and how severe the complications are)
- Any alternatives to the procedure/treatment
- Possible consequences if advice is not followed

The physician should explain to the patient what will occur before, during and after the procedure/treatment is completed. The nature of the procedure should be described and the benefits outlined. The risks and complications must be detailed. Not every possible complication needs to be communicated, but those that are most common and/or most serious should be discussed. All reasonable alternatives should be presented even if they are more hazardous or more costly. If there are no alternatives, the patient should also be informed.

Recording a patient's authorization to a treatment is important. It may be the only legal proof available to defend a physician in a consent action. Most hospitals require completion of a form to satisfy their informed consent policies. Some states also require a formal written process by statute. Risk managers need to identify the statutes in their states to determine the legal requirements that must be met.