**THE MAJOR ELEMENTS OF INFORMED CONSENT AND THE CIRCUMSTANCES UNDER WHICH PROFESSIONALS CAN BREACH THE UNDERSTANDING OF CONFIDENTIALITY IN CLINICAL WORK.**

**Introduction**

Informed consent is the process in which a health care provider educates a patient about the risks, benefits, and alternatives of a given procedure or intervention. The patient must be competent to make a voluntary decision about whether to undergo the procedure or intervention.  Informed consent is both an ethical and legal obligation of medical practitioners and originates from the patient's right to direct what happens to their body. Implicit in providing informed consent is an assessment of the patient's understanding, rendering an actual recommendation, and documentation of the process. The Joint Commission requires documentation of all the elements of informed consent "in a form, progress notes or elsewhere in the record."

The following are the required elements for documentation of the informed consent discussion:

1. the nature of the procedure,
2. the risks and benefits and the procedure,
3. reasonable alternatives,
4. risks and benefits of alternatives, and
5. assessment of the patient's understanding of elements 1 through 4.

It is the obligation of the provider to make it clear that the patient is participating in the decision-making process and avoid making the patient feel forced to agree to with the provider. The provider must make a recommendation and provide their reasoning for said recommendation.

The required standard for informed consent is determined by the state. The three acceptable legal approaches to adequate informed consent are:

1. Subjective standard: *What would this patient need to know and understand to make an informed decision?*
2. Reasonable patient standard*: What would the average patient need to know to be an informed participant in the decision?*
3. Reasonable physician standard*: What would a typical physician say about this procedure?*

Many states use the "reasonable patient standard" because it focuses on what a typical patient would need to know to understand the decision at hand. However, it is the sole obligation of the provider to determine which approach is appropriate for a given situation.

**THE MAJOR ELEMENTS OF INFORMED CONSENT**

1. The nature of the procedure.

A description of the procedure is commonly presented at the beginning of the informed consent process and documentation. It should clearly explain that the potential patient is being asked to undergo the procedure. A potential patient must understand the standard or routine of the procedure being asked to undergo. The purpose and expected outcome of the procedure must be clearly presented.

All the procedures involved in the intervention, e.g., diagnostic tests, number of blood samples, must be detailed to ensure that the patient understands that he or she is agreeing to undergo such procedures. The anticipated duration of the procedure must be clearly stated.

1. The risks and benefits of the procedure

The informed consent process must make the potential patient well aware of all the anticipated risks or foreseeable risks associated with the study. Consideration must be given not only to physical, but also to mental and social risks, e.g., social stigmatization to patients with HIV/AIDS. Patients must be notified promptly if any new risks are identified during the conduct of the procedure.

The amount of information on the possible risks, likelihood of such risks occurring, and their severity and duration, require careful consideration in the planning of the informed consent process. The challenge is to present no more or no fewer risks than necessary.

The informed consent documentation must also include a description of any benefits to the patient or others that may be reasonably expected from the procedure. Benefits must be presented without overstatement or exaggeration with the intent to induce participation. The provision of healthcare services to which the patient is entitled to without undergoing the procedure must not be presented as benefits of the procedure.

Persons with limited access to health care services are vulnerable potential patients for certain procedures. Offering healthcare to individuals who otherwise do not have access to this care, or lack other options for health care, is potentially coercive. Healthcare providers are responsible for ensuring that the potential patient’s decision is not unduly influenced by the opportunity to receive health care.

1. Reasonable alternatives

It is important to present to the potential patient the existing alternatives or choices other than participating in the procedure. The patient should be given information on the advantages and disadvantages of the alternatives and allowed the opportunity to of choosing between participating in the proposed procedure or the alternatives. For some procedures, there is no alternative, the only option would be to not undergo the procedure. In essence, the information gives the person the choice not to participate.

1. Risks and benefits of the alternatives.
2. Assessment of the patient’s understanding of the elements.

Obtaining appropriate informed consent is necessary before any medical procedure is initiated. It is an ethical obligation as well as a legal requirement designed to protect the basic human rights of patients.

Written documentation of informed consent is usually required. However, it is essential to ensure that the potential patient has understood all the information provided. The challenge of informed consent is to provide sufficient information to make an informed decision, while at the same time presenting this information in a way that the potential patient understands.

The patient’s education, maturity, and cultural environment have a strong effect on his or her ability to understand such information. The use of support materials, such as brochures or videos, should be considered.

Healthcare providers may also need to create a mechanism to communicate with others, such as patient’s partners, family members, or friends. In some cases, more than one information session with patients may be necessary.

**CIRCUMSTANCES UNDER WHICH PROFESSIONALS BREACH THE UNDERSTANDING OF CONFIDENTIALITY IN CLINICAL WORK**

1. When the patient is incapacitated.
2. In life threatening emergencies with inadequate time to obtain consent.
3. Voluntary waived consent.

Data repeatedly show that patients remember little of the information disclosed during the informed consent processand that their level of comprehension is often overestimated. Comprehension is related to factors such as patient age, education, intelligence, cognitive function, locus of control and anxiety. Not surprisingly, the measure also relates to the instrument used to assess comprehension, as well as to the topics covered by the questions asked. Furthermore, patient comprehension and recall deteriorate as time between consent and testing of the patient’s understanding increases.

If the patient’s ability to make decisions is questioned or unclear, an evaluation by a psychiatrist to determine competency may be requested. A situation may arise in which a patient cannot make decisions independently but has not designated a decision maker. In this instance, the hierarchy of decision-makers, which is determined by each state’s laws, must be sought to determine the next legal surrogate decision-maker. If this is unsuccessful, a legal guardian may need to be appointed by the court.

Human immunodeficiency virus (HIV) testing is essential for improving the health of people living with HIV and reducing new HIV infections: once diagnosed, persons with HIV can be linked to care and learn how to prevent transmission to others.

Informed consent for testing means that the person being tested understands HIV testing procedures, the reasons for testing and is able to assess the personal implications of testing before deciding whether to be tested.

Given that the consequences of being tested for HIV may be enormous, it is important to realise that, while ordering tests may be standard for the healthcare practitioner, receiving the results may be anything but routine for the patient. The provision of information should allow the health care practitioner to discuss the risks and benefits to the patient in his or her particular situation, thereby facilitating the decision-making process. Pre-test discussion should also assist in preparing patients for a potential positive HIV test result.

The person performing the test should use their professional judgement in seeking informed consent. This should be based on their understanding of the context in which the test is being performed:

* The features which precipitate testing such as clinical presentation, risk exposure, epidemiology and prevalence and patient situation;
* An assessment of the person being tested with respect to their understanding of the HIV testing process and consequences of the result, and
* Patients should also be advised how the test result will be conveyed.

When a person requests or is offered an HIV test, the practitioner should assess a person’s preparedness to be tested and given appropriate information about risk, points of referral if necessary, assurances about confidentiality and privacy. The information should be given in way that is appropriate to the person’s gender, culture, behavior and language.