# The Importance of the Informed Consent for Interventional Radiology Procedures

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***ABSTRACT:*** **The informed consent process has acquired great importance in the practice of medicine. In the past, it was deemed that the patient should trust the doctor as the decision maker; however, this began to change more than 100 years ago when the concept of patient autonomy acquired importance. Ideally, the consent process should include a clear understanding of the patient's health condition, explanation of the procedure, discussion of benefits, risks, and alternatives to the procedure. The purpose of this article is to describe the ideal consent process focused on an interventional radiology practice. (J Radiol Nurs 2016;35:33-36.)**

***KEYWORDS:*** **Informed consent; Interventional radiology; Lung biopsy.**

## INTRODUCTION

The informed consent process is probably one of the most important events in current medical practice. During the informed consent process, it is the health care provider's responsibility to explain a treatment, procedure, or surgery to the patient (Ripley, Tiffany, Lehmann, & Silverman, 2015). This explanation must be conducted in such a way that the patient understands the proposed treatment, should be able to ask questions, and, ultimately, should be able to make an informed decision regarding acceptance or refusal of the proposed treatment (Ripley et al., 2015). The consent form by itself is a legal document that confirms that a conversation was conducted between the health care provider and the patient; however, the consent process is much more than a legal act, it is the opportunity for the health care provider to establish a rapport with the patient and explain to the patient the therapeutic alternatives for the specific condition that the patient may suffer. It has recently been established that the consent process in current practice is often incomplete and does not fulfill patient's expectations (Ripley et al., 2015). This article will focus on the ideal approach to a consent process in the field of interventional radiology. This article will also address some legal aspects of the consent process and last, will address some challenges that are encountered during the process of obtaining consent from a patient.

### *The Informed Consent*

The informed consent process has acquired great importance in the practice of medicine. In the past, it was deemed that the patient should trust the doctor as the decision maker (Requarth, 2015). However, this concept began changing more than 100 years ago, starting in 1914, when it was established that patients had the right to participate in the decision process regarding any procedure performed on their body (Murray, 1990). For a consent process to be valid, a patient needs to understand the disease process, understand the procedure to be performed, the risks, benefits, and alternatives to treatment, and understand their right to refuse a proposed treatment (Murray, 1990; Ripley et al., 2015). Legally, consent for a procedure can be rendered by a patient in the correct state of mind; by the patient's spouse or legal companion, a family member or next of kin, or by a person whom

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the patient has determined to be responsible for his or her health decisions (power of attorney to make medical decisions) (Requarth, 2015). In the rare event that the patient in question is unable to make an informed decision and there is no person with legal authorization to render consent for a procedure, the health care provider may have to rely on the guidelines dictated by the ethics committee, and the procedure may be performed as medically necessary, that is, the procedure is indicated to preserve the patient's life or well-being. This type of authorization usually has to be signed by at least two physicians taking care of the patient, who agree on the importance of performing the procedure expeditiously.

### *The Ideal Consent Process*

Ideally, the consent process should include a clear understanding of the patient's health condition, explanation of the procedure, discussion of benefits, risks, and alternatives to the procedure (Ripley et al., 2015). The patient or the person rendering the consent should have enough time to ask questions regarding the procedure to be performed, and the consent should only be signed when the patient or the person authorized to consent for the patient has full understanding of the procedure. A very important aspect of the consent process is understanding the patient's cultural, family, and religious needs and concepts and identifying language or communication limitations that may interfere with the patient's understanding of the process (Ripley et al., 2015).

### *The Consent Process for Interventional Radiology Procedures*

As much as it would be ideal to have a standardized consent process in interventional radiology (Ripley et al., 2015), in the author's opinion, the practice of interventional radiology is unique in many ways and differs from the practice by most physicians in other fields. This unique practice has a major influence in the consent process for different procedures performed by interventional radiologists. From the author's perspective, interventional radiology procedures can be classified in three major categories:

1. Simple procedures,
2. Procedures of moderate difficulty, and
3. Complex procedures.

Depending on the complexity of the procedure, the consent process may be simple, straightforward, and require minimal explanation to the patient, or it may require a full consult with an in-depth discussion of the procedure, risks, benefits, and potential outcomes.

***Simple Procedures.*** These are procedures with a straightforward indication, with minimal technical challenge and with very low risk for major complications. A good example of a simple procedure would be the placement of a peripherally inserted central catheter (PICC) in an adult patient. In general, it is not difficult for the patient to understand the need for a PICC. By the time a PICC is needed or requested by the treating team, the patient has usually undergone attempts to gain access for a reliable peripheral intravenous line, and most often, these attempts have been unsuccessful. The patient usually knows and understands that there is a need for a reliable intravenous access. For the most part, obtaining consent for placement of a PICC is straightforward, requires only a few minutes, and the risks, benefits, and possible outcomes can be easily explained to the patient during a brief conversation.

***Procedures of Moderate Difficulty.*** These are procedures where the indication is not as straightforward to the patient's understanding, the procedure to be performed may be technically challenging, and there are risks for major complications. A good example of a procedure of moderate difficulty is a percutaneous lung biopsy. The indications for a percutaneous lung biopsy may not be all that clear to the patient, and the interventional radiologist will need to spend a good deal of time explaining the need for this type of procedure. Percutaneous lung biopsy requires careful planning, that is, the health care provider must review the available images and decide the best way to proceed, including patient position, best possible approach, and type of needle to be used (Lalji et al., 2015). A brief review of the most recent laboratory results is in order (i.e., coagulation profile) as well as a review of allergies and uncommon reactions to drugs. Finally, complications during or after a percutaneous lung biopsy may have a lasting negative impact on the patient's condition or quality of life (Tai et al., 2015). In these cases, a brief explanation of the procedure may not be enough to cover all aspects required for a proper consent. The health care provider performing a percutaneous lung biopsy needs to make sure that the patient really understands the reasons why the procedure has been indicated in the context of their disease process. Patients need to know the implications of the results of the biopsy, and how these results may affect their future management (i.e., if a patient does not wish treatment for a lung cancer, why undergo a biopsy to start with?). Finally, patients need to understand complications and the possible consequences of those complications as they relate to their overall condition. The consent process will be more involved and may require