



Rothman Institute Manual of

Total Joint Arthroplasty

Protocol-Based Care



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Consent: When and Where?

Ryan Massimilla, Javad Parvizi

Rothman Protocol

Informed consent is obtained from all patients undergoing a surgical procedure. At the time a patient is scheduled for surgery, the surgeon and members of the team explain the surgical procedure, the benefits and risks of the procedure, and the available alternative treatment. All patients are required to sign an informed consent form, indicating their understanding of all possible risks, benefits, and alternative measures of treatment, for documentation purposes. The consent form at the Rothman Institute also contains a paragraph regarding ongoing research and states that the patients may be contacted by the research team from time to time. Patients are given the opportunity to drop out of research, if desired.

Algorithm for Consent

1. The patient is identified as an appropriate candidate for surgery.
2. The attending physician and members of the team will thoroughly explain the proposed procedure and any alternative methods of treatment to the patient. Risks and benefits of all treatment methods will be explained as well. All questions should be answered by the attending physician prior to the patient signing the consent.

3. The patient's understanding of the procedure, alternative treatments, and risks and benefits will be gauged by the attending physician. The attending physician should offer further explanation as necessary.
4. At the time of scheduling of the procedure, the patient will sign a consent form, indicating they are aware of what the procedure entails, as well as alternative treatments and risks and benefits.
5. The patient has the right to pose any questions and have them adequately answered before and after their procedure.

Discussion

Obtaining the consent of a patient prior to an invasive procedure has become routine in the United States; however, the issue that remains is how to obtain an informed consent. The importance of proper protocols for obtaining informed consent for surgical procedures and maintenance of legal integrity is continuing to evolve. Surgical informed consent can be defined as:

The process of upholding the ethical and legal responsibility of ensuring that a patient, or that patient's representative, is fully understanding of the proposed method of treatment, as well as alternative treatment measures, and is provided with knowledge of the known risks and benefits associated with these measures.¹⁻⁷

Although obtaining a surgical consent is necessary at all institutions throughout the United States, ensuring that it is carried out properly is vital to maintaining integrity in three different areas.

First, legal integrity is upheld. Provision of a thorough surgical informed consent process allows for protection from assault, as well as ensuring that an unwanted

procedure is not performed. This is beneficial for both the patient and the care provider.

Second, the informed surgical consent process allows for maintenance of ethical integrity. The completion of the Surgical Informed Consent Form indicates that the patient's autonomous decision-making abilities are being not only upheld but enhanced. This form indicates that a patient has been educated regarding possible risks and benefits of the proposed procedure, as well as those of alternative treatments. To maintain the highest ethical standards for consent, patients must make decisions utilizing free will and exhibit a firm understanding of the proposed treatment methods.

Third, administrative compliance must be upheld. One important duty of the administrative parties, at their respective institutions, is to ensure that both the proper legal and ethical standards are being met. Obtaining informed surgical consent is important in meeting these standards because it provides documentation that the actual process of consent has taken place. Completion of the consent form also notes that all necessary parties were involved in the process. The informed surgical consent form is one safeguard administrative groups can refer to in order to ensure that all ethical and legal responsibilities are being upheld.

How to Properly Obtain Surgical Informed Consent

Multiple parties, including the attending surgeon, the surgeon's support staff (RN, surgical scheduler, etc.), and registrars, should be held responsible to involve themselves in the process of administering and collecting informed consent properly.

It is the responsibility of the attending surgeon to provide any information necessary regarding the proposed treatment and alternative treatments, including any known risks or benefits associated with those treatment

methods. The attending surgeon should also be able to evaluate the patient's level of understanding, and to decide whether additional measures should be taken to ensure the understanding of special populations.⁶ The surgeon's support staff must be able to confirm that proper consenting has taken place prior to scheduling and undergoing of that procedure.

Employees at the operating room (OR) registration desk are the final checkpoint in ensuring that a patient has been properly consented. They must ensure that the Surgical Informed Consent form has been completed properly and is documented, prior to the patient being admitted for surgery.

Conclusion

The process of obtaining informed surgical consent always begins with the introduction of the proposed method of treatment. At this time, the patient should be given an opportunity to ask any questions pertaining to that treatment, prior to signing any informed consent form. Ideally, the Surgical Informed Consent Form should be signed and completed in the office, before the patient schedules the surgery. The surgical informed consent process should *not* be started in the OR or holding area, where time for questions is limited and the process may become rushed (with the exception of emergent trauma cases).³ Proper informed consent is a continual process that should be maintained and last throughout the surgeon-patient relationship; it does not end merely with the signing of a document.

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Total Joint Arthroplasty
Protocol-Based Care

This book has assembled the most important protocols related to the care of patients undergoing total joint arthroplasty. The protocols in place have been developed based on the available evidence, or if lacking, based on the experience of the high volume joint arthroplasty surgeons at our institution. It is hoped that the reader will be able to implement these protocols in his/her institution without much difficulty. The protocols are developed for one and only one reason: Improve patient care and the outcome of total joint arthroplasty.

- The “chapters” are written in a concise and standard fashion out of respect to our readers who are likely to be busy clinicians, surgeons or healthcare workers.
- Each chapter is complimented by including figures, graphs and tables for visual ease.
- The protocols have been refined over the years with emergence of evidence.

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ISBN 978-93-86261-05-2

