

## Informed consent, psychiatric patient

### Introduction

Except in emergency care situations, when the need for treatment is immediate and consent is implied, a health care provider must obtain a patient's permission for any course of treatment, including surgery, procedures, medical treatments and therapies, and participation in clinical studies.<sup>2</sup> The person performing the procedure or ordering the treatment (typically the doctor) is required to tell the patient everything that would substantially affect the patient's decision whether to receive the treatment. (See *Information to provide during informed consent.*)

#### INFORMATION TO PROVIDE DURING INFORMED CONSENT<sup>2</sup>

*The process of informed consent must include:*

1. a full explanation of the condition
2. an explanation of the procedure or therapy, using demonstrations as needed, that's appropriate for the parent or guardian's and child's level of understanding and provided by the person performing the procedure or therapy
3. a description of alternative treatments or therapies available
4. a description of the expected benefits of the procedure or therapy
5. a description of risks associated with the procedure or therapy
6. sufficient time and encouragement to answer questions
7. discussion that's free from coercion, unfair persuasions, or other inducements to comply with the treatment being discussed.

The doctor must evaluate whether the person has understood the information that was provided and must ascertain that the risks have been accepted and that the patient is giving consent to proceed with the treatment. The patient gives his permission for the treatment by signing a consent form.

Only patients who have appropriate decisional capacity and legal empowerment are considered competent to give their informed consent to medical care. During the treatment of children, parents, legal guardians, or surrogates provide informed consent for diagnosis and treatment, with the assent of the child whenever appropriate. Children who are cognitively able can give informed consent in order to respect the right to self-determination in decision making. (See the "Informed consent, pediatric" procedure.)

Doctors should seek informed consent in most situations. However, they must focus their goal on providing appropriate care and be prepared to seek legal intervention when a patient is at substantial risk. Some procedures are covered by the general consent-to-treat form that was signed upon admission to a health care facility or upon initial treatment.

## Equipment

- Consent document
- Indelible-ink pen
- Optional: Various forms of patient education materials addressing the individual's learning style and literacy skills, including written pamphlets, videos, picture boards, anatomic models and dolls, and a teaching mannequin to provide a visual hands-on experience

## Implementation

1. Gather the consent form, *which is essential for the legal medical record*, along with the necessary equipment and supplies needed to provide the patient with a clear explanation and demonstration of the procedure to be performed.
2. Confirm the patient's identity using two patient identifiers according to your facility's policy.<sup>2</sup>
3. Provide as private an environment as possible as outlined in the Health Insurance Portability Accountability Act of 1996 *to protect the confidentiality of patient information and to limit distractions during the informed consent process*.
4. If not previously done, assess the patient's learning style. In an emergency situation, assessment will have to be rapid based on the person's response and questions about the treatment plan.
5. Assess the patient's legal and cognitive abilities to make informed decisions.<sup>2</sup>
6. Evaluate the patient's understanding of the informed consent process.
7. Reinforce the doctor's explanation of the procedure or treatment to the patient, using the patient's preferred language. You may need to arrange for translator services *to promote communication and the patient's understanding of the procedure*.
8. Assure the patient, within clinical feasibility, that he has the right to refuse any treatment or seek care elsewhere. *There should be no coercion to comply with care nor any evidence of inducements or unfair persuasions*.
9. Throughout the explanation of the treatment and at the end of the session, elicit questions from the patient and determine whether he has any concerns.
10. Assess the patient's understanding of the information. For example, have him repeat back to you what the procedure entails.
11. Obtain appropriate personnel to witness the signature of the patient. The witness should be someone who isn't related to the patient and not involved in providing care during the procedure *to avoid potential conflicts of interest*.
12. Make sure that signed informed consent is included in the patient's chart.

**Pediatric alert:** If the patient is a child, obtain consent from a parent or guardian and the child (if cognitively able).

- Explain to the patient that he has the right to withdraw the consent and cancel the procedure at any time.

- Give a copy of the signed consent form to the patient.
- Avoid violating the right to self-determination whenever possible.
- Provide reeducation as often as needed.
- Document the procedure.<sup>32</sup>

### Special Considerations

- The same standards of informed consent apply to the community setting as to the acute care setting.
- Consent obtained outside the acute care setting is relevant if it's the same provider who obtained the consent to perform the procedure and the consent is less than 24 hours old.
- Many states include informed consent as a patient's right on the list of the Patient's Bill of Rights.

### Documentation

Document all relevant factors, including what information was provided to the patient, methods used to explain the procedure, the patient's understanding of the explanation, the patient's voluntary agreement to treatment, and the patient's competency. Note whether the patient or his family had any questions or concerns and what was done to clarify those concerns.<sup>5</sup>

### Rating System for the Hierarchy of Evidence for Intervention/Treatment Questions

- Level I: Evidence from a systematic review or meta-analysis of all relevant randomized controlled trials (RCTs)
- Level II: Evidence obtained from well-designed RCTs
- Level III: Evidence obtained from well-designed controlled trials without randomization
- Level IV: Evidence from well-designed case-control and cohort studies
- Level V: Evidence from systematic reviews of descriptive and qualitative studies
- Level VI: Evidence from single descriptive or qualitative studies
- Level VII: Evidence from the opinion of authorities and/or reports of expert committees

The following leveling system is from *Evidence-Based Practice in Nursing and Healthcare: A Guide to Best Practice* (2<sup>nd</sup> ed.) by Bernadette Mazurek Melnyk and Ellen Fineout-Overholt. Modified from Guyatt, G. & Rennie, D. (2002). *Users' Guides to the Medical Literature*. Chicago, IL: American Medical Association; Harris, R.P., Hefland, M., Woolf, S.H., Lohr, K.N., Mulrow, C.D., Teutsch, S.M., et al. (2001). *Current Methods of the U.S. Preventive Services Task Force: A Review of the Process*. *American Journal of Preventive Medicine*, 20, 21-35.

## References

1. American Psychiatric Association (2006, May 5). "American Psychiatric Association Practice Guidelines: Psychiatric Evaluation of Adults, Second Edition," [Online]. Accessed April 2020 via the Web at [http://www.psychiatryonline.com/pracGuide/pracGuideChapToc\\_1.aspx](http://www.psychiatryonline.com/pracGuide/pracGuideChapToc_1.aspx). (Level I)
2. The Joint Commission. *Comprehensive Accreditation Manual for Hospitals: The Official Handbook*. Standard NPSG.01.01.01. Oakbrook Terrace, Ill.: The Joint Commission, 2009.
3. The Joint Commission. *Comprehensive Accreditation Manual for Hospitals: The Official Handbook*. Standard RC.01.03.01. Oakbrook Terrace, Ill.: The Joint Commission, 2009.
4. The Joint Commission. *Comprehensive Accreditation Manual for Hospitals: The Official Handbook*. Standard RC.02.01.01. Oakbrook Terrace, Ill.: The Joint Commission, 2009.
5. The Joint Commission. *Comprehensive Accreditation Manual for Hospitals: The Official Handbook*. Standard RI.01.03.01. Oakbrook Terrace, Ill.: The Joint Commission, 2009.
6. The Joint Commission. *Comprehensive Accreditation Manual for Hospitals: The Official Handbook*. Standard RI.01.03.05. Oakbrook Terrace, Ill.: The Joint Commission, 2009.
7. Mohr, W.K. *Psychiatric-Mental Health Nursing: Evidence-Based Concepts, Skills and Practices*, 7th ed. Philadelphia: Lippincott Williams & Wilkins, 2008.
8. Pomerantz, A.M. "Increasingly Informed Consent: Discussing Distinct Aspects of Psychotherapy at Different Points in Time," *Ethics & Behavior* 15(4):351-60, 2005.
9. Videbeck, S.L. *Psychiatric-Mental Health Nursing*, 4th ed. Philadelphia: Lippincott Williams & Wilkins, 2007.

## Informed consent, psychiatric patient

1. Gather the consent form along with necessary equipment and supplies.
2. Confirm the patient's identity.
3. Provide privacy.
4. Assess the patient's learning style.
5. Assess the patient's legal and cognitive abilities to make informed decisions.
6. Evaluate the patient's understanding of the informed consent process.
7. Reinforce the doctor's explanation of the procedure or treatment.
8. Assure the patient that he has the right to refuse any treatment or seek care elsewhere.
9. Elicit questions from the patient and determine whether he has any concerns.
10. Assess the patient's understanding of the information.
11. Obtain appropriate personnel to witness the signature of the patient.
12. Make sure that signed informed consent is included in the patient's chart.
13. Explain to the patient that he has the right to withdraw the consent and cancel the procedure at any time.
14. Give a copy of the signed consent form to the patient or the child's parent or legal guardian.
15. Avoid violating the right to self-determination whenever possible.
16. Provide reeducation as often as needed.
17. Document the procedure.