



American Professional Agency, Inc.



INFORMED CONSENT FOR PSYCHIATRISTS

Informed consent is an interactive process culminating in an agreement between a patient and a physician on a course of treatment. This process spans across all medical disciplines, including psychiatry. Signing a consent form is validation that the process has occurred and an agreement has been reached. Prior to initiating psychiatric treatment, informed consent should be obtained from adult patients or, if the patient is a minor, from a parent/guardian. Given the nature of psychiatric care -- often involving treatment over a period of many years -- consent should be viewed as an ongoing process.

Failure to obtain informed consent - or battery claims- can be alleged in malpractice cases against psychiatrists. Failure to obtain informed consent occurs when a physician does not provide adequate information to the patient to make an informed decision about treatment. The patient must show that if adequate information had been provided, he would have made a different decision. A battery occurs when a patient is treated or touched without prior consent. In claims for battery, the treatment need not to have been negligent or have caused an untoward result. Nonetheless, often the plaintiff will assert a negligence count along with failure to obtain informed consent or battery counts. The only negligence that needs to be shown is that the physician failed to obtain the consent of the patient.

In addition to legal protection, psychiatrists should embrace the informed consent process as a way to demonstrate concern for their patients. A well-performed consent process will make patients feel both informed and involved in their care and may help avoid a claim.

This resource is designed to take the mystery out of the informed consent process and to explain a psychiatrist's responsibility for obtaining and validating consent and to provide suggestions for conversations with patients.

Elements of Informed Consent

It is generally accepted that it is the psychiatrist's duty to obtain informed consent from each patient for each procedure and recommended course of treatment. To satisfy this duty, the psychiatrist must disclose sufficient information in each of the following areas:

1. The patient's diagnosis
2. The patient's prognosis
3. The proposed/recommended treatment
4. The risks and benefits associated with the proposed/recommended treatment
5. Alternative treatments
6. The risks and benefits of alternative treatments and
7. The risks of forgoing treatment should the patient refuse.

Minors/Incapacitated Persons

When dealing with minors, these same steps should be discussed with the parent or guardian. Consent should be obtained from the person who is legally responsible for the minor. If the minor is of such an age and maturity that he would understand the proposed treatment and the risks/benefits of the proposed treatment, the psychiatrist should also discuss these issues with the minor as well as the parent/guardian. Involving the minor patient in the treatment decision process is critical to forming an alliance with the patient and allows him to express his wishes despite his legal inability to choose.

In general, incapacitated persons cannot provide informed consent. There are situations; however, where a person lacks capacity in one area and not in others. It is important to determine the patient's ability to comprehend the recommended treatment and initiate the process for a substitute decision-maker, where appropriate and if not already in place. Each state has differing requirements for appointment of a substitute decision-maker. As such, psychiatrists should refer to specific state laws and regulations regarding this issue.

Black Box Warnings/Off-Label Use

When prescribing/recommending medications that are FDA approved but have black box warnings - or that are considered off-label - be sure to specifically discuss these warnings, and associated risks and benefits with the patient. Furthermore, the psychiatrist should document that the patient is aware of the warnings associated with the use of the proposed medication.

Consent for Clinical Trials

For psychiatrists who participate in clinical trials, a specific consent document is important for each particular study. The informed consent process should be continued throughout the duration of a clinical trial. As with any treatment or procedure, the psychiatrists involved in the trial should explain the details of the study before the participant becomes involved. The informed consent document should include details regarding the study including: purpose, duration, required procedures (if any), and the provider to contact. Further, risks and potential benefits of the experimental treatment should be explained both verbally and within the informed consent document.

Hospital/Clinic Settings

Psychiatrists who practice in a hospital/clinic setting, either on an inpatient or outpatient basis, should also engage in the process of obtaining a patient's informed consent; however the responsibility for signing a consent form, in other words validating the consent, is often delegated to hospital/clinic staff. Hospitals/clinics should establish policies for this practice. Issues to keep in mind when delegating responsibility include:

1. Only licensed professionals - including nurses, physicians, or midlevel providers - should obtain and witness the patient's signature
2. The conversation should be conducted in a private setting rather than a public area and before the medication or treatment is initiated
3. The patient should be asked to state the treatment he is consenting to and asked if all his questions have been answered to his satisfaction (for example, when prescribing medications, initiating ECT or other types of treatment), and
4. If a patient expresses unanswered questions or concerns, he should not sign the form until they have been answered by the psychiatrist.

While it is generally accepted that it is the responsibility of the physician recommending the treatment to obtain the patient's informed consent, when applicable, hospitals/clinics should also validate that the process has been conducted to the patient's satisfaction.

Emergency Situations

In both inpatient and outpatient settings, there are instances in which informed consent cannot be obtained from the patient due to an emergency situation. This can commonly occur in psychiatric settings as emergency issues may arise. Emergency issues can occur when a patient is an imminent threat to himself or others. When an emergency issue arises, thorough documentation of the inability to obtain informed consent is crucial.

An involuntary admission is one type of emergency issue in which consent may not be required. Although unnecessary, when practicable, obtaining consent from a patient who is being involuntarily committed may assist in forming an alliance with the patient.

Another instance when it may be impossible to obtain informed consent involves the unavoidable and forcible administration of a medication due to the patient being a threat to himself or others. Once the emergency situation passes; however, consent must be obtained from the patient for future administration of medications/treatment. Depending on the state; however, a court order may be required to administer medications/treatment without a patient's consent. As each state has specific laws and regulations, it is important to check with your particular state regarding this issue.



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Documentation of the Informed Consent Process

In litigation, when dealing with a claim for failure to provide informed consent, usually the content of the documentation is what is at issue rather than the format of the documentation itself. Documentation of informed consent should be included in the medical record either in a separate consent form or within the medical record treatment notes. There is debate regarding the way in which psychiatrists should document what is disclosed and discussed with the patient. One school of thought is that psychiatrists should list all of the information that was disclosed and the risks and benefits that were discussed. Critics of this method suggest that if a patient suffers a complication or adverse reaction to the treatment that is not included in the list, the psychiatrists may be subject to a claim of failure to obtain informed consent. Alternatively, psychiatrists may document in more of a general way such as stating "risks, benefits and alternatives discussed." Critics of this method believe that it is too general and does not document enough of the consent process.

Although informed consent documentation is evaluated on a case-by-case basis, generally the amount of documentation provided parallels the amount of protection gained. Therefore, psychiatrists should consider including a list of information that was disclosed and discussed, along with a preliminary statement such as "including but not limited to..." Furthermore, any patient education materials provided to the patient (such as brochures, print material or videos that were watched) should similarly be documented.

Special Situations

Special situations that should also be disclosed to patients and also require their informed consent include:

- Students performing or participating in the procedure/treatment
- Audio recordings
- The taking of any photographs or videos, and
- Any procedure or treatment that is experimental, including clinical trials or institutional review board consents.

Conclusion

The informed consent process is crucial in the practice of psychiatry to not only demonstrate concern for your patients but also to protect you from liability in the event that a claim is brought against you. This process should not be taken lightly and is an important step in the overall treatment of the patient.

Presented by:

Susan R. Chmielecki, RN, CPHRM, DFASHRM, JD
President, U.S. Professional Lines

Kristen M. Lambert, JD, MSW, LICSW, CPHRM
Vice President, Risk Management