

Witness Signature on Informed Consent Forms

Posted on [July 20, 2007](#) by [gotw](#)

Is a witness signature required on informed consent forms?

CMS published Revisions to the Hospital Interpretive Guidelines for Informed Consent on April 13, 2007. Tag A-0238 Medical Records [§482.24(c)(2)(v)] speaks to properly executed informed consent forms for procedures and treatments specified by the medical staff or by federal or state law if applicable, to require written patient consent.

The Interpretive Guidelines for this regulation state that an informed consent form, in order to be properly executed, must be consistent with hospital policies as well as applicable state and federal law or regulation. A properly executed informed consent form contains the following minimum elements:

- Name of the hospital where the procedure or other type of medical treatment is to take place
- Name of the specific procedure, or other type of medical treatment for which consent is being given
- Name of the responsible practitioner who is performing the procedure or administering the medical treatment
- Statement that the procedure or treatment, including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or the patient's legal representative
 - Material risks could include risks with a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but high degree of severity. Hospitals are free to delegate to the responsible practitioner, who uses the available clinical evidence as informed by the practitioner's professional judgment, the determination of which material risks, benefits and alternatives will be discussed with the patient.
- Signature of the patient or the patient's legal representative and
- Date and time the informed consent form is signed by the patient or the patient's legal representative.

If there is applicable State law governing the content of the informed consent form, then the hospital's form must comply with those requirements.

The Interpretive Guidelines then outlines additional information a well designed informed consent form might include:

- Name of the practitioner who conducted the informed consent discussion with the patient or the patient's representative.
- ***Date, time, and signature of the person witnessing the patient or the patient's legal representative signing the consent form.***
- Indication or listing of the material risks of the procedure or treatment that were discussed with the patient or the patient's representative.
- Statement, if applicable, that physicians other than the operating practitioner, including but not limited to residents, will be performing important tasks related to the surgery, in accordance with the hospital's policies and, in the case of residents, based on their skill set and under the supervision of the responsible practitioner.
- Statement, if applicable, that qualified medical practitioners who are not physicians who will perform important parts of the surgery or administration of anesthesia will be performing only tasks that are within their scope of practice, as determined under State law and regulation, and for which they have been granted privileges by the hospital.

Joint Commission standard RI.2.40 states that informed consent is obtained. The Elements of Performance outline what a hospital's informed consent policy should describe and what an informed consent discussion should include. The Joint Commission does not specify that the signature of the person witnessing the patient or the patient's legal representative signing the consent form be on the informed consent form.

Reference:

Revisions to the Hospital Interpretive Guidelines for Informed Consent, April 13, 2007
<http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter07-17.pdf>

Other resources: