

Title:**Best Practices in Gaining Informed Consent****Keywords:**

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Summary:

Medical research on humans can involve a number of ethical pitfalls; don't let informed consent be one of them!

Article: Best Practices in Gaining Informed Consent

Informed consent is an important part of any [medical research](#) involving humans. Consent means more than a simple signature on a form; instead it involves all steps taken in the [protection of human subjects](#). Physicians in charge of clinical research studies must be careful to educate potential subjects so they can make a truly informed decision.

Informed consent begins from the first point of contact, which can be a commercial, letter or pre-screening call. Those in charge of the [clinical research study](#) must be sensitive to keep all the information easy to understand and avoid medical and technical jargon. Excessive use of terminology may put the patient in danger because he or she does not understand what is being said, but is too embarrassed to ask for clarification.

After the initial contact, an in-person consent discussion should be arranged. This needs to be scheduled well in advance of the clinical trial start date to give the potential human subject time to consider their participation. During this session, give the subject general information about the clinical trial studies in which the person can participate. You will also be reviewing the purpose of the research, procedures, risks and potential benefits. Give the participant a copy of the consent form so he or she will be able to take it home, read it carefully and talk about it with family and a personal physician. If the person agrees to take part in the research trials, obtain the signed and dated consent form and give the participant a copy.

When there is minimal or more than minimal risk or during investigational device and drug trials, a licensed physician investigator listed on the protocol should get consent from the human subject. Study nurses and staff can help in the consent process, but the physicians should be actively involved in explaining risks and potential benefits.

If the subject is a physician investigator's patient, steps need to be taken to ensure the human subject does not feel an obligation or pressure to be part of the trial. The investigator can have a conversation with or send a letter to the potential participant, but he or she should ask a colleague to follow up with the patient. Investigators can also have nurses or colleagues introduce the patient to the study to take away any kind of undue pressure or stress on the patient.

Obtaining consent from children or minors has a different set of ethical issues and ethical principles than gaining consent from adults. Federal laws stipulate that consent must be given by a parent or legal guardian, but many states have different laws regarding how many parents need to consent and how to establish legal guardianship. In most cases, when the clinical trial involves minimal risk or has greater

than minimal risk but proposed direct benefit to the child, only one parent needs to consent. However, when clinical research involves greater than minimal risk and has no prospect of direct benefit for the child, both parents must give their permission. If the other parent is deceased, unknown, incompetent or reasonably unavailable, you only need to contact one parent. Be especially careful of these circumstances and document your reasons for only speaking with one parent. Try to obtain documentation proving the other parent's death, incompetence, etc.

Assent should also be gained from children seven years of age and older. Before beginning a discussion about the risks and potential benefits with the child, investigators should assess the potential subject's maturity and psychological state. If the investigator feels the child will not be able to process the details of the clinical trial, he or she should document why assent was not pursued.