

Enrollment of Subjects in Significant Pain

This policy applies to patients who would otherwise have decisional capacity but whose capacity may be compromised by significant pain.

Two types of protocols envision enrolling subjects in significant pain:

- A. Patients in whom pain may be expected in the future (women in labor and patients with sickle cell disease) and who are able to discuss and consent to participation in the protocol in advance;
- B. Patients who first present to the medical facility in significant pain at the time of possible enrollment.

Every effort should be made to obtain informed consent at a time when the patient's pain is minimized or alleviated, even if this requires multiple attempts at obtaining consent.

A. Patients in whom pain may be expected in the future:

Patients who can be approached in advance may be: identified, engaged in discussion, provided with the consent form for the protocol and other educational materials and invited to provide provisional consent. If at this time the patient refuses involvement in the protocol, it should be noted on the patient's chart and the patient should not be asked to provide consent at the time that the protocol would be initiated. Patients who provide provisional consent will be told that they will have a second opportunity to consider enrollment at the time the protocol is initiated and be given the opportunity to consent or to refuse at that time. Finally, the patients should be asked whether this provisional consent should be adequate to authorize participation, if at the time they are approached for actual involvement in the protocol, they are in too much pain to have the informed consent discussion and provide consent. If the patient chooses this option then he/she must sign a consent form indicating this choice and permitting later enrollment. All discussions with the patient should be noted in the patient's chart.

Because pain may compromise cognition and judgment, at the time of actual enrollment, the principal investigator or his or her designee must assess the capacity of the patient to provide ethically and legally adequate informed consent and must document that finding in the research record. If the patient is capable of providing informed consent the patient will be: engaged in the discussion of the risks and benefits of the protocol, reminded of his or her prior provisional consent and asked to consent to or to refuse participation. For those patients who lack capacity at the time of enrollment, only those who have signed a prior consent may be participants in the research.

B. Patients who first present to the medical facility in significant pain:

Patients who are in pain and are first approached at the time the protocol will be initiated must be capable of providing contemporaneous informed consent. The principal investigator or his or her designee must assess the capacity of the patient to provide ethically adequate informed consent. If the patient has capacity and consents to participation these facts must be documented in the patient's research record.

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