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Guidelines Regarding Who May Obtain Consent for Subject Participation in Research Activities

Introduction: These guidelines are to assist investigators in determining who is responsible for obtaining consent from prospective research subjects. The Code of Federal Regulations 45 CFR 46.116 states that "the investigator" must obtain "the legally effective informed consent of the subject or the subject's legally authorized representative." However, we recognize that it is not always possible for an investigator personally to obtain informed consent in a university setting where other individuals play an integral part in the care of patients who are eligible to participate in research protocols and where these individuals participate in conducting the research. Although the principal investigator (PI) is always legally responsible for the informed consent process and for establishing the necessary content of the informed consent discussion, it is often reasonable for designated, qualified individuals to obtain informed consent.

When obtaining informed consent for the research project the PI should be particularly cautious if the subject is in a dependent relationship with the researcher or may consent under duress. In that case, a well-informed researcher who is not engaged in the investigation and who is completely independent of this relationship should obtain the informed consent.

The PI is responsible for stating, on Form 1 (Section F) of the research proposal, who will obtain initial and ongoing consent. The reviewing committee determines whether the proposed consent procedure, outlined by the PI, is appropriate.

Issues influencing who may obtain consent for subject participation in research activities:

- the risk level of the research as determined by the reviewing committee, and
- the competence of the subject population.

Definitions of "greater than minimal" and "minimal" risk:

Research is deemed ***greater than minimal risk*** when the probability, and potential magnitude, of harm to subjects in the conduct of the proposed research are greater than those ordinarily encountered in daily life or during performance of routine physical or psychological examinations or tests.

Research is deemed ***minimal risk*** when the probability, and potential magnitude, of harm or discomfort anticipated in the research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
[45 CFR 46.102 (I)]

In minimal ***or*** high risk research, a selected designee who is well versed in the research may explain the research and obtain both oral and written consent. If, however, the prospective subject has questions that he or she would like to discuss with the PI or a co-investigator, such person should be contacted and arrangements made for further discussion before the subject signs the consent form. The reviewing committee may, in certain high-risk research, require that a PI personally be responsible for obtaining written consent.

When the PI selects a designee, the designee should sign the consent form at the time the subject signs it. The consent form also should be signed by the PI, not necessarily at the same time, to document his or her delegation for provision of the responsibility.

Consent in cognitively impaired patients: For research in cognitively impaired patients or patients whose condition may include cognitive impairment, see Guidelines for Research Involving Adult Subjects with Cognitive Impairment.

When the HSC Committee Requires the PI to obtain consent

In some instances the HSC reviewing committee will require that the PI obtain consent him/herself. Usually this occurs in research with greater than minimal risk. If this is the case and you wish to appeal this mandate, please provide the following justification:

1. Why the designee(s) is/are qualified to obtain consent.
2. Why the PI is unable to obtain consent from all the participants him/herself.
3. That the designee(s) has/have a thorough knowledge of all aspects of the study.
4. That the designee(s) has/have more time to spend with the participant, so that a comprehensive discussion of the research can take place.
5. That the participant be given the option to speak with the PI before making his/her decision to participate in the research.