From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Friday, October 29, 2004 1:50 PM
To: [Redacted]
Subject: RE: doubt regarding the informed consent form
Dear Ms [Redacted],

Thank you for your inquiry. The purpose of the section you make reference to in the ICH E6 Good Clinical Practice Consolidated Guidance is to help assure that a person who speaks and understands English, but does not read and write, or not physically able to talk or write can be entered into a study if they are competent and able to indicate approval or disapproval by other means. If (1) the person retains the ability to understand the concepts of the study and evaluate the risk and benefit of being in the study when it is explained verbally (still competent) and (2) is able to indicate approval or disapproval to study entry, they may be entered into the study. The consent form should document the method used for communication with the prospective subject and the specific means by which the prospective subject communicated agreement to participate in the study. An impartial third party (or witness as the ICH guidance suggests) should witness the entire consent process and sign the consent document. A video tape recording of the consent interview is recommended.a recommendation that is intended to help assure the subject understands

An impartial third party or impartial witness means someone who has no vested interest in the subject's participation in the study. Any number of people can fall into this category; a family member can be such a witness provided that person has no vested interest in the subject's participation in the study. It would not be good practice to identify as an impartial witness someone who conceivably gained some advantage from the subject's participation in a study. For example, it would not be good practice to use a member of the clinical trial staff as an impartial witness because one might question this person's impartiality (e.g, did he/she encourage the subject's participation in a study to ensure continued employment?).

I hope this information is helpful to you.

Sincerely,

Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Programs
OSHC/Office of the Commissioner
301-827-3340

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----
From: [Redacted]
Sent: Monday, October 18, 2004 3:44 PM
To: gcpquestions@oc.fda.gov
Cc: [Redacted]
Subject: doubt regarding the informed consent form

Dear all,

Good afternoon!
My name is [Redacted], I am [Redacted].
I would like to clarify a doubt regarding the informed consent form.

According to the ICH- GCP item 4.8.9, " **if a subject is unable to read or if a legally acceptable representative is unable to read, an impartial witness should be present during the entire informed consent discussion."**

I would like to know who is allowed to be the witness in this case?
We understand that should not be a person from the center (as for example, a nurse, a physician or any other employee or person related to the clinical study conduction or to the hospital).
Since we conduct trials for [Redacted]. Usually, the witness is one member of the recipient's family.
I would like to know if this procedure is correct.

I appreciate your attention.

Kind regards,
[Redacted]