From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Friday, April 23, 2004 9:57 AM
To: [Redacted]
Cc: Gilliam, Tina
Subject: RE: FDA question

Dear Ms. [Redacted],

Your e-mail message was referred to our office of a direct reply. I apologize for my delay in preparing a response and hope this information is still helpful to you.

The FDA informed consent regulation (under 21 CFR 50.20) specifically requires that the clinical investigator seek consent from the prospective subject (or the representative) under circumstances that provide the prospective subject sufficient opportunity to consider whether or not to participate in the research study and that minimize the possibility of coercion or undue influence. The practice of providing a prospective subject with a copy of the informed consent document to discuss with family members or others overnight or for several days can be helpful to the subject in making a reasoned decision about participation in the study. Thus, the practice is consistent with the regulations although it may not be necessary in all studies. However, if a potential subject asks for additional time to consider the study, they should be provided with the information about the study (that is, the written consent form) and allowed to take it to whomever they choose for consultation.

In the preamble to the final rule published in the Federal Register on January 27, 1981 (see our web site under the "Preambles" section; http://www.fda.gov/oc/gcp/preambles/46fr.html) under comment #51, FDA writes: "the consent form itself is merely an aid to assure that a required minimum of information is provided to the subject and that the subject consents. The entire informed consent process involves giving the subject all the information concerning the study that the subject would reasonably want to know; assuring that the subject has comprehended this information; and finally, obtaining the subject's consent to participate. The process, to be meaningful, should involve an opportunity for both parties, the investigator and the subject, to exchange information and ask questions."

If the subject (or parent of the subject) needs to consult with others to either understand the information or make a decision about participating in the study, then all efforts should be made by the investigator to facilitate this. During the informed consent process, the investigator (or his/her delegate) needs to adequately address all of the concerns the prospective subject has concerning the nature and conduct of the study. Discussions with family will likely occur "off-site," with the prospective subject using a copy of the informed consent document as a stimulus. Facilitating off-site discussions with family members or other individuals who might assist the prospective subject with making this very important decision by providing written information (the consent form) to be used in these discussion is what the informed consent process is supposed to be.

If an investigator failed to provide a copy of the consent form for overnight review, one could reasonably conclude that the prospective subject was not given sufficient opportunity to consider whether or not to participate in the study and, thus, adequate informed consent had not been obtained. If what you have described is in fact the policy of your IRB, I encourage you to advise them that that policy is inconsistent with FDA policy and every ethical standard written

on the topic of informed consent. See, for example, the Belmont Report by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (see http://www.fda.gov/oc/ohrt/irbs/belmont.html).

I hope this information is helpful to you. Should you have any additional questions, please feel free to contact our office by phone (301-827-3340) or via e-mail (gcpquestions@oc.fda.gov).

Sincerely,

Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Programs (HE-34)
Office of Science and Health Coordination
Office of the Commissioner

This communication does not constitute a written advisory opinion under 21 CAR 10.85, but rather is an informal communication under 21 CAR 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: Gilliam, Tina
Sent: Monday, April 12, 2004 6:52 AM
To: Beers Block, Patricia
Subject: FW: FDA question

-----Original Message-----
From: [Redacted]
Sent: Saturday, April 10, 2004 12:31 PM
To: wmail@oc.fda.gov
Subject: FDA question

Name: [Redacted]

E-Mail: [Redacted]

URL: http://www.fda.gov/oc/ohrt/irbs/default.htm

Comments: This is a question about the informed consent process in human research studies. I tried sending this email through a different contact link, but it bounced back to me (I don't really know which department should receive this query).

I am part of a group that conducts psychiatric research

with children, including treatment studies. The PI has a policy of not allowing potential participants to take consent forms home with them before they are signed (e.g. if the parent wanted to consult with someone else before consenting). She is concerned this could result in confusion and unwillingness to participate if the parent received contradictory and erroneous information from another party. She states that this is also a policy of our IRB, but I wanted to find out the FDA policy (if any) before contacting them. To me, it seems that this policy is potentially coercive and does not respect the subjects' right to autonomy. Could you please clarify? I realize that research subjects must be given copies of the consent form after they are enrolled in the study. Thank you very much.