From: Beers Block, Patricia
Sent: Thursday, February 12, 2004 1:38 PM
To: [Redacted]
Subject: RE: FDA question

Dear [Redacted],

I wanted to add one bit of information to the message below, to make my answer complete. There are instances when studies are conducted that present no more than "minimal risk" to the subjects. Minimal risk is defined in our regulations as follows: "minimal risk means that the probability and 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." All studies for investigational products must be evaluated by an organization called an Institutional Review Board (IRB). If the IRB concludes that a proposed study meets the definition of "minimal risk", the IRB may waive the requirement that the subject (or the subject's legally authorized representative) sign a written consent form.

I hope this addresses your question. Again if you would like any further clarification, please let me know.

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: Beers Block, Patricia On Behalf Of OC GCP Questions
Sent: Thursday, February 12, 2004 1:09 PM
To: [Redacted]
Subject: RE: FDA question

Dear [Redacted],

Your message was forwarded to our office for reply. Thank your for your inquiry.

Perhaps it would be helpful to clarify some of the issues about which you inquire. FDA normally does not conduct studies (although on very rare occasions we do) that rely on the participation of people or "human subjects" (that is people who take or use investigational products under controlled conditions) but focuses its attention on the review of studies that are conducted by clinical

investigators and sponsor-investigators on behalf of sponsors (e.g., companies that want to market products). FDA has regulations that it enforces that address what sponsors and clinical investigators must do when they conduct a research study for products that are regulated by FDA (e.g., medical devices, drug and biologic products). These regulations, found on our Good Clinical Practice Programs web page (http://www.fda.gov/oc/gcp/) under the heading "Regulations" (http://www.fda.gov/oc/gcp/regulations.html), are very specific as to what a person must be told both before and while he/she participates in a research study. Most particularly, all subjects must be provided information in writing that describes such things as the procedures that will be used throughout the study, the risks and benefits the subject might experience as a result of participating in the study, how long the study is expected to last, who to contact should the subject have any questions about the study, and a statement that participation in the research is voluntary (among other things). So, yes, most definitely, any person who agrees to participate in a research study must consent or, as you suggest have permission from the subject, to participating in the study.

I hope this information is helpful to you. Please let me know if you have any other questions; we'd be happy to address them as well.

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

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-----Original Message-----
From: Gilliam, Tina
Sent: Thursday, February 12, 2004 7:40 AM
To: Beers Block, Patricia
Subject: FW: FDA question

-----Original Message-----
From: [Redacted]
Sent: Wednesday, February 11, 2004 9:44 PM
To: wmail@oc.fda.gov
Subject: FDA question

Name: [Redacted]

E-Mail: [Redacted]

Address: [Redacted]

Comments: Does the FDA have to have permission from the people they are conducting the studies on?