From: OC GCP Questions
To: [redacted].
Subject: Consent Question
Date: Monday, March 21, 2016 1:09:25 PM

Good afternoon --

Please see FDA's information Sheet on Informed Consent --

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf It states –

To many, the term informed consent is mistakenly viewed as synonymous with obtaining a subject's signature on the consent form. FDA believes that obtaining a subject's oral or written informed consent is only part of the consent process. Informed consent involves providing a potential subject with adequate information to allow for an informed decision about participation in the clinical investigation, facilitating the potential subject's comprehension of the information, providing adequate opportunity for the potential subject to ask questions and to consider whether to participate, obtaining the potential subject's voluntary agreement to participate, and continuing to provide information as the clinical investigation progresses or as the subject or situation requires. To be effective, the process must provide sufficient opportunity for the subject to consider whether to participate. (21 CFR 50.20.) FDA considers this to include allowing sufficient time for subjects to consider the information and providing time and opportunity for the subjects to ask questions and have those questions answered. The investigator (or other study staff who are conducting the informed consent interview) and the subject should exchange information and discuss the contents of the informed consent document. This process must occur under circumstances that minimize the possibility of coercion or undue influence. (21 CFR 50.20.)

The consent form must contain information to allow the subject to make an informed decision about participation in a clinical investigation (see section III, FDA Informed Consent Requirements and Discussion).4 (21 CFR 50.20 and 21 CFR 50.25.) The consent form serves several purposes, including helping to ensure that the subject receives the required information, providing a "take home" reminder of the elements of the clinical investigation, providing contact information in case additional questions or concerns arise, and documenting the subject's voluntary agreement to participate.

The informed consent process often continues after the consent form is signed. Depending on the clinical investigation, additional information may need to be given to the subject, and the subject may need additional opportunities to ask questions and receive answers throughout the clinical investigation. (See section III.C.5, Providing Significant New Findings to Subjects, for a discussion of when findings developed during the clinical investigation must be communicated to subjects.)

Based on the information above and the limited information in your email FDA questions whether this person should be enrolled in a clinical study.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

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.

From: [redacted]
Sent: Monday, March 21, 2016 12:07 PM
To: OC GCP Questions
Subject: Consent Question

Hello,

If a transplant subject refuses to read or have the consent read to them and basically says I don't want to hear about I just want to be on the study. What should a physician do in this case?

Thank you,
[redacted]

[redacted]

[redacted]

[redacted]