From: OC GCP Questions
To: [redacted]
Subject: RE: General Question regarding Re-Consenting of a Subject
Date: Wednesday, February 12, 2014 2:22:00 PM

Dear ώwŜŘl·ŎůŜŘϐ-

Thank you for your question. Based on the limited information provided in the hypothetical scenario, I believe you indicated that Subject A has dropped out of the study; so therefore, they have withdrawn their consent to continue participating in the study.

Should Subject A wish to rejoin the study at a later date AFTER their withdrawal, there a number of determinations that must be made, and this should be done on a case-by-case basis in light of the nature of the study. For example, it would have to be determined that the subject still qualifies to be in the study, that it is in the subject's best interest to rejoin the study and the subject willingly agrees to rejoin the study, that the sponsor of the study is aware that a subject who previously dropped out of the study wishes to rejoin the study, etc.

If it is determined that Subject A is permitted to rejoin the study after careful assessment of the specific situation, then Subject A must sign the current IRB-approved informed consent form, thus documenting their consent to participate in the study. The initial consent form signed by Subject A when they originally agreed to be in the study cannot be extended to cover the subject's decision to rejoin the study because the original consent was withdrawn when Subject A withdrew from the study.

I recommend that if you run into such a scenario, you work closely with your sponsor, investigator, institution and IRB to discuss the details and determine all that is required to allow a subject who has withdrawn from a study to rejoin the study.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

Janet Donnelly, RAC, CIP
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Office of Special Medical Programs, Food and Drug Administration

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From: [Redacted]
Sent: Monday, February 10, 2014 4:42 PM
To: OC GCP Questions
Subject: General Question regarding Re-Consenting of a Subject

Good afternoon,

I hope this correspondence finds you well. I have a general hypothetical question I am hoping you can help me with in regards to clinical trials and human subjects. For purposes of this question, please see the following scenario: Subject A was a part of a clinical research study, in which the proper consent was agreed upon and executed accordingly. Sometime during the study, Subject A decides that they no longer wish to be a part of the study and leaves. Subject A, at a later date, now wants to re-join such study. My question is whether it is necessary to re-consent Subject A after they have left such study, but now wish to re-join the same study.

Any guidance is greatly appreciated.

Best,
[Redacted]