From: OC GCP Questions
To: [redacted]
Subject: RE: Withdrew Informed Consent
Date: Monday, August 25, 2014 2:20:00 PM

Dear [Redacted]-

Thank you for your question. As you mentioned, FDA has a guidance document titled, "Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials" (see http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm126489.pdf) which describes the FDA's longstanding policy that already-accrued data, relating to individuals who cease participating in a study, are to be maintained as part of the study data. The guidance document also discusses key points regarding FDA's policy on the withdrawal of subjects from a clinical investigation, whether the subject elects to discontinue further interventions or the clinical investigator terminates the subject's participation in further interventions. The last bullet under section IV. (FDA Policy) says:

> If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the investigator must not access for purposes related to the study the subject's medical record or other confidential records requiring the subject's consent. However, an investigator may review study data related to the subject collected prior to the subject's withdrawal from the study, **and may consult public records, such as those establishing survival status. [emphasis added]**

The guidance indicates that the investigator must not access the subject's medical records or other confidential records for purposes of the study (i.e., clinical outcome information such as survival) because the subject has not provided their consent for this, or has withdrawn their consent. However, as the guidance indicates, this does not preclude investigators from looking at public records (e.g., public records establishing survival status).

With that said, it is difficult for me to know whether your IRB-approved informed consent form did or did not say anything specific about collecting survival data. Also, I assume that if a subject withdraws their consent for the study, including any follow up and survival as you indicated, that this means they do not agree to any follow up contact (e.g., directly contacting the subject or other representative regarding survival), or accessing the subject's medical records or other confidential records for this information. I also don't know (however unlikely) whether or not your IRB-approved informed consent form mentions anything specific about accessing public records for survival information. You may want to consult your consent document to make sure that there isn't anything in there that would otherwise preclude your investigators from accessing public records (e.g., a specific statement that the investigator would **not** access public records about survival status for any subject who withdraws consent unless they otherwise agree to this), and consult your legal counsel if you have any specific questions.

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: Friday, August 22, 2014 9:47 AM
To: OC GCP Questions
Subject: Withdrew Informed Consent

Good morning,
This question has come up several times in the past month and we need guidance on how to handle the situation. If a patient withdraws consent for clinical, follow-up and survival on a study, is it okay to search public records for survival information? I know there is a statement in the Guidance for Sponsors, Clinical Investigators and IRBs that an investigator may review study data related to the subject collected prior to the subject's withdrawal from the study, and may consult public records, such as those establishing survival status. But if the patient withdrew consent for survival are we bond to this or can we review public records?

Thanks in advance,

[Redacted]