From: OC GCP Questions
To: [redacted]
Subject: RE: Question on subjects deceased prior to end of study
Date: Friday, May 01, 2015 10:32:32 AM

Thank you for your question; however, I am a bit confused by the statement that a waiver of consent may be considered for subjects that have expired "***after the original follow up period, but before they signed consent for the additional follow up period***." To my thinking, if the original consent (and presumably the original study protocol) had a finite defined period of time in which a subject is going to be followed and a subject completes that time, then their participation in the original study has been completed. Any subsequent collection of data (except for data collected from public records) on subjects who have completed their participation in the original study would require consent as if they were entering a new study. In the case where the subject subsequently died after they have completed the original study period, but before they could be approached to sign a new consent document, then obtaining consent would obviously not be possible. So, if I understand the question correctly, what the investigator is trying to do is to get access to a deceased individual's medical records so that data can be collected from the period of time when the deceased subject completed the original study until the subject's death. Such activity would not be regulated by the FDA and would most likely come under the Health Insurance Portability Act (HIPPA) regulations. I recommend contacting the Office for Civil Rights (http://www.hhs.gov/ocr/privacy/) with your question. Likewise, if the study is supported or conducted by the Department of Health and Human Services (e.g., NIH grant) then you may want to address your question to the Office for Human Research Protections (http://www.hhs.gov/ohrp/). Finally, as background, you should be aware that FDA regulations limits waiver of informed consent to emergency research only as described under 21 CFR 50.23 and 50.24. What you describe here does not sound like it would be eligible for a waiver of informed consent under FDA regulations.

I hope this information is helpful to you. If further information is needed please feel free to contact us once again at the official GCP mailbox, gcp.questions@fda.hhs.gov.

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From: [redacted]
Sent: Thursday, April 30, 2015 11:30 AM
To: OC GCP Questions

Subject: Question on subjects deceased prior to end of study

Hello FDA,

I have a question regarding a study on outcomes of [redacted]. The study is minimal risk (collection of data) in this group of patients and has been going on for a number of years. The study is now being amended to extend the follow up period for a number of years. Surviving subjects will be asked to continue and be re-consented. The study is asking for a waiver in cases where the subject has expired after the original follow up period, but before they signed consent for the additional follow up period. Is it appropriate to grant a waiver of consent to a deceased subject since they really are no longer considered a research subject if not living? Since the study has both living and deceased subjects, how does one deal with this?

[redacted]

[redacted]