From: OC GCP Questions
To: [redacted]
Subject: Question concerning consent and retention of records
Date: Thursday, February 19, 2015 2:19:36 PM

Good afternoon –

A subject can withdraw from a study at any time. Any data collected during the time the subject was actively enrolled should not be destroyed. The sponsor should retain records/data that were collected during the trial, prior to subject's withdraw.

The relevant US FDA regulations on record retention for clinical trials are as follows:

For drug and biologic studies, 21 CFR 312.62(c) states: "Record retention. An investigator shall retain records required to be maintained under this part for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified."

For device studies, 21 CFR 812.140(d) states: "Retention period. An investigator or sponsor shall maintain the records required by this subpart during the investigation and for a period of 2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol."

As you will note, the retention period is dependent on whether the data will be used to support a marketing application with FDA. The sponsor is usually the only party totally knowledgeable about the status of its investigational product (e.g., whether it has been approved for marketing, whether the sponsor no longer intends to seek marketing approval, etc.). Therefore, it is best to check with the study sponsor regarding the status of the investigational product and the need to retain the study records. You should check with each of the study sponsors before discarding any study files.

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

From: [redacted]
Sent: Wednesday, February 18, 2015 3:37 PM
To: OC GCP Questions
Cc: [redacted]
Subject: Question concerning consent and retention of records

Good afternoon,
I have a question that needs some guidance from the FDA. In a clinical trial with more than minimal risk, as an example a subject is unable to give consent at the time of enrollment and consent is given by a legally authorized representative. If the subject then becomes capable at a later time to decide whether to participate and he/she decides to withdraw consent, does the subject have the right to have retrospective records destroyed or does the sponsor have the right to maintain those records.
Thanks

If you were enrolled in this study by your Legally Authorized Representative and later change your mind, you may drop out at any time. If you were enrolled by your Legally Authorized Representative and choose to withdraw from the study, the data that has already been collected can be destroyed and not used for research purposes if that is your wish.

[redacted]