From: OC GCP Questions
To: [redacted]
Cc: CDER DRUG INFO
Subject: FW: Query Regarding Data Retention When Subject Withdrawn
Date: Thursday, October 26, 2017 5:43:00 PM
Attachments: [redacted]

Dear [redacted] -

Thank you for your question, which was forwarded to our office for a response. In general, if a subject withdraws his/her consent to continue participating in a clinical investigation, then all study procedures should cease, including analyses of biospecimens. There should be no further data accrued once an individual makes the decision to withdraw his/her consent.

As addressed in the FDA guidance you referenced, a withdrawal of consent does not extend to the data already obtained during the time the subject was enrolled; i.e., prior to the withdrawal. FDA's longstanding policy has been that all data collected up to the point of withdrawal must be maintained in the database and included in subsequent analyses, as appropriate.

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
Policy Analyst

Office of the Commissioner
Office of Good Clinical Practice
U.S. Food and Drug Administration

From: [redacted]
Sent: Monday, October 23, 2017 1:59 PM
To: CDER DRUG INFO
Subject: Query Regarding Data Retention When Subject Withdrawn

Dear FDA info,

I am requesting additional clarification after reading “Guidance for Sponsors, Clinical Investigators, and IRBs
Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials” published in October 2008.

In situation when biosample was collected prior to subject withdraw, but not yet analyze after subject withdraws from study. Can the sponsor continue to analyze previously collected sample?

Please direct question to:
Office of the Commissioner (OC)
Good Clinical Practice Program (GCPP)

Best regards,