From: OC GCP Questions
To: [redacted]
Subject: RE: Question about biomarker testing
Date: Thursday, July 23, 2015 3:37:00 PM

Dear [redacted]
Your question was forwarded to the Office of Good Clinical Practice by CDER Drug Info.

Based on the limited information provided, we are unable to determine whether the informed consent form(s) signed by the subjects permit the use of the archived tumor blocks for additional specimen collection, or whether any of the specimens may be used for biomarker testing. We recommend that you follow up with your IRB to determine whether the informed consent document(s) signed by the subjects fully address this issue, or whether additional informed consent must be obtained before the archived specimens and tumor blocks can be used for the additional bio-marker testing for [redacted]. You may also want to consult with the FDA division that is overseeing your studies.

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov .

Best regards,

Sheila

Sheila Brown, RN, MS
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

From: [redacted]

Sent: Tuesday, July 21, 2015 11:33 AM

To: CDER DRUG INFO; [redacted]

Subject: Question about biomarker testing

To whom it may concern

Please can you provide your opinion on an issue related to informed consent and the use of biological samples for central bio-marker testing.

Background:

- In the XXX study, patients originally consented to allow the sponsor take a sample from their archived tumor block for central biomarker testing. All patients signed informed consent stating that they would be in the study for a 5-year period, but that the sponsor may test samples for as long as 15 years from the study start, after which time the samples will be destroyed. This language is included in Informed Consent Form versions 1-7.

- Later in the study, the sponsor decided to discontinue biomarker testing. They also reduced the follow-up period, which reduced the time on study from 5 years to 2 years. At that time, patients signed a new consent stating that they would be on the study for a 2-year period and tissue collection for genetic analysis would be stopped, but any material and information collected so far would still be analyzed.

- These patients are no longer receiving treatment and many of them have completed follow-up. The study is still within the follow-up period, and we are in the process of consenting patients who have come off study to participate in extended follow-up to collect survival data.

Question:

The sponsor would like to perform central biomarker testing for those patients who provided the original consent. However, we have learned that a sample was not taken from the archived tumor for some patients while they were in the study. Based on the language in the informed consent forms signed by the patients, we would like your opinion on whether it is acceptable for the sponsor to take a sample from the archived tumor for central biomarker testing, or whether additional consent is required to take samples for testing. Please note that the sample will come from the archived tumor blocks that are retained at the clinical sites in a biorepository, and the testing will be for [redacted] as stated in the original informed consent form. Some of the subjects are now out of the study (they completed the 5-year period OR the 2-year follow up they consented to)

Thank you very much for your help.