From: OC GCP Questions
To: [redacted]
Subject: Procedures not performed "solely" to determine eligibility
Date: Wednesday, February 22, 2017 12:05:00 PM
Attachments: [redacted]

Good afternoon –

Please see our answer below. Your question was discussed with others in OGCP at FDA.

From the limited information in your email, it appears the primary reason for obtaining the “extra” biopsies is to conduct molecular and biomarker testing, the results of which are being used for clinical purposes. As you stated in your email, the procedure for obtaining biopsies are collected for non-research clinically appropriate reasons.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Friday, February 17, 2017 1:52 PM
To: OC GCP Questions
Subject: Re: Procedures not performed "solely" to determine eligibility

Thank you, Doreen!

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Good afternoon –

I will have to consult with a few of my colleagues before I can get back to you. We can probably respond by the middle of next week.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Thursday, February 16, 2017 2:22 PM
To: OC GCP Questions
Subject: Procedures not performed "solely" to determine eligibility

Hello,

I'm hoping someone can answer a question regarding when a procedure is a "research procedure" in the context of evaluating a patient for a potential clinical trial. I did not quite know definitely how to answer.

The question put to me is this: Clinical trials are often the preferred or only treatment options for patients with advanced cancers. It is standard practice for physicians to order extra core biopsies be

taken from patients undergoing diagnostic biopsies for the purpose of molecular testing (not research), biomarker testing (not research), but also knowing that often tumor tissue is needed to enroll a patient onto a clinical trial.

In the FDA guidance "Screening Tests Prior to Study Enrollment - Information Sheet," it is stated that "informed consent must be obtained prior to initiation of any clinical screening procedures that is performed **solely** for the purpose of determining eligibility for research."

In this case, the additional core biopsies would be ordered regardless if a specific clinical trial was available, but also with the knowledge that these additional cores would be used for evaluation for enrollment **if** a clinical trial was available or becomes available. Thus, the additional cores would not be taken **solely** for the purpose of research, but that it is one of a few expressed purposes for obtaining extra cores. In other words, the physician knows the additional cores may be used for research at the time of ordering the additional cores, but there are other non-research clinically appropriate reasons for ordering extra cores. This is not a case wherein a physician orders a procedures and it just so happens to be used later to screen a patient for enrollment in a clinical trial. This is a case wherein a physician orders a procedure expressly knowing it is necessary if the patient is to be evaluated for enrollment in a clinical trial, but again, the procedure is not being orderly **solely** for research purposes.

Is this a "research procedure" for which informed consent and IRB review is required?

Thank you,