From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, May 19, 2004 9:11 AM
To: **[Redacted]**
Subject: RE: Specimens used for Research

Dear **[Redacted]**, There are a few comments that I'd make related to the guidance that you've received thus far (and that you've described below).

Under FDA's medical device regulations, "subject" is defined as a "...human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease." See 21 CFR 812.3(p). Note that this definition includes specimens and does not mention anything about whether the specimens are identifiable or not. Thus, FDA's regulations appear to apply equally to specimens that are identifiable and those that have been deidentified.

Your IRB would need to determine whether the research would be eligible for review under an expedited review procedure, presumably invoking category 5. If I were the reviewer, I would question whether the fact that the specimens will be collected in the future impacts on the study's eligibility for expedited review because I would find it harder to say (if this study were approved) that the specimens were collected solely for nonresearch purposes--but that may be the case.

Informed consent of the subject would need to be obtained prior to surgery. FDA regulations do not contain a waiver provision or exception to the requirement for informed consent that would apply in this situation.

If your institution has a multiple project assurance or federal wide assurance with OHRP and if, in that assurance, you agreed to review all research regardless of the source of funding in accordance with that assurance then the guidance from OHRP would apply. And, finally, yes, a protocol/IRB application would need to be developed and submitted to your IRB for its standard review process.

I hope this is helpful in filling in those holes.

Sincerely,

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----
From: **[Redacted]**
Sent: Tuesday, May 18, 2004 3:53 PM

To: 'gcpquestions@oc.fda.gov'
Subject: Specimens used for Research

I received a reference from **[Redacted]** in regard to my phone question--thank you.
Expecting to be challenged locally, I just want to be sure I clearly understand the guidance I've obtained.

A local pharmaceutical company would like to procure from our hospital **[Redacted]** tissue specimens obtained from patients with rheumatoid arthritis undergoing **[Redacted]** or joint replacement. Cells from such specimens would be used in vitro to test compounds in development for arthritis.

Since these specimens will be obtained prospectively from future discarded clinical samples, this research activity is not Exempt, although it may qualify for Expedited Review. Consent will either need to be obtained from the subject at the time of surgery, or waiver of consent requested and justified.

The samples will be anonymous and totally deidentified.

My guidance comes from the OHRP regs which would apply to this situation even though the study is not federally funded. Is that correct?

And also, the pharmaceutical company would need to submit a protocol +/or IRB application establishing either a specimen repository or specific research study protocols.... in other words, follow our established IRB process for review.

Have I missed any "loop holes", they ask me? :)
Just want to be sure.

Thank you,
[Redacted]