From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Thursday, September 09, 2004 12:21 PM
To: [Redacted]
Cc: [Redacted]
Subject: RE: Guidance: Research Involving Coded Private Information/
Biologica l Specimens

Dear [Redacted],

I asked CBER to clarify their rationale for posting the OHRP guidance on their website. I understand from CBER that they routinely post guidances of interest on their website. The posting was for information purposes only regarding research conducted or supported by HHS. For guidance on related FDA-regulated research, you can contact (for medical devices) Joanne Less or (for biologics) Elizabeth Callaghan.

I hope this information is helpful to you.

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy, GCPP, FDA

-----Original Message-----
From: [Redacted]
Sent: Tuesday, August 31, 2004 9:08 PM
To: gcpquestions@oc.fda.gov
Cc: [Redacted]
Subject: FW: Guidance: Research Involving Coded Private Information/
Biologica l Specimens

Dear Good Clinical Practices Office:

Could you please clarify the intent of CBER in listing the document ("Guidance: Research Involving Coded Private Information or Biological Specimens") in the forwarded e-mail below as guidance and sending out this e-mail. Was the intent for information purposes only regarding research conducted or supported by HHS, or was CBER indicating that this guidance could apply to research that is under the oversight of CBER and/or the other divisions of FDA? The guidance itself states that it is limited to research that is conducted or supported by HHS. The guidance also states that it does not apply to FDA regulated research, as follows:

"NOTE: Some HHS conducted or supported research involving coded private information or
specimens may be subject to Food and Drug Administration (FDA) regulations. The FDA
regulatory definitions of human subject (21 CFR 50.3(g), 21 CFR 56.102(e)) and subject (21
CFR 312.3(b), 21 CFR 812.3(p)) differ from the definition of human subject under HHS
regulations at 45 CFR 46.102(f). This guidance document does not apply to research regulated
by FDA that involves coded private information or specimens. Anyone needing guidance on
such FDA-regulated research should contact the FDA."

We request this clarification so that we can be prepared if a sponsor submitting FDA regulated research cites this guidance and requests a waiver of consent for research with coded private information or biological specimens. This type of request would most likely come from one of the sponsors who are conducting research with the various [Redacted] and other diagnostic assays that are under CBER's jurisdiction.

We appreciate any clarification you can provide on this issue.

Sincerely,

[Redacted]

-----Original Message-----
From: CBER NEWS [mailto:cbernews@CBER.FDA.GOV]
Sent: Monday, August 30, 2004 6:58 AM
To: CBERINFO@LIST.NIH.GOV
Subject: Guidance: Research Involving Coded Private Information/
Biologica l Specimens

Guidance on Research Involving Coded Private Information or
Biological Specimens
Posted: 8/30/2004

This document is available on the Internet at
http://www.fda.gov/cber/guidelines.htm#spec

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