From: Toth-Allen, Jean
Sent: Wednesday, June 21, 2006 9:14 AM
To: [Redacted]
Subject: RE: question about informed consent regulations for FDA regulated studies

Dear [Redacted],

Please excuse the delay in my response.

If a study meets IND exemption criteria or IDE exemption criteria other than those related to diagnostics, the study is likely either a post-market study or a marketing study. (The second study type can result in information relevant to a labeling change.) In both cases, these would be considered FDA-regulated studies. While they may be exempt from the main parts of 21 CFR Parts 312 or 812, they are not exempt from human subject protections contained in Parts 50 and 56.

As to an address to pose a question directly to CDER, please try DRUGINFO@fda.hhs.gov.

Hope this information is useful.

If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.

Sincerely yours,
Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
OSHC, Office of the Commissioner, US 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.

From: [Redacted]
Sent: Wednesday, June 07, 2006 12:46 PM
To: OC GCP Questions
Subject: FW: question about informed consent regulations for FDA regulated studies

Thank you Dr. Toth-Allen. That is a helpful clarification. I have two follow-up questions:
1) In informing our investigators about the need to have informed consent for any human data/specimens used in "FDA-regulated" studies (outside IVD studies) I'd like to be crystal clear about what falls under FDA-regulation when studies do not involve an IND or IDE. I realize this is a basic question, but is any study that involves the administration of a drug or device that does NOT involve an IND or IDE considered to not fall under "FDA regulation"?
2) What email address did you use to contact CDER? I sent an email to DSI@fda.hhs.gov that is listed on http://www.fda.gov/oc/gcp/contactogcp.html#drug regarding this question, and the email bounced back to me as "unknown address".
Thanks much!
[Redacted]

-----Original Message-----
From: Toth-Allen, Jean [mailto:jean.toth-allen@fda.hhs.gov]
Sent: Tuesday, June 06, 2006 10:15 AM
To: [Redacted]
Subject: RE: question about informed consent regulations for FDA regulated studies

Dear [Redacted]:

Thank you for your inquiry regarding application of the new guidance regarding IVD specimens. Please excuse my delay in responding.

The guidance document is only applicable to in vitro diagnostic (IVD) studies regulated as devices. FDA would not agree with the interpretation that studies using specimens that are undertaken as an investigational new drug (IND) are exempt from the informed consent regulations merely because the definition of subject in the IND regulations does not specifically include specimens. The Food, Drug, and Cosmetic Act (the Act) requires informed consent for investigational studies of both pharmaceuticals and devices, with the only exemptions applicable in emergency situations. There is also no mention of delinked or anonymized samples in the Act. As a result, informed consent from all subjects involved in the study in any way has been required for all FDA-regulated studies. It is for that reason that the guidance in question was written, to provide enforcement discretion for scenarios that are not specifically addressed in the Act and which FDA sees as presenting impediments to new product development, particularly in the emerging fields of pharmacogenomics and pharmacogenetics. Your inquiry has been forwarded to both the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) and it is possible they may also respond to you with more specific comments in this regard, as most of their studies are regulated as INDs.

With regard to the definitions of research found in 45 CFR Part 46 which include consideration of certain studies as "not human subject research," these definitions would not apply to FDA-regulated research, even if the research is federally-funded. Both sets of regulations would apply if a study is both federally funded and FDA-regulated but FDA regulations would need to be followed where they are the more stringent.

Hope this information is useful.

If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.

Sincerely yours,
Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
OSHC, Office of the Commissioner, US FDA

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From: [Redacted]
Sent: Wednesday, May 24, 2006 3:04 PM
To: OC GCP Questions
Subject: question about informed consent regulations for FDA regulated studies

I'm hoping you can help clarify my understanding of an issue:
[Redacted] recently released this summary on the FDA guidance on informed consent for invitro diagnostic device studies, which clarifies situations in which the imperative to seek informed consent from sources of tissue donations may not be enforced by the FDA.
In the [Redacted] summary, they make the following assertion: Unlike the definition in the IDE regulations, the definition of a "subject" under IND regulations makes no reference to "a human...on whose tissues and investigational device is used". Their interpretation is that "tissue studies in support of an IND application arguably do not require investigators to obtain informed consent from specimen sources".
1) Is this a reasonable interpretation?
2) Beyond tissue studies per se, if research involves involving FDA regulated projects involve no interaction/intervention with humans, nor identifiable private information, can it also be considered "not human subject research" as in the OHRP guidance
http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf.
Thank you for your assistance!
[Redacted]