From: Lepay, David on behalf of OC GCP Questions
Sent: Tuesday, July 23, 2002 4:22 PM
To: 'Michelle L. Carter'
Subject: RE: Experimental medicine

Dear Ms. Carter:
You are correct. There are no additional FDA regulatory requirements for informed consent of HIV participants beyond those found in 21 CFR Part 50. If this is a pediatric study, provisions of our Subpart D regulation (found in 21 CFR Part 56) would also apply --- i.e., including the child's assent and parental consent.

Sincerely,
Dave Lepay

-----Original Message-----
From: Michelle L. Carter [mailto:MLCarter@mijs.com]
Sent: Tuesday, July 23, 2002 4:19 PM
To: OC GCP Questions
Subject: RE: Experimental medicine

Dr. Lepay,

Thank you for your prompt reply. I apologize that I was not clear. I have 21 CFR 50, and I simply wanted to be certain that that was all that is necessary. There is extensive federal regulation of HIV, and I wanted to be sure nothing futher was necessary to protect the special needs of those infected with HIV. Is 21 CFR 50 all that is necessary?

Thank you,
Michelle Carter

-----Original Message-----
From: OC GCP Questions [mailto:GCPQuestions@OC.FDA.GOV]
Sent: Tuesday, July 23, 2002 4:06 PM
To: Michelle L. Carter
Subject: RE: Experimental medicine

Dear Ms. Carter:
I'm not clear as to the interpretation of your question. As part of any informed consent in a clinical investigation, the subject must be informed
of the risks and benefits of the study as well as alternatives to participation (which would include other treatments: for HIV or the condition in question). For effective informed consent, the subject needs
to understand these risks/benefits and alternatives, which certainly means
some basic understanding about the disease/condition under study.

The required elements of informed consent in an FDA-regulated clinical investigation are specified in regulation and can be accessed in 21 CFR Part
50 (available through FDA's GCP website at www.fda.gov/oc/gcp [link to Regulations]).

If I have not answered your query, perhaps you can help me better understand
the information that you are seeking.

Sincerely,
David A. Lepay, MD PhD
Senior Advisor for Clinical Science and
Director, Office for Good Clinical Practice,
OSHC, Office of the Commissioner, US FDA

-----Original Message-----
From: Michelle L. Carter [mailto:MLCarter@mijs.com]
Sent: Tuesday, July 23, 2002 3:30 PM
To: gcpquestions@oc.fda.gov
Subject: Experimental medicine

When you are administering experimental medicine, does the informed consent contract of an HIV patient require HIV specific language?