From: Hommel, Carolyn - OC
Sent: Tuesday, April 13, 2004 4:41 PM
To: [Redacted]
Subject: RE: Link to the guidance for studies conducted under 21 CFR 50.24

Dear Mr. [Redacted]:

In response to your question, FDA does not maintain a list of state or local laws related to informed consent or informed consent waivers. Perhaps a law school near you would be able to direct you to resources (e.g., statutes, databases) in this area, that could provide the information you seek.

Also, I wanted to let you know that I contacted the Center for Biologics Evaluation and Research about your concerns. They will evaluate the information that you provided, and determine any necessary followup.

I hope this is helpful.

Sincerely,

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
5600 Fishers Lane, Room 9C24
Rockville, MD 20857

Phone: 301/827-3340
Fax: 301/827-1169

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, April 13, 2004 4:35 PM
To: 'Hommel, Carolyn - OC'
Subject: RE: Link to the guidance for studies conducted under 21 CFR 50.24

Dear Mrs. Hommel,

Thank you for the information. On more question: The sponsor stated that some states have laws against informed consent waivers; Florida does for sure and New Jersey may also have a law against it. Could you send me a list of states and cities that do not currently allow waivers? Such as the types listed in appendix "A" "(2) If state or local law(s) prohibits entry of subjects into research without their express consent. 21 CFR 50.24 does not preempt state or local laws. Those conducting emergency research need to be

familiar with the laws of the specific states in which the research will be conducted."

Thank you so much,
[Redacted]

-----Original Message-----
From: Hommel, Carolyn - OC [mailto:Carolyn.Hommel@OC.FDA.GOV]
Sent: Monday, April 12, 2004 3:51 PM
To: [Redacted]
Subject: Link to the guidance for studies conducted under 21 CFR 50.24

Dear Mr. [Redacted]:

As promised, here is the link for FDA's draft guidance for Sponsors, Clinical Investigators, and Institutional Review Boards on the Exception from Informed Consent Requirements for Emergency Research (21 CFR 50.24).
http://www.fda.gov/ora/compliance_ref/bimo/err_guide.htm

After we talked, it occurred to me that you may also be interested in reading the "preambles" to these regulations. The "preambles" are the Federal Register notices that announce FDA's interest in formulating, amending or repealing a rule, and offering the public the opportunity to comment on the agency's proposal. The Federal Register notice explains the legal issues and basis for the proposal, and provides information about how interested persons can submit written data, views, or arguments on the proposal. Any comments that are submitted are addressed in subsequent publications that are part of the agency's decision-making process.
The preamble includes all of the printed information immediately preceding the codified regulation. The preamble provides information about the regulation such as why the regulation is being proposed, the FDA's interpretation of the meaning and impact of the proposed regulation, and in those cases where the agency has solicited public comment, the agency's review and commentary on those comments . The preamble can also include an environmental impact assessment, an analysis of the cost impact, comments related to the Paperwork Reduction Act, and the effective date of the implementation or revocation (as the case may be) of the regulation.

The preambles are posted on FDA's Good Clinical Practice website: http://www.fda.gov/oc/gcp . Once there, in the middle column, click on "New! Preambles to GCP Regulations". The two notices that you are interested in are:

* Protection of Human Subjects, Proposed Rule, September 21, 1995, and
* Protection of Human Subjects; Informed Consent and Waiver of Informed Consent Requirements in Certain Emergency Research; Final Rule (October 2, 1996)

I hope this is helpful to you.

Sincerely,

Carolyn Hommel

Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination Office of the Commissioner U.S.

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