From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Friday, September 15, 2006 1:26 PM
To: [purged]OC GCP Questions
Cc: Lee, Bonnie; 'Carome, Michael A (HHS/OPHS)'
Subject: RE: public health surveillance research

[purged],

Yes, links to FDA's regulations pertaining to human subject protection and the conduct of clinical trials can be found on FDA's Good Clinical Practice webpage: http://www.fda.gov/oc/gcp . Once at the site, click on "Good Clinical Practice/Clinical Trials Regulations" in the middle column.

Carolyn

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 14-B17
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.

From: Carome, Michael A (HHS/OPHS) [mailto:Michael.Carome@hhs.gov]
Sent: Thursday, September 14, 2006 4:37 PM
To: [purged]; OC GCP Questions
Cc: Lee, Bonnie
Subject: RE: public health surveillance research

[purged],

If the public health research in question is conducted or supported by the Department of Health and Human Services (HHS), the relevant regulations would be the HHS regulations at 45 CFR part 46 which can be viewed on the Office for Human Research Protections website at http://www.dhhs.gov/ohrp/humansubjects/guidance/45cfr46.htm.

Mike

Michael A. Carome, MD
CAPT, U.S. Public Health Service
Associate Director for Regulatory Affairs
Office for Human Research Protections

From: [purged]
Sent: Tue 9/12/2006 5:53 PM
To: OC GCP Questions
Cc: Carome, Michael A (HHS/OPHS)
Subject: RE: public health surveillance research

Hello Bonnie,
Thank you for getting back to me. The products we'd be using in the research are opioid analgesics. Are the regulations you mentioned below available to download from the FDA website?
[purged]

From: Lee, Bonnie [mailto:bonnie.lee@fda.hhs.gov] On Behalf Of OC GCP Questions
Sent: Tuesday, September 12, 2006 3:46 PM
To: [purged]
Cc: Carome, Michael A (OS)
Subject: RE: public health surveillance research

Dear [purged],

Generally, if your research involves an FDA regulated product, FDA's regulations would apply. To know which regulations, I would need to know the type of product you would be using in your research. I suspect that your public health

surveillance research is instead subject to the HHS regulations at 45 CFR 46; those regulations may apply to this type of research. I have copied Mike Carome in the Office for Protection from Research Risks; he may be able to help you.

I'm sorry that I can't be more helpful.

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.

From: [purged]
Sent: Monday, September 11, 2006 12:56 PM
To: OC GCP Questions
Subject: public health surveillance research

Hello,
I wanted to find out the FDA regulations for public health surveillance research. I see the guidelines for clinical research, but was wondering what the FDA required for surveillance. Can you point me to some documents?
Thank you!

[purged]