From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Friday, September 17, 2004 10:09 AM
To: [Redacted]
Subject: RE: question
Dear [Redacted],

The proposed regulation you refer to has not been published yet. It is an amendment to the exception from the general requirement for informed consent in certain circumstances involving the use of investigational in vitro diagnostic devices to identify chemical, biological, radiological, or nuclear agents in a potential terrorist event or other public health emergency.

The agency is proposing this action because it is concerned that, during a potential terrorism event or other public health emergency, delaying testing of specimens to obtain informed consent may threaten the life of the subjects or others who have been exposed to or who may be at risk of exposure to a chemical, biological, radiological, or nuclear agent.

The Unified Agenda represents projects and initiatives that are active within FDA/HHS; updates on these initiatives will be posted as they become available on our Good Clinical Practice website (www.fda.gov/oc/gcp).

I hope this information is 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.

-----Original Message-----
From: [Redacted]
Sent: Wednesday, September 08, 2004 9:59 AM
To: 'gcpquestions@oc.fda.gov'
Subject: question

Thank you in advance for responding to this question.
In the HHS/FDA unified agenda, there is a reference to a final regulation under development entitled, "Determination That Informed Consent is Infeasible or is Contrary to the Best Interest of Recipients." I'd like to ask when and if a proposed rule on this topic was ever published (I have not been able to find one), and if not what the FDA hopes to accomplish through the proposal.
Thanks,
[Redacted]