From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Thursday, August 29, 2002 10:45 AM
To: [purged]
Subject: RE: Criteria for enrolling prisoners

Dear [purged],

FDA does not have additional requirements that pertain to research involving prisoners; rather, our general requirements for IRB review and informed consent (21 CFR parts 56 and 50) would apply to such research. However, if the research is conducted or supported by the Department of Health and Human Services (HHS), or conducted in an institutions that has assured HHS that it will review all research in accordance with the Common Rule, then the research would be subject to 45 CFR 46, including Subpart C which provides additional protections pertaining to research involving prisoners as subjects. Although those additional protections are not required by FDA, they are a good model to follow. You can find the HHS regulations at: http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm. I hope this information is helpful to you.

Sincerely,

Bonnie

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-----Original Message-----
From: [purged]
Sent: Wednesday, August 28, 2002 9:33 AM
To: 'gcpquestions@oc.fda.gov'
Subject: Criteria for enrolling prisoners
Importance: High

For informational purposes can you please advise on what is required in
Studies involving prisoners.

I know that the IConsent has to reflect the trial will involve prisoners and
that the IRB has to have a prisoner as one of its members.

What are the other criterias?

Thank you,
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