From: Hommel, Carolyn - OC
Sent: Monday, April 19, 2004 3:45 PM
To: [Redacted]
Cc: Lepay, David; Lee, Bonnie
Subject: RE: FDA FORM 1572 /Which of several IRBs?

Dear Dr. [Redacted],

In your e-mail, you asked if more than one IRB can be listed in item 5 of the Form FDA 1572, for example, if multiple IRBs are responsible for reviewing and approving a study. The information you provided during our telephone conversation this morning was helpful in clarifying your question. You described a situation in which a study will be conducted by several sites, each of which has its own (local) IRB that will review and approve the study. You said that after each local IRB completes its review, the local IRB sends a report of its review/approval to the IRB of the Surgeon General of the Army, which then conducts its own review, in order to approve the funding of the study and allow it to proceed. You also noted that the local IRBs will perform continuing review of the study, but that the IRB of the Surgeon General of the Army will not do any continuing review of the study.

Item 5 of the Form FDA 1572 requests the "Name and address of the Institutional Review Board (IRB) that is responsible for review and approval of the study(ies). Because both the local IRB and the IRB of the Surgeon General of the Army will be conducting reviews, and each site would need the approval of both to proceed, I would recommend listing both names on the 1572.

I hope this is helpful.

Sincerely,

Carolyn Hommel
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Office of the Commissioner
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-----Original Message-----
From: [Redacted]
Sent: Monday, April 12, 2004 2:25 PM
To: 'david.lepay@fda.hhs.gov'
Cc: [Redacted]
Subject: FDA FORM 1572 /Which of several IRBs?

Dr. David Lepay,

The FDA Form 1572, in item 5, requires an investigator to enter the name and address of the IRB that is responsible for review and approval of the study.
However, the problem comes when more than one IRB needs to be involved in the review and approval of a study, before it may begin.

When that happens, the question that we need answered is, "Which of these multiple, or even two, IRBs needs to be listed on Form 1572."

Would you be kind enough to help me with a response? I am certain that this is not the first time you have been asked this question.

Best regards,
[Redacted]