From: Woollen, Stan - OC
Sent: Thursday, February 03, 2005 11:02 AM
To: [Redacted]
Cc: CDER DRUGINFO
Subject: Enrollement in competing studies

Dear [Redacted],

You won't find guidance on this topic on our webpage. Many of the questions you raise are ethical. I would recommend you consult with your IRB.

All things being equal, however, my advice would be to let the subject decide for him self which trial they would like to participate in.

Sincerely,

Stan W. Woollen
Associate Director for Bioresearch Monitoring
Good Clinical Practice Programs
OSHC, Office of the Commissioner

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: Monday, January 31, 2005 10:12 PM
To: CDER DRUGINFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [Redacted]
E-Mail: [Redacted]

Comments: I have looked at your site extensively and cannot find any guidance for the following:
If an institution has competing studies ie.

a patient with a heart failure qualifies for more than one study in a department, how should the decision be made on which study the patient should be enrolled in? What if the studies pay the institution about the same? What if there is a big difference in how much an institution recieves for one study versus another? What if one is an industry sponsored study and another is sponsored by an investigator in the department ie. holds the investigator holds the IND?
Thank you for any guidance or resources you can provide me with.

[Redacted]