From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Friday, November 19, 2004 3:49 PM
To: [Redacted]
Cc: CDER DRUGINFO
Subject: RE: clinical protocol review

Dear [Redacted], Your email (below) was forwarded to me for response. Although it is acceptable for most members to receive a summary of the protocol, you need to be sure that at least one member of the [Redacted] receives and reviews all the information and is in a position to discuss it at the meeting. We also expect that if a member wants to review the full protocol and investigator's brochure they will be made available to that member with sufficient time to look through it (e.g., having it at the meeting may not suffice depending upon the member's concerns). I hope this is responsive to your question and is helpful.

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA

-----Original Message-----
From: [Redacted]
Sent: Monday, November 01, 2004 2:47 PM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [Redacted]

E-Mail: [Redacted]

Comments: We are reviewing our [Redacted] policies and procedures. Currently we give a copy of the protocol to each [Redacted] member. Is it necessary for each member of the [Redacted] to receive a copy of the clinical trial protocol and or Investigator brochure or is it sufficient to receive a summary document of the protocol? We would like to reduce some of the paper but need to be compliant with the regulations.
Thanks.