From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Tuesday, February 14, 2006 12:30 PM
To: [purged]
Subject: RE: Question about television interview

Dear [purged],

Under FDA's emergency research rule (21 CFR 50.24), the agency requires consultation with the community from which research subjects will be drawn and in which the research will be conducted as well as disclosure of information about the research before it occurs and the results of the research when it is concluded. Participation in television programs is one of the ways to effectively communicate information to the communities and (if it's a call-in show) obtain feedback. I think that it is reasonable to provide some guidance to the individual who will be talking about the need for balance in information he/she provides. FDA's regulations at 21 CFR 312.7(a) address the promotion of an investigational drug and the issue you raise:

(a) Promotion of an investigational new drug. A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug. This provision is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay media. Rather, its intent is to restrict promotional claims of safety or effectiveness of the drug for a use for which it is under investigation and to preclude commercialization of the drug before it is approved for commercial distribution.

I hope this information is helpful to you.

Sincerely,

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA
Note new email address: Bonnie.Lee@FDA.HHS.GOV
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: [purged]
Sent: Tuesday, February 07, 2006 6:10 PM
To: gcpquestions@oc.fda.gov
Subject: Question about television interview

To whom it may concern:

We are a central IRB and have had a request from one of our investigators who would like his sub-investigator to go on a cable television show and speak about a study in which they are currently investigators.

Are there any guidelines on the role of the IRB in this matter? Is a television interview about an ongoing study allowed? If so, are there any guidelines to be followed? Does the IRB have a responsibility to review/approve anything?

It seems as if this could easily cross a line into recruitment, for which the IRB would normally approve any materials. Yet, it is a non-scripted interview and approval of specific dialog/recording would be impossible.

I appreciate your consideration of this matter.

Thank you,
[purged]