From: Toth-Allen, Jean
Sent: Thursday, October 26, 2006 2:59 PM
To: [purged]
Cc: Dada, Kavita
Subject: Review of images in Phase II and III clinical trials

Dear [purged]:

Your inquiry was forwarded to us for response.

I am not entirely sure what you mean by an "Independent Review Committee," particularly given the context of your question. There are two bodies that are associated with clinical studies that take part in study review: an institutional review board (IRB), also known as an ethics committee (EC) outside of the United States, and a Data Monitoring Committee (DMC), also known as a Data Safety Monitoring Board (DSMB).

IRBs receive regular progress reports for studies they have approved. While such reports might summarize image analyses, particularly if they demonstrate results and/or adverse effects, IRBs would not receive the actual study reports nor the images themselves and would have neither the means nor reason to break a study blind.

DMCs are set up specifically to take periodic looks at a study to determine if there are undue risks to subjects - or obvious benefit for studies related to serious diseases or conditions. Their purpose is to determine if the study is putting subjects at undue risks and therefore needs to be modified or even stopped or is so successful it should be considered complete so applications for approval can go forward as soon as possible. Therefore, they need to unblind the study by the very nature of their purpose. It is obviously essential that they have procedures in place to ensure that information resulting from such unblinding is not disclosed beyond the board members except when it is necessary to protect the safety or welfare of study subjects. FDA has issued a guidance document regarding the functioning of DMCs which is available at http://www.fda.gov/OHRMS/DOCKETS/98fr/01d-0489-gdl0003.pdf.

Hope this information is useful. If you need further information and/or have additional questions, please submit them to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.

Sincerely yours,

Jean Toth-Allen, Ph.D.
Good Clinical Practice Program
OSHC, Office of the Commissioner, US FDA

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: Monday, October 23, 2006 5:52 PM
To: CDER DRUG INFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [purged]

E-Mail: [purged]

Comments: Are there any regulatory documents/procedures describing how an Independent Review Committee has to analyze the images from PhaseII or III clinical trials in a blinded way (CT, MRI, X-rays)?