From: Lepay, David on behalf of OC GCP Questions
Sent: Sunday, July 25, 2004 7:30 AM
To: **[Redacted]**
Cc: Lee, Bonnie; Hommel, Carolyn - OC
Subject: RE: question

Dear **[Redacted]** :
Bonnie Lee from our office provides the following response to your query:

Dear **[Redacted]**, I am concerned that your limited definition of a research activity could cause misleading information to be provided to subjects because the changes in the consent form or the advertising were not also reflected in the protocol. Basically, it's the IRB's responsibility to review the information that will be provided to subjects either through the consent process or through related advertising for the study. If there are minor changes to that information, during the period for which approval has been given, then those minor changes can be reviewed through the expedited review process. See 21 CFR 56.110(b). The expedited reviewer may approve the changes or refer them to the full committee for review. As stated in the regulations and as further described in Ms. Hommel's email, the expedited reviewer may not disapprove the change.

I hope this is helpful to you.

Sincerely,

David A. Lepay, MD PhD
Senior Advisor for Clinical Science and
Director, Good Clinical Practice Programs,
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: **[Redacted]**
Sent: Wednesday, July 21, 2004 9:17 AM
To: OC GCP Questions
Subject: RE: question

Please replace my last e-mail with this one, I think this better explains my inquiry:

[Redacted] 's interpretation of a "change in research activity" is the result of a change in the protocol. Minor changes to informed consent documents or advertising materials previously approved by **[Redacted]** do not usually occur as the result of a protocol change. Therefore, it is our opinion that if a reviewer uses the expedited review process in these cases, and disapproves a change, full board review would not be required. Do you agree?

Another situation:

If a reviewer approves the protocol and informed consent for a study that qualifies for expedited review but requires changes to the advertising materials why would this require full board review? According to the FDA Information Sheets, advertisements are considered an extension of

the informed consent. The revised advertisement does not reflect a change in research activity. Why would this require full board review?

Regards,
[Redacted]

-----Original Message-----
From: Hommel, Carolyn - OC [mailto:Carolyn.Hommel@OC.FDA.GOV]**On Behalf Of** OC GCP Questions
Sent: July 09, 2004 1:31 PM
To: **[Redacted]**
Subject: RE: question

Dear Ms. **[Redacted]**:

I think your interpretation is correct.

FDA's regulations pertaining to expedited review state, "...In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the nonexpedited review procedure set forth in 56.108(c)." [See 21 CFR 56.110.]

So, I would interpret this to mean that if the individual performing the expedited review believes that the research activity (e.g., consent changes, recruiting materials) should be disapproved, then the matter should be referred for review by the convened IRB, as required by
21 CFR 56.108(c).

I hope this answers your question.

Sincerely,

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
5600 Fishers Lane, Room 9C24
Rockville, MD 20857

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-----Original Message-----
From: **[Redacted]**
Sent: Tuesday, July 06, 2004 2:45 PM
To: FDA
Subject: question
Importance: High

When informed consent changes and/or recruiting materials qualify for expedited review, and the expedited reviewer disapproves the revisions, would the FDA require review by full board? It is our interpretation of the regulations that only a change in research activity that is disapproved requires full board review.

Your prompt response is greatly appreciated.

Thanks,
[Redacted]