From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Friday, July 09, 2004 2:31 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)
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Rockville, MD 20857

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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: 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]