From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Tuesday, September 13, 2005 2:52 PM
To: [Redacted]
Subject: RE: IRB Review

Dear Ms. [Redacted]:

Your question about whether IRB review is required for studies involving a legally marketed device that is used according to the approved labeling was sent to me for a response. I apologize for the delay in responding to you.

Studies that are exempt from the IDE regulation (such as ones that are conducted with legally marketed products in accordance with the approved/cleared labeling) should still have IRB review and informed consent (IC). If the study is being conducted for submission to FDA, then FDA's IRB and IC regulations need to be followed [21 CFR 56 and 50]. However, when studies of legally marketed devices are being conducted to address reimbursement issues, marketing issues, etc., and are not being conducted for submission to FDA, we suggest that the IRB consider reviewing the study under the Common Rule (see, for example, the HHS codification of the Common Rule at 45 CFR 46).

Depending on the device and other aspects of the study, the IRB may be able to review the study using an expedited review procedure. Here is a link for FDA's expedited IRB review requirements: http://www.fda.gov/oc/gcp/regulations.html [Once there, click on Part 56, and select 56.110 from the list]. Here is a link to the list of procedures that are eligible for expedited review: http://www.fda.gov/oc/ohrt/irbs/expeditedreview.html. It is up to the IRB to decide whether or not they will do an expedited review. The IRB can always do a full review, if they feel it is necessary.

I hope this is helpful.

Sincerely,

Carolyn Hommel
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Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
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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: Wednesday, July 20, 2005 1:30 PM
To: gcpquestions@oc.fda.gov
Subject: IRB Review

I am trying to clarify the IRB review process for studies being conducted using humans for legally marketed devices. My question is:

If a physician is evaluating a legally marketed product during a procedure involving a patient (consumer preference test) AND they are using the device within it's approved indication or intended use AND they will provide feedback to the manufacturer on the device, is it required by FDA regulations that an IRB be involved in the review and approval of this activity?

While a legally marketed device may be exempt from IDE requirements if used within it's intended use, I am having trouble confirming that the IRB review (and subsequent NSR assessment) is required for these types of studies.

Thank you for your assistance,

[Redacted]