From: Brown, Sheila (OGCP)
To: [redacted]
Cc: Kalb, Soma
Subject: Transfer of IRB Oversight Responsibility to an External IRB for Device Trials
Date: Thursday, October 15, 2015 3:39:00 PM
Attachments:

Dear [redacted],

Although the statute (federal law governing FDA oversight of medical products, of which a part of Section 520(g) is quoted below) requires local IRB approval for medical device clinical trials, the Center for Devices and Radiological Health (CDRH), has generally followed 56.114 (cooperative review for IRBs) and the policy for use of a central IRB for multi-site studies that is outlined in the guidance document referenced in this email. The IDE regulations at 21 CFR 812 are silent on this topic.

Section 520(g) of the Food, Drug, and Cosmetic Act (Section360j.(g)(3) of the U.S. Code) states:

> "Procedures and conditions prescribed pursuant to paragraph (2)(A) shall require, as a condition to the exemption of any device to be the subject of testing involving human subjects, that the person applying for the exemption-
>
> (A) submit a plan for any proposed clinical testing of the device and a report of prior investigations of the device (including, where appropriate, tests on animals) adequate to justify the proposed clinical testing-
>
> (i) to the local institutional review committee which has been established in accordance with regulations of the Secretary to supervise clinical testing of devices in the facilities where the proposed clinical testing is to be conducted…
>
> http://uscode.house.gov/view.xhtml?req=%28title:21%20section:360j%20edition:prelim%29%20OR%20%28granuleid:USC-prelim-title21-section360j%29&f=treesort&edition=prelim&num=0&jumpTo=true

21 CFR 56.114 states, "In complying with these regulations, institutions involved in multi-institutional studies may use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort."

FDA's guidance, entitled "Using a Centralized IRB Review Process in Multicenter Clinical Trials" may be helpful. It can be found at http://www.fda.gov/RegulatoryInformation/Guidances/ucm127004.htm

You may also contact Soma Kalb, Ph.D., Director of the CDRH IDE Program, at soma.kalb@fda.hhs.gov for device trial questions.

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov .

Best regards,

Sheila

Sheila Brown, RN, MS
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

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From: [redacted], October 14, 2015 3:34 PM
To: OC GCP Questions
Subject: Transfer of IRB Oversight Responsibility to an External IRB for Device Trials

To Whom It May Concern,

I would like some clarification as to whether or not oversight responsibility can be transferred from a local institutional IRB for **device trials** to an external IRB. During some recent commentaries I read related to the NPRM changes, one stated that local IRB's would still be responsible for reviewing studies that require local IRB review, such as device trials. This is the first I have heard this, and I am not clear if I misunderstood what is being said, or if indeed this is correct. Please let me know the regulatory requirements related to transfer of IRB oversight for device trials, or if my question should be directed to someone else. Your assistance is truly appreciated.

Kind Regards,
[redacted]