From: OC GCP Questions
To: [redacted]
Subject: RE: Non-significant risk device determination.
Date: Monday, March 20, 2017 9:29:00 AM
Attachments: [redacted]

Dear [redacted],

Per 56.108(c), "Except when an expedited review procedure is used (see §56.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting."

FDA's information sheet guidance, *Significant Risk and Nonsignificant Risk Medical Device Studies*, states the following in Section V.:

- IRBs should have standard operating procedures that explain how the IRB makes SR and NSR determinations and that the decision should be documented. FDA considers this determination to be part of the IRB's responsibilities for conducting its initial review of a study. (See 21 CFR 56.108)

- IRBs should make the SR or NSR determination about a study by reviewing relevant information at a convened meeting. This information includes the description of the device, reports of prior investigations conducted with the device, the proposed investigational plan, and subject selection criteria. The sponsor should provide the IRB with a risk assessment and the rationale used in making its SR or NSR determination.

- An IRB may agree or disagree with the sponsor's initial NSR assessment.

- If the IRB determines the study is NSR, the IRB may approve the study using the criteria at 21 CFR 56.111. The study may begin without submission of an IDE application to FDA.

- If the IRB disagrees with the sponsor's NSR assessment and decides the study is SR, the IRB must tell the clinical investigator, and where appropriate, the sponsor. (See 21 CFR 812.66)

The SR/NSR information sheet can be found on FDA's website at https://www fda.gov/ucm/groups/fdagov-public/@fdagov-afda-gen/documents/document/ucm126418.pdf

If the IRB is not comfortable making an SR/NSR determination for a particular study, they may ask the study sponsor (or sponsor-investigator) to submit a "pre-submission" to FDA for a study risk determination. Information for this process may be found in the instructions on pp 20-21 in the guidance, *Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff*, which can be found at http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm311176.pdf . The submission should be sent to CDRH at the following address:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

You may also find the following information sheets to be helpful:
Frequently Asked Questions About Medical Devices
https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf

IRB Continuing Review after Clinical Investigation Approval at https://www fda.gov/ucm/groups/fdagov-public/@fdagov-afda-gen/documents/document/ucm294558.pdf .

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

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From: [redacted]
Sent: Friday, March 17, 2017 11:54 AM
To: OC GCP Questions
Subject: Non-significant risk device determination.

Good morning. I have a question regarding who can make the determination of a non-significant risk device. We have a device that a researcher would like us to make a determination as to whether it is non-significant risk. My IRB administrator did not feel comfortable making that determination, so we sent it to our IRB Chair who determined that it is non-significant risk (and the study is minimal risk). Therefore we would like to know if the Chair (or qualified IRB member) is allowed to make that determination, or whether that needs to be made at a fully convened board meeting.
Thank you,
[redacted]

[redacted]