From: Wolanski, Nicole
To: [redacted]
Subject: SR/NSR determination at full board review
Date: Wednesday, November 18, 2015 3:21:00 PM

[redacted],

It was a pleasure meeting you at the PRIM&R conference in Boston over the weekend. You asked whether significant risk (SR)/nonsignificant risk (NSR) determinations of a device study have to be made at a full board meeting of the IRB. Please see the information below in response to that question.

- SR/NSR determinations at convened meeting

  As stated in the Significant Risk and Nonsignificant Risk Medical Device Studies Information Sheet, "IRBs should make the SR or NSR determination about a study by reviewing relevant information at a convened meeting." In making a SR/NSR decision, the IRB is determining if the sponsor's categorization of the study as NSR is accurate, i.e., that the study should not instead be considered SR.

  Note, if an IRB agrees that a proposed study is NSR and approves it, the study then meets the criteria for abbreviated requirements and ***is considered to have an IDE*** (see 21 CFR 812.2(b)). So, an NSR device study is considered to have an IDE application, and therefore, does not meet the criteria in expedited review category 1(b)(i).

- Expedited Review by an individual IRB member

  Expedited review provides the only condition under which an IRB decision can be made by an individual member of the IRB rather than at a convened meeting. Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure, as stated in 21 CFR 56.110.

  For a device study to meet condition 1b under expedited review, it must be an exempt investigation/not require an IDE application, see below for examples:

  - 812.2(c)(2) - FDA considers devices that are cleared ***or approved*** (i.e., legally marketed) *and* used in a study according to its cleared/approved labeling to be exempt in this way (not just cleared devices as the regulation specifically states).

  - 812.2(c)(3) - Devices studies with investigational products that could qualify for the exempt status under 1(b)(i), and therefore expedited review. These are usually in vitro diagnostic (IVD) studies for which the sponsor strictly adheres to the conditions for exemption.

  For studies that are exempt from the IDE regulations, the IRB does not need to decide whether the study poses a significant risk or nonsignificant risk, however, the IRB must still review the study in accordance with the IRB regulations before the investigation may begin.

If an investigation does not meet one of the conditions for expedited review, it must be reviewed by the full board (21 CFR 56.108(c)).

I hope this information is helpful. Please send any additional questions to gcp.questions@fda.hhs.gov.

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