From: OC GCP Questions
Sent: Friday, October 23, 2015 1:18 PM
To: [redacted]
Subject: RE: IRB review of NSR device

Dear [redacted]:

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. (Though studies that are approved via expedited review must be shared with the full IRB at the next convened meeting.) If a study does not meet one of the conditions for expedited review (See: http://www.gpo.gov/fdsys/pkg/FR-1998-11-09/pdf/98-29748.pdf), it must be reviewed by the full board no matter what its status is under 21 CFR Part 812, the Investigational Device Exemption (IDE) regulation.

The conditions for a device study to be NSR differ from the requirements a study must meet to be eligible for expedited review. In general, the latter requires minimal risk to the subjects. There is no requirement that an NSR study be minimal risk, just not a significant risk as defined at 21 CFR 812.3(m). Since in making a SR/NSR decision, the IRB is actually determining if the sponsor's categorization of the study as NSR is accurate, i.e., that the study should not instead be considered SR, such a decision could not be made under expedited review for which an even stricter norm is applied - that the study present only minimal risk to subjects. While it is not impossible for an NSR study to also be a minimal risk study, that is very uncommon.

Guidance documents that may be useful to you include:

Significant Risk and Nonsignificant Risk Medical Device Studies: http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf
IRB Continuing Review After Clinical Investigation Approval: http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM294558.pdf (Refer to the section on Expedited Review beginning on page 11)

I hope that this information is helpful. Please contact us at gcp.questions@fda.hhs.gov if you have further questions. Since many questions and concerns regarding good clinical practices have been addressed over time, some individuals may find it useful to access a set of redacted GCP inquiries found at the following web address: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm .

Sincerely,

Bridget A. Foltz, MS, MT(ASCP)
Policy Analyst, Office of Good Clinical Practice
Office of the Commissioner, Food and Drug Administration

From: [redacted]
Sent: Thursday, October 22, 2015 4:20 PM
To: OC GCP Questions
Subject: IRB review of NSR device

Hi,

Please assist us with the following question:

"Does a minimal risk NSR device study being conducted under abbreviated IDE requirements need to be reviewed by a full convened board for initial approval? Or can this study be reviewed via expedited review for initial approval?"

I have been researching this topic extensively and everything I have read has indicated that this review could be done by either the full board or via expedited review if it is in fact NSR **and** minimal risk.

I appreciate your time.

Kind regards.