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PROTECTING RESEARCH SUBJECTS AND RESEARCHERS

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Using Single IRBs in FDA-Regulated Research (#3)

We continue this month with more of FDA's many proposals to change existing regulations and to add new ones on the protection of human research subjects.

For instances where FDA believes an exception to single IRB review is allowable, the agency focuses on particular types of studies, as we see in the following FEDERAL REGISTER notice.

"2. Cooperative Research Involving a Highly Specialized FDA-Regulated Medical Product

FDA is proposing, at § 56.114(b)(2)(ii), an exception from the use of single IRB review for research involving a highly specialized FDA-regulated medical product for which unique, localized expertise is required" (87 Fed. Reg. 58758, September 28).

When a Mandated Single IRB Review Is an "Obstacle"

"For example, for certain highly specialized FDA-regulated medical products, expertise in the use of the product may be limited to only a few specialists at geographically dispersed locations.

In such cases, the investigators, research staff, and IRBs associated with the investigational sites would have the critical knowledge and training relevant to the product, and therefore, these IRBs would have the capability to most efficiently conduct initial review and oversee the research, while maintaining appropriate human subject protections.

We believe that mandating the use of a single IRB could be an obstacle to initiating important research when the localized expertise is readily available, but none of the IRBs associated with the investigational sites can serve as the single IRB of record.

FDA believes that this proposed criterion for exception from use of single IRB review would be met in such a case, although we expect that such exceptions would be rare occurrences.

3. Cooperative Research on Drugs Exempt From the IND Regulations

FDA is proposing, under § 56.114(b)(2)(iii), an exception from mandatory use of single IRB review for research on drugs that is exempt from the requirements for an IND

NOTE #1: Quoted materials in this newsletter appear exactly as originally published in source documents, including any misspellings, grammatical errors, or missing words. However, we will on occasion insert words or edit text and/or formating in brackets [ ] to make the material easier to read.

NOTE #2: Emphases are added to articles by HRR by underlining or adding ***bold/italics*** to selected text, unless stated otherwise.

NOTE #3: Articles **T**o **B**e **C**ontinued in subsequent issues are marked at the end of the article with **{TBC}**.

ALSO IN THIS ISSUE

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application under § 312.2(b) (21 CFR 312.2 (b))" (ibid).

"Lower Risk" for Human Subjects Is Key

"FDA does not require submission of an IND application for certain clinical investigations of lawfully marketed drugs that meet the criteria under § 312.2(b) (see 52 FR 8797, March 19, 1987). Such studies are generally lower risk clinical investigations of products that are lawfully marketed.

Unlike clinical investigations that are conducted under the IND requirements, increased efficiencies leading to earlier initiation of clinical investigations exempt from the IND requirements generally would not provide the benefit of bringing new drugs or new uses of drugs to patients sooner.

4. Cooperative Research on Medical Devices That Meets the Abbreviated Requirements or the Requirements for Exempted Investigations ….

FDA is proposing an exception from the requirement for single IRB review under § 56.114(b)(2)(iv) for research on medical devices that meets the abbreviated requirements under § 812.2(b) or that meets the requirements for exempted investigations under § 812.2(c), to the extent [that] the exempted investigation would be subject to part 56" (supra at pp. 58758-58759).

Single IRB Review "Efficiency" May Not Matter Too Much

"This proposed exception would encompass research that presents a lower risk to subjects and, in certain instances, may not involve a therapeutic intervention or invasive procedure (e.g., studies of certain diagnostic devices).

The proposed exception would also encompass research that is not focused on bringing new devices to the market for patients.

Therefore, the initial administrative burden of establishing cooperative review agreements may not be offset by the anticipated benefits of single IRB review efficiencies, such as improvement in the review and handling of safety reports and faster initiation of research that facilitates the development of new medical products ….

FDA is requesting feedback from stakeholders on the following specific circumstances to assist the agency in determining whether additional exceptions to the single IRB review requirement would be warranted" (supra at p. 58759).

When a Single IRB Cannot Meet Needs of Community

"First, FDA is requesting comment on whether it is appropriate to include an exception for cooperative research for which use of a single IRB is unable to meet the needs of specific populations.

Such an exception might apply, for example, to research that involves recruiting members of a distinct patient population or community (e.g., cultural, religious) for which the local perspective is particularly important if the single IRB of record is unable to obtain sufficient supplemental information to consider that community's needs.

SACHRP recommended that this exception be considered and provided the following example that illustrates when this exception may be appropriate.

There may be an instance where research involves 'an intervention with pregnant women at one site and then follow-up with the neonates at another site.

Unless a single IRB had adequate expertise in pregnant women, obstetrical practices, and neonatal medicine, human subject protections might best be served by having the elements relevant to pregnant women reviewed by an IRB that has extensive expertise with that area and the element relevant to the neonates reviewed by a pediatric IRB.'

In this example, particularly for obstetrical or pediatric research that involves complex medical issues, a single obstetrical or pediatric consultant on an IRB that mainly reviews research in adults may not have the sufficient range of expertise necessary to review the protocol" (ibid). © {TBC}