FDA's Proposed Rule for IRBs on Cooperative Research

In September 2022, the FDA announced a Notice for Proposed Rule Making (NPRM) titled Institutional Review Boards; Cooperative Research. This rule, if finalized, will mandate the use of a single IRB (sIRB) for review of all FDA-regulated cooperative research. Below, we provide Salus IRB clients with pertinent information regarding this proposed rule and its potential impact.

Definitions

Cooperative Research: Clinical investigations that involve more than one institution (i.e. multi-site research).

Single IRB (sIRB): An IRB that serves as the reviewing IRB for all sites involved in cooperative research.

Summary of the Proposed Rule

The FDA's proposed rule will replace the current cooperative research requirements (21 CFR 56.114) and will:

1) Require any institution in the United States participating in cooperative research to rely on review and approval by a single IRB. This would apply only to the parts of the research conducted in the United States.
2) Require documentation and recordkeeping for research that takes place at an institution where the IRB of record is an external IRB. The current cooperative research requirements in 21 CFR 56.114 allow, but do not mandate, the use of single IRBs.

The purpose of these proposed changes is to harmonize, as much as possible, the Common Rule with the FDA's cooperative research requirements. The 2018 changes to the Common Rule included a single IRB mandate for cooperative research. This Common Rule mandate has been in effect since January 2020. The FDA believes that mandatory, single IRB review for multi-site studies would streamline the review process and increase efficiency for the oversight of these studies, while also reducing administrative burden.

The FDA's proposed rule identifies four (4) exceptions that are not entirely aligned with the Common Rule. The exceptions are as follows:

1) Cooperative research for which more than single IRB review is required by law (including tribal law).
2) Cooperative research involving a highly specialized, FDA-regulated medical product (no definition is given for this type of product).
3) Cooperative research on drugs exempt from IND regulations.
4) Cooperative research on medical devices that meets the abbreviated requirements or the requirements for exempted investigations.

Impact to Salus Clients & Salus IRB Review

Salus IRB has more than 35 years of experience as an sIRB for multi-site studies and expects to see an increase in the volume of multi-site studies that are submitted for review if the FDA-proposed rule goes into effect. Salus IRB has policies and procedures in place to ensure timely, accurate and consistent reviews/ oversight for all sites involved in multi-site studies.

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Below, we address the potential impact to two groups of clients: 1) Clients that have one or more sites engaged in multi-site studies where Salus is the local IRB for the client site(s) only. 2) Clients engaged in multi-site studies where Salus IRB is the sIRB for all sites in the multi-site study.

Single-Site Client in Multi-Site Studies

The FDA is silent on who is responsible for selecting the sIRB, so as not to contradict the requirements for IRB review provided in 21 CFR 312 and 21 CFR 812. If the proposed rule is finalized, there are important considerations that may influence the selection of the sIRB. Clients with a significant number of sites in a multi-site trial may be given priority in selecting the sIRB for the entire study. Conversely, because the FDA holds study sponsors responsible for ensuring that all sites and investigators involved in their research, obtain IRB review and approval, study sponsors may decide to select the sIRB for their studies, thus mandating all sites involved in their study to use the selected IRB.

The FDA sought comments on whether an exception is necessary for studies that involve a small number of sites (see ***Summary*** section above for a list of other proposed exceptions). This exception, if adopted, would allow certain clients to continue with the status quo. If this exception is in the final rule, the FDA is expected to define the threshold for a small number of sites.

For clients who oversee sites engaged in multi-site research, where Salus is the local IRB for the client site only, we encourage additional discussion with our team on how this proposed rule may impact your current operations. Please email clientservices@salusirb.com for further details.

Current sIRB Clients

For sponsor clients already familiar with our sIRB review process, we do not anticipate changes to our processes that will impact our continuous oversight of new and ongoing studies. However, the final FDA rule may include exceptions and requirements not currently discussed in the NPRM. Once the final rule goes into effect, our team will review and provide additional guidance in a timely manner.

Conclusions

The FDA's proposed rule seeks to harmonize with the Common Rule, thereby formalizing an ongoing industry practice. This proposed rule, if finalized, will affect new, multi-site studies that are reviewed and approved on or after the effective date of the final rule. There are benefits to sIRB review, such as the reduction of administrative burden as different IRBs tend to have different requirements, policies and processes. With streamlined processes and experience in sIRB review, Salus is ready to serve as the IRB of record for multi-site studies, should clients choose to pursue sIRB review before the FDA's final rule is effective. Salus is an AAHRPP-accredited, non-profit, independent IRB with expertise in oncology trials, SBER and other types of biomedical research. Contact us today for more information on how we can continually meet your IRB review needs.

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