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Top 3 Key Areas for Improvement:

Avoiding IRB Warning Letters

Along with sponsors, monitors, and investigative sites, IRBs play a big role in overseeing the conduct of clinical research. Per the FDA's IRB Information Sheets — Research and Review (updated 9/98), IRBs "are responsible for continuing review of ongoing research to ensure that the rights and welfare of human subjects are protected."

THAT'S A TALL ORDER!

As we continue in our series of analyzing warning letter findings, we move from clinical investigators to IRBs, assessing their level of compliance with 21 CFR Part 56. A random review of warning letters issued to IRBs in recent years showed 3 key areas in need of improvement including written procedures, timeliness of continuing review, and adequate documentation. A few examples of the citations are provided.

1

Failure to have adequate written procedures for IRB functions and operations as required per 21 CFR 56.108

- No procedures for determining significant risk or non-significant risk
- No procedures for conducting continuing review
- Procedures did not accurately reflect actual practice

2

Failure to conduct continuing review of research at intervals of not less than once per year as required per 21 CFR 56.109

- Requesting information from the investigator months after it was due
- Back-dating approval of continuing review
- Not documenting continuing review for 3 years
- 12 of 34 active studies had not been reviewed in over 17 months

3 Failure to maintain adequate documentation as required in 21 CFR 56.115

- Meeting minutes did not reflect number of members who voted for, against, or abstained
- There was no corresponding protocol or informed consent on file for an approved study
- IRB approved a study between 1999-2005 but had no records showing any IRB activity during that time period
- Letter sent to the investigator indicating that his study was approved, but the corresponding IRB minutes made no mention of the study even being discussed or reviewed

As referenced by Ramsey and Vulcano in the June 2010 issue of the Monitor, "Warning letters have been issued to institutional review boards (IRB) at near record-high levels in the past two years…" Using those warning letters as a tool to help improve the processes at your IRB can be a way to not only avoid the same fate, but also get even better at what the FDA has charged you with…. the enormous responsibility of safeguarding patients.

About IMARC Research

IMARC assists clinical researchers pursuing FDA and worldwide approvals by preparing, educating and guiding site teams from Day One to control the complex management of trials via cost-effective monitoring, auditing and training services — resulting in the support, proof and assurance they seek to overcome chaos caused by complexity while achieving compliance through consistency — based on competent, committed consultation and setting the highest standards for site outcomes and study partnerships.

References:
Ramsey, J. and Vulcano, D. (2010). FDA Warning Letters to IRBs. Monitor June 2010; 15-19.
http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm115834.htm

For more information on how you can help prepare your sites for a better outcome, starting from Day One, please contact John E. Lehmann at 440.801.1540 or via e-mail at jlehmann@imarcresearch.com