Ascension Wisconsin

Research Integrity and Protection Newsletter

September 2017

FDA Inspection: What Happens After a Site Receives a 483?

The FDA's focus for conducting inspections is on strengthening the oversight and protection of human subjects and the integrity of data collected in FDA-regulated clinical trials. The goals are to protect the rights, safety and welfare of study participants; to assess the reliability and accuracy of clinical trial data; and to assess compliance with applicable clinical research regulations. If objectionable conditions are observed during an inspection, they are listed as observations on a 483 and issued to the Principal Investigator. A Principal Investigator who accepts responsibility for findings will demonstrate recognition of the seriousness of the violations and their commitment to comply with applicable laws and regulations. A written response to the 483 is a best practice.

Annually, the FDA publishes inspectional observation summaries on their website with the most recent summary containing information on 4528 inspections conducted in Fiscal Year 2016. The most common Clinical investigator findings for device studies cited on 483s in 2016 are broken down below. You can visit the imarc website to download the white paper.

Clinical Investigator Oversight

Investigators must initiate study activities with a thorough understanding of their obligations and responsibilities. Expectations and requirements are usually specified in the Investigator's Agreement. Ensure the Investigator is familiar with the laws and regulations governing clinical research. The clinical investigator can delegate appropriately qualified personnel to assist with study conduct and should be available to lead regular study team meetings to discuss study progress and review any issues that may arise during study conduct.

Issues with Subject Protection and Consenting

Start with familiarizing the study team with the informed consent regulations. Develop mechanisms to ensure adequate version control of consent documents, as well as knowing that subjects must sign and date their consents for research.

Incidence of Protocol Deviations

Adhering to the protocol ensures that all subjects have been treated alike and that the ensuing data can be pooled together from different sources for analysis of results. With as much work as running a well-controlled trial requires, the incidence of protocol deviations should be minimized to the extent possible so that your site's data can be included in the final analysis.

Poor Record Keeping

The clinical study team should be thoroughly familiar with Good Clinical Practices (GCPALCOA-CCEA). Data should be attributable, legible, contemporaneous, original and accurate. Recently, complete, consistent (without logical contradictions), enduring (permanently recorded) and available (retrievable within a reasonable amount of time) have been added to the ALCOA acronym.

ALCOA-C Checklist Revision

This checklist reflects the recently updated guidelines (ICH GCP E2 Rev2) and how clinical research professionals should apply them to their study.

Get more info and the Checklist HERE

Revised Consent Form Templates

The informed consent form templates standardize the language for all Ascension Wisconsin and include requirements of the revised Common Rule.

The new templates will be posted in Mentor to begin using on 10/2/17.
The following training sessions are being offered (sign-up required):

- Tuesday, October 10th 2-2:30pm
- Wednesday, October 11th 9:30-10am

SIGN UP HERE

Individual training and Q&A also available during IRB office hours:
Tuesdays 12-2 (414-465-3059) and Fridays 8-10 (414-465-3134); IRB@ascension.org

(Training for Clinical Research Office staff will be scheduled; do not sign up for the sessions above)

Investigational Product Accountability

100% investigational product accountability is required by the regulations. This represents not only what investigational product is "on the shelf" at your site or that has been used for subjects, but what has been received from the Sponsor, including what may have been hand-delivered by a Sponsor representative or returned to the Sponsor.

Questions? Comments? Contact Research Integrity and Protection at RIPO@Ascension.org