



Un-trained personnel may be hazardous to you practice!

By Jacqueline Stader

Trained personnel: How important are they? Here are excerpts from a few FDA warning letters. After reading them, you may view the importance of training in a different way.

"A July 10, 2006 response from our attorneys of record, [redacted] and [redacted], of [redacted] notes that "Dr. Wolf recognizes and understands that, as Principal Investigator, the Inspectional Observations made by the FDA Investigators and other auditors are his responsibility," and that "responsibilities as Principal Investigator extended beyond simply referring potential study subjects to the research study coordinator."

The response also included a letter to you, dated 7/5/06 from [redacted]. Dean of the [redacted] noted that "you and your research team have inadequate training in clinical research and that one trial was performed in a sloppy, careless, and inconsistent manner." He further recommends that you and your research staff "promptly make arrangements to receive appropriate, thorough training in clinical research."

Please provide us with documentation of the clinical research training that has been or will be undertaken, including the names and titles of all study personnel, a description of the training, and dates that such training has been or will be completed.

A July 28, 2006, letter from [redacted] and [redacted] of [redacted] and [redacted] included a document titled "Randall K. Wolf, MD - Standard Operating Procedures as Investigator in Clinical Trials." This document details a number of promises made in your name regarding the conduct of clinical trials. This response is not acceptable, because this document is not dated and not signed by you. We have no evidence that you agree with the promises made in this document, or that you have even reviewed the document. Please provide us with a signed and dated copy of the "Standard Operating Procedures as Investigator in Clinical Trials" or a statement signed and dated by you in which you agree to the promises made in the document.

The June 19, 2006, response from [redacted] also included a number of new SOPs adopted by the Department of [redacted] regarding human subject research. The letter noted that training on these SOPs will be provided this summer. Please provide us with documentation that all personnel involved in the two studies discussed in this letter have been appropriately trained on these SOPs.

This is just a sample of the statements in FDA warning letters. But in reality this element of clinical research is often overlooked or underplayed by sites that are relatively new to the research scene. I'll share with you that, I've had more than a few dozen study coordinators reveal that they were told they were 'Smart Cookies' and could figure it out, or even worse they were told that it was 'just a little paper work', which is like saying the North Pole is just a little chilly!

All too often the need for trained study coordinators isn't realized until it's too late, and then backtracking or getting out of the FDA hot water tank becomes high priority. These actions are sadly, too little too late.

Offices that are new to research can also fall into precarious situations for failure to provide proper Standard Operating Procedures, and training the staff on these procedures that define the clinical research activities in detail.

Recently I queried FDA auditors and was told that their #1 question upon entering a site for an audit was to view the sites Standard Operating Procedures.

Well, imagine the sites surprise when asked for something that does not even exist at many sites. Believe me that is *not* the time to think about preparing SOPs.

After reading the warnings, it's safe to say that the FDA doesn't accept ignorance as a form of defense, nor do they allow placing blame on the study coordinator. These warning letters show that the FDA expects study coordinators and research personnel to be properly trained. It's clear that the FDA places all responsibility back on the PI who signed the FDA Form 1572.

Study Coordinators play a vital role in clinical research. Well trained coordinators, manage the study duties more efficiently, understand FDA guidelines and regulations and usually are stronger at recruiting. Educating clinical research staff is the key. The better trained the coordinator is, the better the research site functions. Whether training is obtained through seminars, lectures, teleclasses, self-learning or even through Standard Operating Procedures in the office, it's the most important element of any research site.

If an ounce of prevention is worth a pound of cure, one would wonder why are study coordinators not receiving the training they need?

For information on how Ophthalmic Research Training Services can help with these efforts please contact us at 419-343-7384 or email: jstader@ortsedu.com

To read the complete warning letters and others go to www.ortsedu.com and click on the Resource Page.

Copyright © 2007, by Jacqueline Stader. All rights reserved.

Jacqueline Stader is a Clinical Research Lecturer and Trainer. She supports clinical research personnel by sharing proven techniques, strategies, information and tips that inform and educate.

Visit her website at www.ortsedu.com

~~~~~