Your key to understanding an FDA inspectors position and needs before and during an audit

THE CLINICAL INVESTIGATOR'S MANUAL

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IX. ADDITIONAL MATERIAL / APPENDICIES

1. Position papers on the ethics of research involving human subjects

- **The Declaration of Helsinki** – Recommendations Guiding Medical Doctors In Biomedical Research Involving Human Subjects.
- **The Belmont Report** – Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Essential reading.

2. Statement of the Investigator (FDA "form 1572" & HPB "3005") See and understand what you are signing when you agree to be PI

3. The Protocol examples of what they contain and how they are set up. This document must be well known to the PI as to claim otherwise is very unwise

4. Forms used in Clinical Research Shortcuts to success and clean data

A short and a long form for the History and Physical Exam
Adverse Event recording, follow-up and summary forms
Examples of the usefulness of COSTART
Subject Safety Profile form - your educating your staff
Clinical study client update form
Financial disclosure form - now a requirement

5. Research Study Budgets and Finances – a description of the process and what you must include as expenses to be fair to yourself and your group

6. Fraud, Warning letters and other potholes in the road to good clinical research

The FDA Guide for Detecting Fraud in Bioresearch Monitoring Inspections Example warning letters

7. Draft Guidance's

Guidance for Pediatric studies - General considerations for Pediatric Pharmacokinetic studies for drugs and Biological products
Others to follow

190 pages -10 October, 2000

