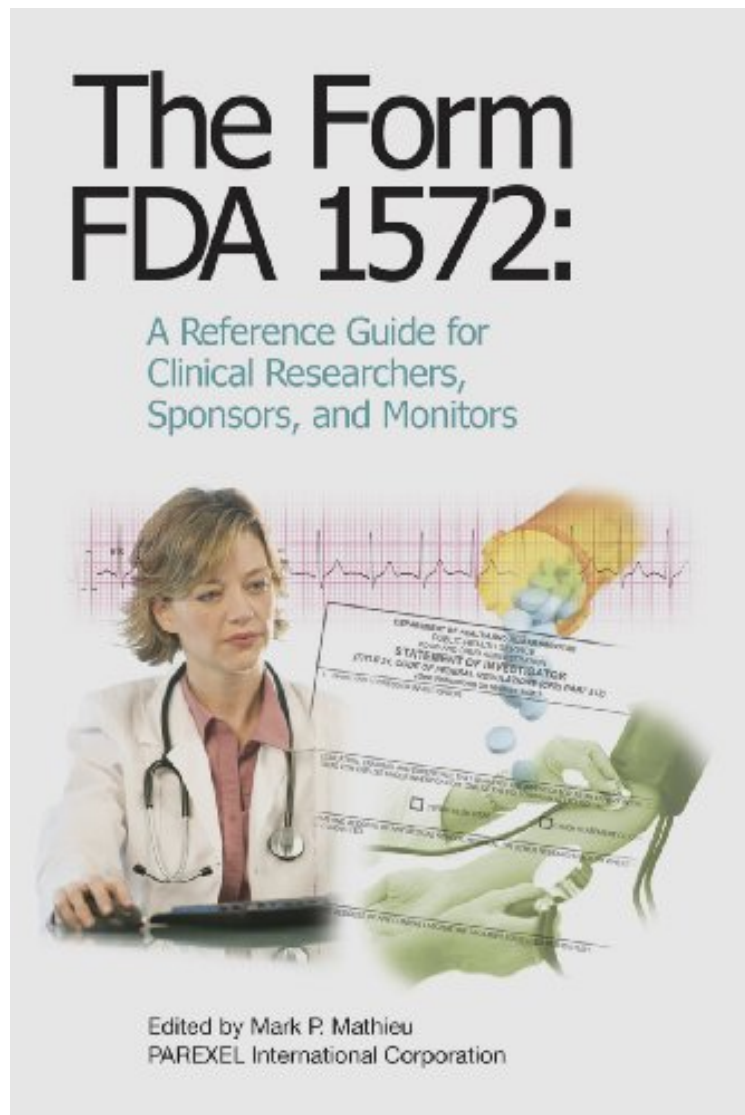


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The Form FDA 1572: A Reference Guide for Clinical Researchers, Sponsors, and Monitors

Mark P. Mathieu

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This year alone, well over 20,000 clinical investigators from around the globe will complete the mandatory Form FDA 1572-Statement of Investigator before participating in FDA-regulated clinical trials. And many of them may not truly appreciate the growing complexities involved in completing the mandatory form-and the implications for these researchers and study sponsors if they fail to complete the form appropriately. They should. Over the last year, the FDA has issued significantly more warning letters to clinical investigators. More importantly, the failure to complete the 1572 correctly has become an increasingly common citation in the very latest warning letters! Today, the fact that even experienced clinical investigators continue to struggle with long-standing 1572-related questions is further complicated by the growing complexity of modern clinical trials. Multiple satellite sites, what the FDA calls the dispersing of study functions, and other emerging factors have made completing this otherwise mundane form a challenge. Add to this the reality that growing numbers of clinical investigators participating in FDA-regulated trials are located outside the United States--approximately 42% of all clinical investigators signing 1572s in 2007-and may not have any experience with the mandatory form. We've taken our own experiences, in-depth discussions and correspondence with the FDA, and the agency's latest regulations and guidance documents and created a state-of-the-art reference guide for the proper completion of the Statement of Investigator form. In doing so, we've addressed all the most often-asked--but never answered--questions and also explored emerging areas of uncertainty related to the growing complexity of today's clinical trials, including: * When must a non-US clinical investigator sign a 1572? * How can a clinical investigator determine when a member of the site staff should be identified as a subinvestigator? * What are the legal/regulatory implications of signing a 1572-is it a legal contract? * When can a sponsor consider a clinical investigator to meet the appropriate expert standard? * What do we do now that at least one foreign country has banned the use of the 1572 for its clinical investigators? * How should co-investigators be handled in the 1572? * Must clinical investigators sign 1572s for satellite sites? * What must a study sponsor do beyond collecting the paper in the 1572 process? Who Should Read This Guide: * Clinical trial monitors * Clinical investigators and site staff * Research center compliance managers * IRB managers * Clinical study auditors * Clinical regulatory affairs staff.