

## **"Clinical Research Quality System Manual"**

**Nancy J. Stark, 2009, 355 pages, Clinical Device Group, \$3,000**

**Review by Norman M. Goldfarb**

"Clinical Research Quality System Manual" provides a comprehensive and meticulous set of documents for medical device companies to conduct clinical research. Although the title of the manual may suggest that the contents are limited to quality assurance, it actually covers a broad scope of activities required to ensure high-quality research.

The manual includes 154 policies, standard operating procedures (SOPs), diagrams, forms and checklists. For example, the study close-out section includes these documents:

- Close-Out Visits SOP
- Close-Out Report
- Financial Disclosure (End of Study) SOP
- Financial Disclosure (End of Study) Form
- Investigator Files SOP
- Investigator File Checklist
- Sponsor's Study File
- Study File Checklist

This book has been selected for  
**[The First Clinical Research Bookshelf](#)**  
Essential reading for clinical research professionals

The manual includes editable electronic versions of all documents. The documents can be customized easily with a company's particulars. They can be adapted to fit any company's processes, which should not be too difficult given that they describe procedures at the typical SOP's high level. Figure 1 on the next page presents a short sample SOP for investigator's brochures. As a special bonus, the documents are aesthetically pleasing.

The manual is available at <http://www.clinicaldevice.com/>.

### **Author**

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Figure 1. Sample SOP

<b>Investigator's Brochures</b>	<b>SOP 18.0</b>
Original Issue Date: .....xx/xx/xx	Reason ..... to establish standard
Revision Date: .....	Reason .....
Approval: _____	Date: _____
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<b>1.0 Purpose</b>	
1. This procedure describes how to prepare an Investigator's Brochure.	
<b>2.0 Related Policies</b>	
1. An Investigator's Brochure shall be prepared for every clinical trial conducted in the US or OUS.	
<b>3.0 Scope</b>	
1. This procedure is applicable to all non-exempt clinical trials conducted by Dulcé Devices.	
<b>4.0 Definitions</b>	
1. An Investigator's Brochure is an embryonic package insert; it provides an investigator with all the information necessary for the safe and judicious use of an investigational device.	
<b>5.0 Attachments</b>	
1. Investigator's Brochure checklist	
<b>6.0 Procedures</b>	
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A. Clinical Research Associate	
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1. Prepare a draft Investigator's Brochure by following the checklist provided in the Attachment.	
2. Identify by date and revision number.	
3. Route to Director, Clinical Research for review and approval.	
4. Update when significant new information becomes available and provide to investigators.	
5. Include as a study document in the Sponsor's Study File.	
<b>7.0 References</b>	
1. Procedures xxx-xxx.	
2. Declaration of Helsinki.	
3. Belmont Report.	
4. 21 CFR Part 812, 11, 50, 54, 56.	
5. 21 CFR Part 820.30.	
6. ISO 14155, Parts 1 and 2.	