

# Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors

## Frequently Asked Questions About Medical Devices

*Additional copies are available from:*

Office of Good Clinical Practice  
Office of Special Medical Programs, Office of the Commissioner  
Food and Drug Administration  
10903 New Hampshire Ave., WO32-5129  
Silver Spring, MD 20993-5129  
(Tel) (301)-796-8340

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf>

or

Division of Small Manufacturers, International, and Consumer Assistance  
Office of Communication, Education and Radiation Programs  
Center for Devices and Radiological Health  
Food and Drug Administration  
10903 New Hampshire Ave., WO66-4521  
Silver Spring, MD 20993  
Tel: 1-800-638-2041 or 301-796-7100  
[dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov)

or

Office of Communication, Training and Manufacturers Assistance, (HFM-40)  
Center for Biologics Evaluation and Research  
Food and Drug Administration  
1401 Rockville Pike

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### *Vintage Documents from Clinical Device Group*

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Best regards,  
Nancy J Stark, PhD  
President, Clinical Device Group Inc

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