



# 2003 Chicago Cystic Fibrosis Awareness Day Clinical Trials Seminar

## ➤ On the internet:

**Where do I find out about CF-related clinical trials?**

<http://www.cff.org/research/> - Cystic Fibrosis Foundation page with information on CF research and clinical trials

<http://www.clinicaltrials.gov/> -- National Institute of Health site provides up-to-date information 'about federally and privately supported clinical research in human volunteers.'

<http://www.centerwatch.com/> -- Center Watch Clinical Trials Listing Service 'The information source for the clinical trials industry.'

<http://www3.nbnet.nb.ca/normap/newcfmeds.htm> -- Guide to CF drugs/procedures currently being investigated. Excellent layout with links to articles, press releases and additional information.

**Are any CF-related clinical trials going on in the Chicago area?**

<http://www.rush.edu/patients/children/research.html> -- Clinical Trials at Rush

[http://www.luh.org/templates/luhs/clinical\\_trials/index.cfm](http://www.luh.org/templates/luhs/clinical_trials/index.cfm) -- Clinical Trials at Loyola

<http://www.uchospitals.edu/clinicaltrials/> -- Clinical Trials at the University of Chicago (with links to other internet clinical trial pages)

## ➤ Books:

*The Investigator's Guide to Clinical Research, 2<sup>nd</sup> ed.*, by Dr. David Ginsberg, CenterWatch, Inc., Boston, MA, 1999.

*Protecting Study Volunteers in Research: A Manual for Investigative Sites, 2<sup>nd</sup> ed.*, by Cynthia McGuire Dunn, M.D. and Gary L. Chadwick, Pharm. D, MPH, CIP, CenterWatch, Thomson Healthcare, Inc., Boston, MA, 2002

*Responsible Conduct of Research*, by Adil E. Shamoo and David B. Resnik, Oxford University Press, New York, New York, 2003.

*Designing Clinical Research: An Epidemiologic Approach, 2<sup>nd</sup> ed.*, Stephen B. Hulley, MD, MPH ed., Lippincott Williams & Wilkins, Philadelphia, PA, 2001

*The 2002 Official Parent's Sourcebook on Cystic Fibrosis: A Revised and Updated Directory for the Internet Age*, James N. Parker, MD and Philip M. Parker, PhD, eds., ICON Group International, Inc., San Diego, California, 2002.

Here is a brief description of the key U.S. Regulatory Agencies that monitor drug research, clinical trials, and marketed drugs:

➤ **U.S. Food and Drug Administration (FDA):** <http://www.fda.gov/> The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, the nation's food supply, cosmetics, and products that emit radiation.

**Good Clinical Practice (GCP):** <http://www.fda.gov/oc/gcp/> "Researchers use GCP standards to design, conduct, perform, monitor, audit, record, analyze, and report clinical trials. The Good Clinical Practice Program is the focal point within FDA for issues arising in human research trials regulated by FDA."

**Center for Drug Evaluation and Research (CDER):** <http://www.fda.gov/cder> The CDER focuses on chemically synthesized drugs and is involved in four major activities: New Drug Development and Review, Generic Drug Review, Over-the-Counter Drug Review (including prescription drug advertising), and Post Drug Approval Activities. In addition, the Center is a crucial part of the drug development process. Its multi-disciplinary members provide guidelines for large-scale trials, help researchers who are submitting data to the FDA, and evaluate data in New Drug Applications.

**Center for Biologics Evaluation and Research (CBER):** <http://www.fda.gov/cber> CBER is the "Center within the FDA responsible for ensuring the safety and efficacy of blood and blood products, vaccines, allergenics, and biological therapeutics. CBER's regulation of biological products has expanded in recent years to include a wide variety of new products such as biotechnology products, somatic cell therapy and gene therapy, and banked human tissues."

**Center for Devices and Radiological Health (CDRH):** <http://www.fda.gov/cdrh/> The offices at CDRH "ensure that medical devices are safe and effective, and help reduce unnecessary exposure to radiation from medical, occupational and consumer products".

**Federal Register:** <http://www.gpoaccess.gov/fr/index.html> Use this site to access the official daily publication for rules, proposed rules, and notices of Federal agencies and organizations, as well as executive orders and other presidential documents. (I suggest browsing the Table of Contents in HTML format and/or using the advanced search option.) Want to have your say? Go to: <http://www.regulations.gov/> On this site, you can "find, review, and submit comments on Federal documents that are open for comment and published in the *Federal Register*, the Government's legal newspaper."

**MedWatch:** <http://www.fda.gov/medwatch/> The FDA safety information and adverse event reporting program has four main goals: clarify what should be reported to the FDA, increase awareness of drug reactions ease the reporting process, and provide feedback about product safety. Here, physicians and consumers can report problems with marketed drugs, and thus be a part of the post-marketing surveillance system. (For questions about the making a report to MedWatch, see the "submit report" page online.)

➤ **Department of Health and Human Services (DHHS), Office for Civil**

**Rights (OCR):** <http://www.hhs.gov/ocr/index.html> This department ensures that people have equal access to and opportunity to participate in all HHS programs without facing unlawful discrimination.

**Health Insurance Portability and Accountability Act (HIPAA) and the Standards for Privacy of Individually Identifiable Health Information (Privacy Rule)** <http://www.hhs.gov/ocr/hipaa> "establishes a set of national standards for the protection of certain health information. The Privacy Rule standards address the use and disclosure of individuals' health information by organizations subject to the Privacy Rule as well as standards for individuals' privacy rights to understand and control how their health information is used. The OCR is responsible for implementing and enforcing the Privacy Rule." For a Privacy Rule booklet, see: [http://privacyruleandresearch.nih.gov/pdf/HIPAA\\_Privacy\\_Rule\\_Booklet.pdf](http://privacyruleandresearch.nih.gov/pdf/HIPAA_Privacy_Rule_Booklet.pdf)

**Office for Human Research Protections (OHRP)** <http://ohrp.osophs.dhhs.gov/> "The OHRP website provides numerous resources regarding human subject protections", including Federalwide Assurances (wherein institutions agree to comply with all regulations governing federally sponsored research), Institutional Review Board (IRB) registration, compliance oversight information, policy guidance on human subject regulations, and a

"quality improvement program to help institutions evaluate and improve the quality of their human research protection program."