Professional Resources

Information and Websites current as of September 2012

Reference Books	Description
****A Clinical Trials Manual From The Duke Clinical Research Institute: Lessons From a Horse Named Jim**, 2nd Edition by Margaret B. Liu, Kate Davis	First half of the manual provides the historical framework, rules and regulations, definitions, and necessary oversight of clinical trials. Remaining chapters focus on how clinical trials are conducted and emphasize the practical application of the information presented in the first half. Updated to reflect recent regulatory and clinical developments, the manual reviews the conduct of clinical trials research in an increasingly global context. This new edition has been further expanded to include: • In-depth information on conducting clinical trials of medical devices and biologics • The role and responsibilities of Institutional Review Boards, and • Recent developments regarding subject
****Principles and Practice of Clinical Research**, 3rd Edition Edited by John I. Gallin, Frederick P. Ogribene	796 page hard copy book that provides an overview of the regulatory, ethical and scientific aspects of clinical research. Book was developed from NIH's clinical research training course The third edition of this innovative work again provides a unique perspective on the clinical discovery process by providing input from experts within the NIH on the principles and practice of clinical research. Molecular medicine, genomics, and proteomics have opened vast opportunities for translation of basic science observations to the bedside through clinical research. Incorporates new chapters on Managing Conflicts of Interest in Human Subjects Research, Clinical Research from the Patient's Perspective, The Clinical Researcher and the Media, Data Management in Clinical Research, Evaluation of a Protocol Budget, Clinical Research from the Industry Perspective, and Genetics in Clinical Research
****Good Clinical Practice: A Question & Answer Reference Guide** www.barnettinternational.com Phone: 1-800-856-2556 x2301	Addresses the most frequently asked questions in clinical research. Provides FDA supported interpretation of regulations in answering the questions. Updated yearly. ***One of the most useful books in clinical research.***
****CenterWatch Publications**: • Becoming a Successful Clinical Research Investigator • Guide to Patient Recruitment and Retention • Protecting Study Volunteers in Research • The CRC's Guide to Coordinating Clinical Research • The CRA's Guide to Monitoring Clinical Research http://store.centerwatch.com/c-29-training-education.aspx Phone: 617-948-5152	Step-by-step resource publications filled with tips, instructions and insights for health professionals interested in conducting clinical trials.

**** Suggested for the Basic Research Library**

**Barnett CFR/ICH Guidelines Reference Handbooks www.barnettinternational.com Phone: 1-800-856-2556 x2301 or **Clinical Research resources CFR/ICH Guidelines Reference Handbooks www.clinicalresearchresources.com Phone: 866-427-4843	Variety of Handbooks. Examples • FDA Good Clinical Practice 2012 Reference Guide • Comprehensive Clinical Research Desk Reference for Drug and Medical Device Trials • SPANISH LANGUAGE 2012 Selected FDA Regulations and ICH Guidelines for Clinical Studies for US Drug Approval • Selected Regulations/Guidance for Medical Device Studies • Regulations/Guidance on the Protection of Human Subjects: Clinical Investigator, IRB & Sponsor Responsibilities Updated yearly
Responsible Conduct of Research, Shamoo and Resnick	From the introduction of Responsible Conduct of Research "Presents a comprehensive introduction to the ethical issues at stake in the conduct of research."
Guide to Good Clinical Practice by Thompson Publishing Company (purchase also includes online access) www.thompson.com Phone: 1-800-677-3789, Fax: 1-800-999-5661	• Easy access to regulations and Guidelines; table of contents and index • Analysis of good clinical practices • Monthly Newsletter containing updates and news about clinical research • Updates to the manual as new information becomes available
Conducting Clinical Research; A Practical Guide for Physicians, Nurses, Study Coordinators, and Investigator, 2nd edition, Judy Stone, MD	Truly practical guide for conducting research studies. Good reference for the whole research team
Health Literacy From A To Z: Practical Ways to Communicate your Health Message.; Helen Osborne (Author)	Practical what-to-do and how-to-do-it. Relevant to communication for the busy health professional. Contains the key principles and strategies of effective health communication. Presented in a simple, informal manner.
Clinical Research Coordinator Handbook ; Deborrah Norris (Author)	Provides useful and practical information to assist the Study Coordinator in their role.

Professional Organizations	Miscellaneous
Drug Information Association (DIA) www.diahome.org Phone: 1-215-442-6100	Includes a quarterly journal, Drug Information Journal
Association of Clinical Research Professionals (ACRP) 1-703-254-8100 www.acrpnet.org	Includes a Monitor, bi-monthly journal Provides separate certification exam for the CRA and the CRC and PI
Society for Clinical Research Associates (SoCRA) 1-800-762-7292 www.socra.org	Includes a quarterly journal, SoCRA Source Provides one certification exam for all clinical research professionals
RAPS (Regulatory Affairs Professional Society) www.raps.org 1-301-770-2920	Includes monthly journal "Focus" Provides certification exam for all clinical research professionals

Journals/Subscriptions	Miscellaneous
DIA Journal www.diahome.org	• Quarterly • Included with membership (see DIA under Professional Organizations) • ***Journal articles also available on line. Search and download capabilities. You do not have to be a member to access the journals.***
The Monitor www.acrpnet.org	• Bi-monthly • Included with ACRP membership (see ACRP under Professional Organizations)
Applied Clinical Trials (ACT) http://appliedclinicaltrialsonline.findpharma.com/appliedclinicaltrials	Monthly
Research Practitioner http://store.centerwatch.com/c-29-training-education.aspx Phone: 866-219-3440; option 4	Every other month
Clinical Trials Advisor http://www.fdanews.com/newsletters	Biweekly
Focus www.raps.org	• Monthly • Included with RAPS membership (see RAPS under Professional Organizations)
CenterWatch Phone: 1-800-765-9647 www.centerwatch.com	Monthly CenterWatch news online

ListServes	Miscellaneous
IRB Forum To subscribe (no charge): http://tinyurl.com/8tn625s	Daily e-mail. Promotes the discussion of ethical, regulatory and policy concerns with human subjects' research. You may submit questions regarding issues or concerns at your site (anonymously if preferred), read other discussions with or without participating. Focus is mainly on human subject research in federally funded studies (as opposed to issues and discussion about commercial studies).
Federal Register Table of Contents To subscribe (no charge): http://listserv.access.gpo.gov and select Online mailing list archives, FEDREGTOC-L, Join or leave the list (or change settings); then follow the instructions.	Daily e-mail. Receive a listing of all the Notices, Proposed and New Rules and Guidances for all gov. departments published in the Federal Register (FR) that day. Can quickly scroll down to "Food and Drug Administration" or "National Institutes of Health" for their listings. Links to the actual FR document provided.

WEB SITES

Item	Web Site
FDA KEY WEB SITES	
Food, Drug and Cosmetic Act	http://tinyurl.com/23vhk8h
Food and Drug Administration- Home Page	http://www.fda.gov
Center for Biologics Evaluation and Research (CBER)	http://www.fda.gov/cber
Center for Drug Evaluation and Research (CDER)	http://www.fda.gov/cder
CDER: Information for Clinical Investigators	http://www.fda.gov/Drugs/InformationOnDrugs/ucm135162.htm
Center for Devices and Radiological Health (CDRH)	http://www.fda.gov/MedicalDevices/default.htm
CDRH Device Advice	http://www.fda.gov/medicaldevices/deviceregulationandguidance/default.htm
Code of Federal Regulations (21 CFR)	http://www.gpoaccess.gov/cfr/index.html
FDA Forms	http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm
FDA Guidance Documents	http://www.fda.gov/RegulatoryInformation/Guidances/default.htm
FDA - Information Sheets	http://www.fda.gov/oc/ohrt/irbs/default.htm
FDA – ORA Compliance Program Guidance 7348.809 (Institutional Review Boards)	http://www.fda.gov/ICECI/EnforcementActions/BioresearchMonitoring/ucm282667.htm
FDA – ORA Compliance Program Guidance 7348.810 (Sponsors, CROs, and Monitors)	http://www.fda.gov/ICECI/EnforcementActions/BioresearchMonitoring/ucm133777.htm
FDA – ORA Compliance Program Guidance 7348.811 (Clinical Investigators)	http://www.fda.gov/ICECI/EnforcementActions/BioresearchMonitoring/ucm133562.htm
FDA Warning Letters	http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm
Investigator Disqualified/Restricted/Assurance List	http://www.fda.gov/ora/compliance_ref/bimo/dis_res_assur.htm
Office Of Good Clinical Practice (OGCP)	http://tinyurl.com/8gvl34z
Replies to Inquiries to FDA on Good Clinical Practice	http://tinyurl.com/82ngf6o
DHHS/ FEDERALLY FUNDED STUDIES KEY WEBSITES	
Certificates of Confidentiality	http://grants.nih.gov/grants/policy/coc/
HHS News and Fact Sheets	http://www.hhs.gov/news/
HHS Frequently Asked Questions	http://answers.hhs.gov/
National Institutes of Health (NIH) Home Page	http://www.nih.gov
OHRP (Office for Human Research Protection)	http://www.hhs.gov/ohrp/
OHRP IRB Guidebook	http://www.hhs.gov/ohrp/archive/irb/irb_guidebook.htm
ORI (Office of Research Integrity)	http://ori.dhhs.gov/
Office of Extramural Research	http://grants.nih.gov/grants/oer.htm
Regulations	http://www.hhs.gov/ohrp/humansubjects/index.html
Policy and Guidance	http://www.hhs.gov/ohrp/policy/index.html
Determination Letters	http://www.hhs.gov/ohrp/compliance/letters/index.html
Recent Compliance Oversight Determinations (by topic area)	http://www.hhs.gov/ohrp/compliance/findings/index.html
ADDITIONAL KEY WEBSITES	
ICH GCP Guideline (E-6)	http://www.ich.org/products/guidelines.html
The Belmont Report	http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html
Declaration of Helsinki	http://www.wma.net/en/30publications/10policies/b3/
The Nuremberg Code	http://history.nih.gov/research/downloads/nuremberg.pdf
Clinical Trials Registry	http://clinicaltrials.gov/

Item	Web Site
FDA Training and Education	http://www.fda.gov/Training/default.htm
HHS.OHRP Training and Education	http://www.hhs.gov/ohrp/education/
Clinical Trials Network Best Practices Training and Resources	https://www.ctnbestpractices.org/
OTHER WEBSITES OF INTEREST	
Agency for Healthcare Research and Quality (AHRQ)	http://www.ahcpr.gov
American Medical Association	http://www.ama-assn.org/
Applied Clinical Trials	http://www.actmagazine.com/appliedclinicaltrials
Association of American Medical Colleges	http://www.aamc.org
Association of American Universities	http://www.aau.edu
Bio Online	http://www.bio.com
Bioethics Website with educational links, tutorials	http://www.nih.gov/sigs/bioethics
BioSpace	http://www.biospace.com
Biotechnology Industry Organization (BIO)	http://www.bio.org
British Medical Journal	http://bmj.com
Canadian Institutes of Health Research	http://www.cihr-irsc.gc.ca
Canadian Medical Association	http://www.cma.ca
Canadian Standards Council	http://www.scc.ca
CanReg, Inc	http://canreg.ca
CDER What's New	http://www.fda.gov/cder/whatsnew.htm
Center for Biologic Research and Evaluation (CBER) What's New	http://tinyurl.com/9rggero
Centers for Disease Control and Prevention (CDC)	http://www.cdc.gov/about/
Centerwatch Clinical Trials	http://www.centerwatch.com
CIOMS – Council for Int'l Org of Medical Sciences	http://www.cioms.ch
Clinical Data Interchange Standards Consortium	http://www.cdisc.org
Clinical Researcher	http://www.clinical-researcher.com
ClinicalTrials.gov (site for registering clinical trials)	http://www.clinicaltrials.gov/
Clinical Trials Networks: Best Practices	https://www.ctnbestpractices.org/
Declaration of Helsinki (1989 version – recognized by FDA)	http://www.fda.gov/RegulatoryInformation/Guidances/ucm124932.htm
Declaration of Helsinki (2000 version)	http://www.wma.net/en/20activities/10ethics/10helsinki/index.html
Department of Health and Human Services (HHS)	http://www.hhs.gov/
Drug Approval List	http://www.fda.gov/Drugs/InformationOnDrugs/default.htm
EMEA – European Agency for the Evaluation of Medicinal products	http://www.ema.europa.eu/ema/index.jsp?curl=/pages/home/Home_Page.jsp&jsenabled=true
FDA - Information for patients	http://www.fda.gov/oashi/home.html
FDA Medwatch	http://www.fda.gov/medwatch
FDA - News	http://www.accessdata.fda.gov/news/
Federal Register Online	http://www.gpoaccess.gov/fr/index.html
FOI – FDA Information and Documentation	http://www.foiservices.com
Food, Drug, and Cosmetic Act	http://www.fda.gov/opacom/laws/fdcact/fdctoc.htm
Freedom of Information Room	http://www.fda.gov/RegulatoryInformation/foi/default.htm

Item	Web Site
GrantsNet	http://www.grantsnet.org
Health Canada Home Web Site	http://www.hc-sc.gc.ca/english/index.html
ICH – Int'l Conference on Harmonization	http://www.ich.org
IFPMA Int'l Federation of Pharmaceutical Manufacturers Associations	http://www.ifpma.org
Information for Health Professionals	http://www.fda.gov/oc/oha
IOM - Institute of Medicine	http://www.iom.edu
IRB Forum - (Discussion Group – can submit /read questions and the answers and resources provided by the members)	http://www.irbforum.org/
ISO - International Standards Organization	http://www.iso.org/iso/home.htm
Laws enforced by FDA	http://www.fda.gov/opacom/laws/
MedDRA	http://www.meddramsso.com
Medical Group Management Association (MGMA)	http://www.mgma.com
Medical information	http://www.medscape.com
Medical information	http://www.medline.com
National Human Genome Research Institute	http://www.genome.gov
New England Journal of Medicine (NEJM)	http://content.nejm.org
NIEHS Research Ethics	http://www.niehs.nih.gov/research/resources/bioethics/
Office of the Inspector General (OIG) Reports	http://oig.hhs.gov/
Pan American Health Organization	http://www.paho.org
Pediatric Medicine page	http://www.fda.gov/cder/pediatric/
Medical, Pharmaceutical & Healthcare Professional Online Home Page (MediLexicon)	http://www.pharma-lexicon.com/index.php
PharmaLive	http://www.pharmalive.com/
PhRMA – Pharmaceutical Research & Manufacturers Association	http://www.phrma.org
Public Responsibility in Medicine & Research (PRIM&R)	http://www.primr.org
PubMed (National Library of Medicine)	http://www.ncbi.nlm.nih.gov/entrez/query.fcgi
Regsource.com	http://www.regsource.com/
Research Investigator's Source, Inc.	http://www.clinicalinvestigators.com
The Canadian Health Network	http://www.hc-sc.gc.ca
The Lancet	http://www.thelancet.com
U.S. National Library of Medicine (NLM)	http://www.nlm.nih.gov
US Government Printing Office	http://www.access.gpo.gov
WHO – World Health Organization	http://www.who.int/en
WMA – World Medical Association	http://www.wma.net