# 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.<br>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:<br>• In-depth information on conducting clinical trials of medical devices and biologics<br>• The role and responsibilities of Institutional Review Boards, and<br>• 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<br><br>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**<br>www.barnettinternational.com<br>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**:<br>• Becoming a Successful Clinical Research Investigator<br>• Guide to Patient Recruitment and Retention<br>• Protecting Study Volunteers in Research<br>• The CRC's Guide to Coordinating Clinical Research<br>• The CRA's Guide to Monitoring Clinical Research<br>http://store.centerwatch.com/c-29-training-education.aspx<br>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**

Produced by the National Clinical Translational Science Awards
Clinical Research Coordinator Committee

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| **Barnett CFR/ICH Guidelines Reference Handbooks<br>www.barnettinternational.com<br>Phone: 1-800-856-2556 x2301<br>or<br>**Clinical Research resources CFR/ICH Guidelines Reference Handbooks<br>www.clinicalresearchresources.com<br>Phone: 866-427-4843 | Variety of Handbooks. Examples<br>• FDA Good Clinical Practice 2012 Reference Guide<br>• Comprehensive Clinical Research Desk Reference for Drug and Medical Device Trials<br>• SPANISH LANGUAGE 2012 Selected FDA Regulations and ICH Guidelines for Clinical Studies for US Drug Approval<br>• Selected Regulations/Guidance for Medical Device Studies<br>• Regulations/Guidance on the Protection of Human Subjects: Clinical Investigator, IRB & Sponsor Responsibilities<br>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)<br>www.thompson.com<br>Phone: 1-800-677-3789, Fax: 1-800-999-5661 | • Easy access to regulations and Guidelines; table of contents and index<br>• Analysis of good clinical practices<br>• Monthly Newsletter containing updates and news about clinical research<br>• 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 |
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| Drug Information Association (DIA)<br>www.diahome.org<br>Phone: 1-215-442-6100 | Includes a quarterly journal, Drug Information Journal |
| Association of Clinical Research Professionals (ACRP)<br>1-703-254-8100<br>www.acrpnet.org | Includes a Monitor, bi-monthly journal<br>Provides separate certification exam for the CRA and the CRC and PI |
| Society for Clinical Research Associates (SoCRA)<br>1-800-762-7292<br>www.socra.org | Includes a quarterly journal, SoCRA Source<br>Provides one certification exam for all clinical research professionals |
| RAPS (Regulatory Affairs Professional Society)<br>www.raps.org<br>1-301-770-2920 | Includes monthly journal "Focus"<br>Provides certification exam for all clinical research professionals |

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

| ListServes | Miscellaneous |
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| IRB Forum<br>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<br>To subscribe (no charge): http://listserv.access.gpo.gov<br>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 |
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| **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 |
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| 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 |
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| 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 |