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, 2 nd 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, 3 rd 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. <i>One of the most useful books in clinical research.</i>
**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.

**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 Conducting Clinical Research; A Practical Guide for Physicians, Nurses, Study Coordinators, and Investigator, 2 nd edition, Judy Stone, MD	 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 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)	Includes monthly journal "Focus"
www.raps.org	Provides certification exam for all clinical research professionals
1-301-770-2920	

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) <a c-29-training-education.aspx"="" href="http://appliedclinicaltrialsonline.findpharma.com/appliedclinicaltrials</td><td>Monthly</td></tr><tr><td>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	Daily e-mail. Promotes the discussion of ethical, regulatory and policy concerns with human
To subscribe (no charge): http://tinyurl.com/8tn625s	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	Daily e-mail. Receive a listing of all the Notices, Proposed and New Rules and Guidances for all
To subscribe (no charge): http://listserv.access.gpo.gov	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
and select Online mailing list archives, FEDREGTOC-L, Join or leave the list (or change settings); then follow the instructions.	actual FR document provided.

WEB SITES

Item	Web Site
FDA 1	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 F	UNDED 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/

FDA Training and Education	Item	Web Site
Clinical Trials Network Best Practices Training and Resources OTHER WEBST TES OF INTEREST Agency for Healthcare Research and Quality (AHRQ) American Medical Association Applied Clinical Trials Applied Clinical Trials Association of American Medical Colleges Bittp://www.amm.gorge Association of American Medical Colleges Bittp://www.amm.gorge Bittp://www.am	FDA Training and Education	http://www.fda.gov/Training/default.htm
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Agency for Healthcare Research and Quality (AHRQ) http://www.alma.as.norg/ American Medical Association http://www.alma.as.norg/ Association of American Medical Colleges http://www.alma.cbi. Association of American Universities http://www.alm.cbi. Bio Online http://www.bio.com Bio Online http://www.bio.org Biothiss Website with educational links, tutorials http://www.bio.org Biother Organization (BIO) http://www.bio.org Biritish Medical Journal http://www.bio.org British Institutes of Health Research http://www.chi.org.ag.ca Canadian Institutes of Health Research http://www.chi.org.ag.ca Canadian Standards Council http://www.chi.org.ag.ca Center for Biologic Research and Evaluation (CDC) http://www.chi.org.ag.ca Center for Discoler Research and Evaluation (CDC) http://www.chi.org.ag.ca Centers for Discoac Council and Prevention (CDC) <t< td=""><td>Clinical Trials Network Best Practices Training and Resources</td><td>https://www.ctnbestpractices.org/</td></t<>	Clinical Trials Network Best Practices Training and Resources	https://www.ctnbestpractices.org/
American Medical Association Applied Clinical Trials Applied Clinical Trials Association of American Medical Colleges Association of American Universities Intro/www.amu.edu Intro/www.amu.edu Intro/www.amu.edu Intro/www.amu.edu Intro/www.amu.edu Intro/www.amu.edu Intro/www.incom Intr	OTHER WE	BSITES OF INTEREST
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Association of American Medical Colleges Association of American Universities Association of American Universities Association of American Universities Bito Online Bito Online Bito Online Bito Online Bito Medical Sevente with educational links, tutorials Bitosepace Bitosepac	American Medical Association	http://www.ama-assn.org/
Association of American Universities Bio Online Bio Online Biochies Website with educational links, tutorials Intp://www.hip.ocm Biochies Website with educational links, tutorials Intp://www.hip.or/www.hip.or/www.hip.or/www.hip.or/www.hip.or/www.hip.or/www.hip.or/www.hip.or/www.hip.or/www.hip.or/www.hip.or/www.hip.or/ British Medical Journal British Medical Association Intp://www.dec.go.acm.acm.acm.acm.acm.acm.acm.acm.acm.acm	Applied Clinical Trials	http://www.actmagazine.com/appliedclinicaltrials
Bio Online Bio Online Biochtics Website with educational links, stuorials http://www.hib.gov/ige/biochtics BioSpace http://www.hib.gov/ige/biochtics BioSpace http://www.hib.gov/ige/biochtics Biotechnology Industry Organization (BIO) http://www.hib.gov/ige/biochtics British Medical Journal http://www.fib.gov/ige/biochtics British Medical Journal http://www.fib.gov/ige/biochtics British Medical Journal http://www.fib.gov/ige/biochtics Canadian Medical Association http://www.fib.gov/ige/biochtics/gov/ige/biochtics	Association of American Medical Colleges	http://www.aamc.org
Biochics Website with educational links, tutorials BioSpace BioSpace Biotechnology Industry Organization (BIO) British Medical Journal Canadian Medical Association British Medical Association Canadian Standards Council Canadian Medical Association British New British New Center for Biologic Research and Evaluation (CBER) What's New British New Center for Biologic Research and Evaluation (CDC) British New Centerwards Clinical Trials British Medical Sciences British Medi	Association of American Universities	http://www.aau.edu
BioSpace Biotenhology Industry Organization (BIO) Birtish Medical Journal Buty/Mnyww.bio.org Canadian Institutes of Health Research Lutp://www.cinir.irsc.gc.ca Lutp://www.cinir.irsc.gc.ca Lutp://www.cinir.irsc.gc.ca Lutp://www.cinir.irsc.gc.ca Lutp://www.cinir.irsc.gc.ca Lutp://www.cinir.irsc.gc.ca Lutp://www.cinir.cate Lutp://w	Bio Online	http://www.bio.com
British Medical Journal http://www.bin.org British Medical Journal http://www.chir-irse.ge.ca Canadian Institutes of Health Research Canadian Standards Council http://www.chir-irse.ge.ca Canadian Standards Council http://www.cc.ca Canadian Standards Council http://www.cc.ca Canadian Standards Council http://www.cc.ca Caneeg. Inc CDER What's New bittp://www.fda.gov/cder/whatsnew.htm Center for Biologic Research and Evaluation (CBER) What's New bittp://www.cde.gov/bout/ Centers for Disease Control and Prevention (CDC) bittp://www.cde.gov/bout/ Centers for Disease Control and Prevention (CDC) bittp://www.cde.gov/bout/ Centers for Disease Control and Prevention (CDC) bittp://www.cinical-researcher.com Clinical Trials bittp://www.cinical-researcher.com clinical Data Interchange Standards Consortium bittp://www.clinical-researcher.com Clinical Researcher Clinical Trials Sov (site for registering clinical trials) bittp://www.clinical-researcher.com bittp://www.clinical-researcher.com/ Declaration of Helsinki (1989 version - recognized by FDA) beclaration of Helsinki (2000 version) beclaration of patents bittp://www.man.ne/en/20activities/10telsinki/index.html Department of Health and Human Services (HHS) bittp://www.man.gov/RegulatoryInformation/Guidances/ucm124932.htm bittp://www.	Bioethics Website with educational links, tutorials	http://www.nih.gov/sigs/bioethics
British Medical Journal Canadian Institutes of Health Research Canadian Institutes of Health Research Canadian Standards Council Canadian Standards Canad	BioSpace	http://www.biospace.com
Canadian Institutes of Health Research Canadian Medical Association Antip://www.cac.ga Antip://www.cac.	Biotechnology Industry Organization (BIO)	http://www.bio.org
Canadian Medical Association http://www.cma.ca CanReg. Inc CDER What's New Attp://www.fda.gov/cder/whatsnew.htm Center for Biologic Research and Evaluation (CBER) What's New Attp://www.cde.gov/about/ Centers for Disease Control and Prevention (CDC) Centers for Disease Control and Prevention (CDC) Attp://www.centerwatch.com CIOMS - Council for Int'l Org of Medical Sciences Attp://www.centerwatch.com Clinical Trials Interchange Standards Consortium Attp://www.cdise.org Clinical Researcher Clinical Trials Networks: Best Practices Intp://www.clinical-researcher.com Clinical Trials Networks: Best Practices Intp://www.clinical-researcher.com/ Declaration of Helsinki (1989 version - recognized by FDA) Declaration of Helsinki (2000 version) Declaration of Helsinki (2000 version) Department of Helsinki (2000 version) Attp://www.man.net/en/20activities/10ethics/10helsinki/index.html Department of Health and Human Services (HHS) Drug Approval List EMEA - European Agency for the Evaluation of Medicinal products FDA - Information for patients Http://www.fda.gov/Drugs/Information/Drugs/default.htm EMEA - European Agency for the Evaluation of Medicinal products FDA - News Http://www.fda.gov/news/da.gov/news/ Federal Register Online FDA - News http://www.fda.gov/news/ Federal Register Online FOO, Drug, and Cosmetic Act http://www.fda.gov/news/ flag.gov/news/ flag.gov/news/ flag.gov/negoun/laws/flag.gov/news/	British Medical Journal	http://bmj.com
Canadian Standards Council CanReg, Inc Chee from Biologic Research and Evaluation (CBER) What's New Center for Biologic Research and Evaluation (CDC) Intp://www.fda.gov/cder/whatsnew.htm Center for Disease Control and Prevention (CDC) Intp://www.cdc.gov/about/ Centers for Disease Control and Prevention (CDC) Intp://www.centerwatch.com Clinical Trials Clows - Council for Int'l Org of Medical Sciences Intp://www.coms.ch Clinical Data Interchange Standards Consortium Intp://www.clinical-researcher.com Clinical Researcher Clinical Trials, gov (site for registering clinical trials) Intp://www.clinical-researcher.com Clinical Trials, gov (site for registering clinical trials) Intp://www.clinical-researcher.com Clinical Trials Networks: Best Practices Intp://www.clinical-researcher.com Clinical Trials Networks: Best Practices Intp://www.clinical-researcher.com Intp:	Canadian Institutes of Health Research	http://www.cihr-irsc.gc.ca
CDER What's New http://www.fda.gov/cder/whatsnew.htm Center for Biologic Research and Evaluation (CBER) What's New http://www.fda.gov/about/ Centers for Disease Control and Prevention (CDC) http://www.cdc.gov/about/ Centers for Irical Trials http://www.cdc.gov/about/ Centers for Int'l Org of Medical Sciences http://www.centerwatch.com Clinical Trials per for Int'l Org of Medical Sciences http://www.cdisc.org Clinical Data Interchange Standards Consortium http://www.clinical-researcher.com Clinical Trials gov (site for registering clinical trials) http://www.clinical-researcher.com Clinical Trials Networks: Best Practices http://www.clinical-rials.gov/ Clinical Trials Networks: Best Practices http://www.clinical-rials.gov/ Declaration of Helsinki (1989 version – recognized by FDA) http://www.clinicaltrials.gov/ Declaration of Helsinki (2000 version) http://www.ma.net/en/20activities/10ethics/10helsinki/index.html Department of Health and Human Services (HHS) http://www.ma.net/en/20activities/10ethics/10helsinki/index.html Department of Health and Fundament of Medicinal products http://www.mda.gov/Drugs/Information/OnDrugs/default.htm DEMEA - European Agency for the Evaluation of Medicinal products http://www.mda.gov/osahi/home.html FDA - Information for patients http://www.ema.europa.eu/ema/index.isp?curl=/pages/home/Home Page isp&isenabled=true FDA - News http://www.fda.gov/news/ Federal Register Online http://www.gosarvices.com Food, Drug, and Cosmetic Act http://www.foiservices.com	Canadian Medical Association	http://www.cma.ca
CDER What's New http://www.fda.gov/cder/whatsnew.htm Center for Biologic Research and Evaluation (CBER) What's New http://tinvurt.com/grgero Centers for Disease Control and Prevention (CDC) http://www.cdc.gov/about/ Centers for Disease Control and Prevention (CDC) http://www.cdc.gov/about/ Centers for Disease Control and Prevention (CDC) http://www.cdic.gov/about/ Centers for Disease Control and Prevention (CDC) http://www.cdic.gov/about/ Centers for Disease Control and Prevention (CDC) http://www.cdise.gov/about/ Clinical Trials ClowS - Council for Int'l Org of Medical Sciences http://www.clinical-researcher.com Clinical Data Interchange Standards Consortium http://www.clinical-researcher.com Clinical Researcher Clinical Researcher Clinical Researcher Clinical Researcher Clinical Researcher Clinical Researcher Clinical Trials Networks: Best Practices http://www.clinical-researcher.com http://www.fda.gov/RegulatoryInformation/Guidances/ucm124932.htm http://www.fda.gov/RegulatoryInformation/Guidances/ucm124932.htm http://www.fda.gov/RegulatoryInformation/Guidances/ucm124932.htm http://www.fda.gov/Drugs/InformationOnDrugs/default.htm http://www.fda.gov/Drugs/InformationOnDrugs/default.htm http://www.ema.europa.cu/ema/index.jsp?curl=/pages/home/Home Page.jsp&jsenabled=true http://www.gov/pacess/gov/refault.htm http://www.gov/redex/fdator.html http://www.gov/redex/fdator.html http://www.gov/redex/fdator.html http://www.gov/redex/fdator.html	Canadian Standards Council	http://www.scc.ca
Center for Biologic Research and Evaluation (CBER) What's New http://www.cdc.gov/about/ Centers for Disease Control and Prevention (CDC) http://www.cdc.gov/about/ Centerwatch Clinical Trials http://www.cdisc.org Clinical Trials of Medical Sciences http://www.cdisc.org Clinical Data Interchange Standards Consortium http://www.cdisc.org Clinical Attendange Standards Consortium http://www.clinical-researcher.com Clinical Researcher Clinical Frials Networks: Best Practices https://www.clinical-researcher.com Clinical Trials Networks: Best Practices https://www.clinical-researcher.com/ Declaration of Helsinki (1989 version – recognized by FDA) http://www.mda.gov/RegulatoryInformation/Guidances/ucm124932.htm Declaration of Helsinki (2000 version) http://www.mma.net/en/20activities/10ethics/10helsinki/index.html Department of Health and Human Services (HHS) http://www.mma.net/en/20activities/10ethics/10helsinki/index.html EMEA – European Agency for the Evaluation of Medicinal products http://www.ma.europa.eu/ema/index.jsp?curl=/pages/home/Home_Page.jsp&isenabled=true FDA - Information for patients http://www.eda.gov/nedwatch FDA - News http://www.eda.gov/nedwatch FDA - News http://www.access.data.fda.gov/nedwatch FDA - Federal Register Online http://www.access.data.fda.gov/news/ Federal Register Online http://www.goaccess.gov/fr/index.html FOI - FDA Information and Documentation http://www.fda.gov/opacom/laws/fdcact/fdctoc.htm	CanReg, Inc	http://canreg.ca
Centers for Disease Control and Prevention (CDC) http://www.cdc.gov/about/ Centerwatch Clinical Trials http://www.coims.ch http://www.coims.ch Clinical Data Interchange Standards Consortium http://www.clinical-researcher.com Clinical Researcher Clinical Researcher Clinical Trials.gov (site for registering clinical trials) http://www.clinical-researcher.com Clinical Trials Networks: Best Practices https://www.clinicaltrials.gov/ Clinical Trials Networks: Best Practices https://www.clinicaltrials.gov/ Declaration of Helsinki (1989 version – recognized by FDA) http://www.dta.gov/RegulatoryInformation/Guidances/ucm124932.htm Department of Health and Human Services (HHS) http://www.whs.gov/ Drug Approval List http://www.fda.gov/Drugs/InformationOnDrugs/default.htm http://www.ema.europa.eu/ema/index.jsp?curl=/pages/home/Home_Page_jsp&jsenabled=true FDA - Information for patients http://www.fda.gov/medwatch http://www.fda.gov/medwatch http://www.fda.gov/medwatch FDA - News http://www.gccessdata.fda.gov/news/ Federal Register Online FOI - FDA Information and Documentation http://www.foiservices.com http://www.foiservices.com http://www.foiservices.com http://www.foiservices.com http://www.foiservices.com http://www.foiservices.com http://www.foiservices.com	CDER What's New	http://www.fda.gov/cder/whatsnew.htm
Centerwatch Clinical Trials http://www.centerwatch.com LIOMS – Council for Int'l Org of Medical Sciences http://www.cims.ch http://www.cims.ch http://www.cims.ch http://www.cims.ch http://www.cims.ch http://www.cimical-researcher.com Clinical Researcher http://www.clinical-researcher.com Clinical Trials Networks: Best Practices https://www.clinicaltrials.gov/ Clinical Trials Networks: Best Practices https://www.clinicaltrials.gov/ Declaration of Helsinki (1989 version – recognized by FDA) http://www.ctnbestpractices.org/ 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 http://www.ema.europa.eu/ema/index.jsp?curl=/pages/home/Home_Page.jsp&jsenabled=true http://www.fda.gov/medwatch http://www.fda.gov/medwatch http://www.gov/medwatch http://www.goaccess.gov/fr/index.html FOA - News http://www.goaccess.gov/fr/index.html FOI - FDA Information and Documentation http://www.fda.gov/opacom/laws/fdcact/fdctoc.htm	Center for Biologic Research and Evaluation (CBER) What's New	http://tinyurl.com/9rggero
CIOMS – Council for Int'l Org of Medical Sciences http://www.cioms.ch http://www.clinical-researcher.com http://www.clinical-researcher.com Clinical Trials.gov (site for registering clinical trials) Clinical Trials Networks: Best Practices Declaration of Helsinki (1989 version – recognized by FDA) Declaration of Helsinki (2000 version) Department of Health and Human Services (HHS) Drug Approval List EMEA – European Agency for the Evaluation of Medicinal products FDA - Information for patients FDA - Medwatch FDA - News 1http://www.fda.gov/nedwatch http://www.fda.gov/nedwatch http://www.goo.cess.gov/frindex.html FOI - FDA Information and Documentation http://www.goo.cess.gov/frindex.html FOI - FDA Information and Documentation http://www.fda.gov/opacom/laws/fdacat/fdctoc.htm	Centers for Disease Control and Prevention (CDC)	http://www.cdc.gov/about/
Clinical Data Interchange Standards Consortium http://www.cdisc.org Clinical Researcher http://www.clinical-researcher.com Clinical Trials Networks: Best Practices https://www.clinicaltrials.gov/ Clinical Trials Networks: Best Practices https://www.cthbestpractices.org/ Declaration of Helsinki (1989 version – recognized by FDA) http://www.fda.gov/RegulatoryInformation/Guidances/ucm124932.htm Declaration of Helsinki (2000 version) http://www.man.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.ma.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 News http://www.fda.gov/medwatch FDA News http://www.goaccess.gov/ft/index.html FOI - FDA Information and Documentation http://www.goaccess.gov/ft/index.html FOI - FDA Information and Documentation http://www.fda.gov/oapacom/laws/fdcact/fdctoc.htm	Centerwatch Clinical Trials	http://www.centerwatch.com
Clinical Researcher Clinical Trials.gov (site for registering clinical trials) http://www.clinical-tresearcher.com 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.man.et/en/20activities/10ethics/10helsinki/index.html Department of Health and Human Services (HHS) 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.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	CIOMS – Council for Int'l Org of Medical Sciences	http://www.cioms.ch
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Clinical Trials Networks: Best Practices https://www.ctnbestpractices.org/ beclaration of Helsinki (1989 version – recognized by FDA) http://www.fda.gov/RegulatoryInformation/Guidances/ucm124932.htm beclaration of Helsinki (2000 version) http://www.man.et/en/20activities/10ethics/10helsinki/index.html bepartment of Health and Human Services (HHS) brug Approval List http://www.fda.gov/Drugs/InformationOnDrugs/default.htm 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.accessdata.fda.gov/news/ Federal Register Online http://www.gooaccess.gov/fr/index.html FOI - FDA Information and Documentation http://www.foiservices.com http://www.fda.gov/opacom/laws/fdcact/fdctoc.htm	Clinical Researcher	http://www.clinical-researcher.com
Declaration of Helsinki (1989 version – recognized by FDA) Declaration of Helsinki (2000 version) Department of Health and Human Services (HHS) Drug Approval List EMEA – European Agency for the Evaluation of Medicinal products FDA - Information for patients FDA - News Drug Aperoval EDA - News Drug Aperoval	ClinicalTrials.gov (site for registering clinical trials)	http://www.clinicaltrials.gov/
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Department of Health and Human Services (HHS) Drug Approval List EMEA – European Agency for the Evaluation of Medicinal products FDA - Information for patients EDA – News FDA - News FDA - News FOA - News Fob - FDA Information and Documentation FOA - FDA Information and Documentation FOA - FOA Information and Documentation FOA - FOA Information and Cosmetic Act FOA - Drug, and Cosmetic Act http://www.fda.gov/opacom/laws/fdcact/fdctoc.htm	Declaration of Helsinki (1989 version – recognized by FDA)	http://www.fda.gov/RegulatoryInformation/Guidances/ucm124932.htm
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EMEA – European Agency for the Evaluation of Medicinal products FDA - Information for patients http://www.fda.gov/oashi/home.html FDA Medwatch FDA - News http://www.fda.gov/medwatch Federal Register Online FOI – FDA Information and Documentation FOI – FDA Information and Documentation FOOd, Drug, and Cosmetic Act http://www.fda.gov/opacom/laws/fdcact/fdctoc.htm	Department of Health and Human Services (HHS)	http://www.hhs.gov/
FDA - Information for patients FDA Medwatch FDA - News Federal Register Online FOI - FDA Information and Documentation FOI - FDA Information and Documentation FOI - FDA Information Accorded to http://www.foiservices.com Food, Drug, and Cosmetic Act http://www.fda.gov/oashi/home.html http://www.fda.gov/medwatch http://www.gov/oashi/home.html http://www.fda.gov/news/ http://www.gov/oashi/home.html http://www.foiservices.com http://www.foiservices.com http://www.foiservices.com/laws/fdcact/fdctoc.htm	Drug Approval List	http://www.fda.gov/Drugs/InformationOnDrugs/default.htm
FDA Medwatch FDA - News http://www.fda.gov/medwatch 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	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 - 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	FDA - Information for patients	http://www.fda.gov/oashi/home.html
Federal Register Online FOI – FDA Information and Documentation http://www.foiservices.com Food, Drug, and Cosmetic Act http://www.fda.gov/opacom/laws/fdcact/fdctoc.htm	FDA Medwatch	http://www.fda.gov/medwatch
FOI – FDA Information and Documentation http://www.foiservices.com Food, Drug, and Cosmetic Act http://www.foiservices.com http://www.fda.gov/opacom/laws/fdcact/fdctoc.htm	FDA - News	http://www.accessdata.fda.gov/news/
Food, Drug, and Cosmetic Act http://www.fda.gov/opacom/laws/fdcact/fdctoc.htm	Federal Register Online	http://www.gpoaccess.gov/fr/index.html
	FOI – FDA Information and Documentation	http://www.foiservices.com
Freedom of Information Room http://www.fda.gov/RegulatoryInformation/foi/default.htm	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