

## Northwest IRB Fresh Sheet – Resource Guide

### March 2006 through March 2009

#### Articles:

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#### Books:

- ***A Message of Love, Hope, and Optimism for People Who Are Sick or Worried: From a Human Subjects Research Participant*** by Steven S. Coughlin
- ***Agent GCP and The Bloody Consent Form Guidebook*** by Daniel Farb
- ***Being Human: Core Readings in the Humanities***, edited by Leon Kass (formerly published as *Being Human: Readings from the Presidents Council on Bioethics*)
- ***Belmont Revisited: Ethical Principles for Research with Human Subjects*** by James F. Childress, Eric M. Meslin and Harold T. Shapiro
- ***Beyond Consent: Seeking Justice in Research*** by Jeffrey Kahn, Anna Mastroianni and Jeremy Sugarman
- ***Beyond Regulations: Ethics in Human Subjects Research*** by King N, Henderson G, and Stein J
- ***Beyond Regulations: Ethics in Human Subjects Research (Studies in Social Medicine)*** by Nancy M.P. King and Jane Stein
- ***Bioethics Briefing Book*** from The Hastings Center  
<http://www.thehastingscenter.org/Publications/BriefingBook/Default.aspx>.
- ***Children in Medical Research: Access versus Protection (Issues in Biomedical Ethics)*** by Lainie Friedman Ross
- ***Ethics and Research on Human Subjects. International Guidelines*** Proceedings of the XXVIth COIMS Conference, COIMS Round Table Conference, No 26; Bankowski, Z., Levine, R.J.  
<http://www.who.int/bookorders/anglais/detart1.jsp?sesslan=1&codlan=1&codcol=83&codcch=26>
- ***Ethics and Research with Children: A Case-Based Approach*** by Eric Kodish
- ***Ethics in Mental Health Research: Principles, Guidance, and Cases*** by James M. DuBois, Saint Louis University, Oxford University Press
- ***Ethics in Neurobiological Research with Human Subjects*** by Adil E. Shamoo
- ***Ethics of Research Involving Human Subjects: Facing the 21<sup>st</sup> Century*** by Harold Y. Vanderpool
- ***Ethics of the Use of Human Subjects in Research: (Practical Guide)*** by Adil E. Shamoo
- ***Federal Protection for Human Research Subjects: An Analysis of the Common Rule and Its Interactions with FDA Regulations and the HIPAA Privacy Rule*** by Lee O. Jastone
- ***HIPAA Compliance Handbook 2006*** by Patricia I. Carter
- ***Improving the Quality of Cancer Clinical Trials: Workshop Summary***, The National Academies Press, 2008
- ***Medical Apartheid: The Dark History of Medical Experimentation on Black Americans from Colonial Times to the Present*** by Harriet A. Washington, New York: Doubleday, 2007.

- **Protecting Human Subjects: Departmental Subject Pools and Institutional Review Boards** by Garvin Chastain and R. Eric Landrum
- **Protecting Participants and Facilitating Social and Behavioral Sciences Research** by Constance Citro, Daniel Ilgen and Cora Marrett. National Academies Press.
- **Protecting Student Records and Facilitating Educational Research: A workshop summary** by Margaret Hilton, Rapporteur, National Research Council. National Academies Press
- **Side Effects: A Prosecutor, a Whistleblower, and a Bestselling Antidepressant on Trial** by Alison Bass
- **The Cambridge Textbook of Bioethics** edited by Peter A. Singer and A.M. Viens  
<http://www.cambridge.org/catalogue/catalogue.asp?isbn=9780521694438>
- **The Ethics and Regulation of Research with Human Subjects**, edited by Carl H. Coleman
- **The Man Who Shocked The World: The Life and Legacy of Stanley Milgram** by Thomas Blass: Basic Books 2004

#### Ethics Codes and Standards:

- **Belmont Report** - <http://hhs.gov/ohrp/humansubjects/guidance/belmont.htm>
- **Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects** - [http://www.cioms.ch/frame\\_guidelines\\_nov\\_2002.htm](http://www.cioms.ch/frame_guidelines_nov_2002.htm)
- **Declaration of Helsinki** - [www.wma.net/e/policy/b3.htm](http://www.wma.net/e/policy/b3.htm)
- **European Union Clinical Trials Directive** <http://www.eortc.be/Services/Doc/clinical-EU-directive-04-April-01.pdf>
- **International Conference on Harmonization – Guideline for Good Clinical Practice** - <http://www.fda.gov/cder/guidance/959fnl.pdf>
- **Nuremberg Code** - [www.hhs.gov/ohrp/references/nurcode.htm](http://www.hhs.gov/ohrp/references/nurcode.htm) or <http://www.nihttraining.com/ohrsite/guidelines/nuremberg.html>
- **The Common Rule** - <http://www.hhs.gov/ohrp/references/comrul2.pdf>
- **Title 21 Food and Drug Administration, Department of Health and Human Services, Part 50 Protection of Human Subjects** - [http://www.access.gpo.gov/nara/cfr/waisidx\\_01/21cfr50\\_01.html](http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr50_01.html)
- **Title 45 Public Welfare, Department of Health and Human Services, Part 46 Protection of Human Subjects** - [www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm)
- **Title 45 Public Welfare, Department of Health and Human Services, Part 46 Protection of Human Subjects. SubPart 46.107 IRB Membership** - <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr.htm#46.107>
- **Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (Canada)** - <http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm>
- **US Public Health Service Syphilis Study background** - <http://www.tuskegee.edu/global/story.asp?S=1207512>

#### Internet resources:

- **Aberdeen Area Tribal Chairmen's Health Board, Research Ethics and IRB Resources for Tribes and Researchers** - Scroll down the page to 'How to review research to benefit tribal communities, including how to build and sustain a tribal IRB' and 'How to conduct research in AI/AN Communities'. Multiple power point presentations, web links, model protocols, etc.  
[www.aatchb.org/epi/docs/researchethics.htm](http://www.aatchb.org/epi/docs/researchethics.htm)
- **Alzheimer's Association: Protection of Participants in Research** - [http://www.alzwa.org/docs/resources/research/FS\\_Protection\\_of\\_Research\\_Participants\\_ethical\\_issues.pdf](http://www.alzwa.org/docs/resources/research/FS_Protection_of_Research_Participants_ethical_issues.pdf)
- **Association of American Medical Colleges**
  - **2006 National Conference on Alternative IRB Models: Optimizing Human Subject Protection** - <http://www.aamc.org/research/irbreview/start.htm>
  - **Principles for Protecting Integrity in the Conduct and Reporting of Clinical Trials** - <http://www.aamc.org/research/clinicaltrialsreporting/start.htm>

- **Association of Asian Pacific Community Health Organizations** – Community-Based Participatory Research (CBPR) toolkit for health centers and investigators working with Asian Americans, Native Hawaiians and Pacific Islanders  
<http://www.aapcho.org/site/aapcho/section.php?id=11295>
- **Brigham Young University - Idaho** - useful information about informed consent, oral histories, classroom vs. research activity and a human subjects tutorial. <http://www.byui.edu/IR/IRB.htm>
- **Centers for Disease Control and Prevention**
  - Guidelines for Defining Public Health Research and Public Health Non-Research  
<http://www.cdc.gov/od/science/regs/hrpp/researchDefinition.htm>
  - Institutional Review Board information <http://www.cdc.gov/od/science/regs/hrpp/irbs.htm>
- **CenterWatch Clinical Trials Listing Service** – industry-sponsored clinical trials actively recruiting patients, searchable by therapeutic area or geographic region.  
<http://www.centerwatch.com/patient/trials.html>
- **Citizens for Responsible Care and Research** - List of IRBS registered with the Office for Human Research Protections. [www.circare.org/info/researchbythenumbers1.htm](http://www.circare.org/info/researchbythenumbers1.htm)
- **ClinicalTrials.gov** – registry of federally and privately supported clinical trials conducted in the US and around the world. [www.clinicaltrials.gov](http://www.clinicaltrials.gov)
- **Community-Campus Partnerships for Health (CCPH), Ethics & IRBs** - multiple links, useful resources. [www.ccpb.info](http://www.ccpb.info), <http://depts.washington.edu/ccph/links.html#ethics> or [http://depts.washington.edu/ccph/pdf\\_files/resources\\_CBPR\\_108.pdf](http://depts.washington.edu/ccph/pdf_files/resources_CBPR_108.pdf)
- **Cutting Edge Information: Streamlining Clinical Trials** – report focuses on patient recruitment, budgeting and performance assessments, and clinical operations structure and work flow. Free summary is available. Cost for full report is approximately \$8000.  
<http://www.cuttingedgeinfo.com/clinicaltrialbenchmarking/>
- **Department of Energy**
  - Protection of Human Subjects - <http://humansubjects.energy.gov/>
  - **NEW** Analyzing your Human Research Protection Program – A systemic approach to creating an effective structure. <http://humansubjects.energy.gov/doe-resources/files/hrpanalysis.pdf>.
- **Department of Health and Human Services**
  - **Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection** -  
<http://www.hhs.gov/ohrp/humansubjects/finreltn/finalguid.pdf>
- **Department of Social & Health Services, Human Research Review Section/Washington State Institutional Review Board** - <http://www1.dshs.wa.gov/rda/hrrs/default.shtm>
- **Environmental Protection Agency** - Human Health Research Program site with the latest information on its research to protect public health. Contains an overview of research, information on the research process and resource materials. <http://www.epa.gov/hhrp/>
- **Ethics in the Context of Research and Indigenous Peoples: A Bibliography** – a list of articles and related resources on the topic of ‘ethics in Indigenous health research’.  
[http://www.ksdpp.org/docs/ethics\\_database.pdf](http://www.ksdpp.org/docs/ethics_database.pdf)
- **Food and Drug Administration**
  - Forms - <http://www.fda.gov/opacom/morechoices/fdaforms/cder.html>
  - Good Clinical Practice - <http://www.fda.gov/oc/gcp/default.htm>
  - Information for Clinical Investigators -  
[http://www.fda.gov/cder/about/smallbiz/clinical\\_investigator.htm](http://www.fda.gov/cder/about/smallbiz/clinical_investigator.htm)
  - IRB Information sheets - <http://www.fda.gov/oc/ohrt/irbs/default.htm>
  - IRB -  
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=56>
  - Preambles to GCP Regulations - <http://www.fda.gov/oc/gcp/preambles/default.htm>
  - Protection of Human Subjects -  
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=50>
- **Genetic Engineering & Biotechnology News**
  - Subscription (free) – [www.genengnews.com](http://www.genengnews.com)
  - Podcast – Clinical Trial Ethics in the Developing World, Interview with Jonathan Kimmelman, August 7, 2008 (approx 20 minutes) -  
<http://www.genengnews.com/genecasts.aspx>
- **Institute of Medicine**
  - Health Research and the Privacy of Health Information – the HIPAA Privacy Rule  
<http://www.iom.edu/CMS/3740/43729.aspx>

- HIPAA Background Information  
<http://www.iom.edu/Object.File/Master/43/949/HIPAA%20Background.pdf>
- **Institutional Review Board and Ethical Issues in Research Call Series** audio files and handouts. For more information on the series, visit <http://depts.washington.edu/ccph/irbcalls.html>  
Audio files & handouts are available at <http://depts.washington.edu/ccph/pastpresentations.html>
- **Institutional Review Board-Spokane** – reviews studies for 5 hospitals and WSU. Site includes emergency and single patient, HIPAA, adverse event reporting, and advertising and marketing guidelines as well as forms for researchers.  
<http://www.spokane.wsu.edu/research&service/HREC/IRB/index.asp>
- **Kahnawake Schools Diabetes Prevention Project – Code of Research Ethics** – extensive set of principles and procedures used throughout this ongoing (14 years +) study.  
[http://www.ksdpp.org/i/ksdpp\\_code\\_of\\_research\\_ethics2007.pdf](http://www.ksdpp.org/i/ksdpp_code_of_research_ethics2007.pdf)
- **National Cancer Institute**
  - **Human Participant Protections Education for Research Teams** - free two-hour tutorial designed for those involved in conducting research involving human participants. Satisfies the NIH human subjects training requirement for obtaining Federal Funds. <http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>
  - **States that require health plans to cover patient care costs in clinical trials**  
<http://www.cancer.gov/clinicaltrials/ctlaws-home>
- **National Conference of State Legislatures** maintains a frequently updated database of state health privacy laws including genetic privacy (<http://www.ncsl.org/programs/health/genetics/prt.htm>) and medical records' privacy (<http://www.ncsl.org/programs/lis/privacy/medprivacy.htm>). Many useful external links and other resources are also available.
- **National Institutes of Health (NIH)** – <http://www.nih.gov>
  - **Office of Extramural Research: Human Subjects Web Site** - HHS and NIH requirements and resources for applicants/grantees, offerors/contractors, peer reviewers and institutional officials. <http://grants2.nih.gov/grants/policy/hs/>
  - **Ethics in Clinical Research** - [http://clinicalresearch.nih.gov/ethics\\_vol.html](http://clinicalresearch.nih.gov/ethics_vol.html)
  - **Office of Human Subjects Research** - <http://ohsr.od.nih.gov/>
  - **Clinical Research: Policy Analysis & Coordination Models of IRB Review** - [http://crpac.od.nih.gov/issue\\_IRB.asp](http://crpac.od.nih.gov/issue_IRB.asp)
  - **Guidelines for the Conduct of Research Involving Human Subjects at the NIH** - <http://ohsr.od.nih.gov/guidelines/GrayBooklet82404.pdf>
  - **A Guide to Preventing Conflicts of Interest in Human Subjects Research at NIH** - [http://www.nihtraining.com/ohsr/site/new/COI-CR\\_1-4-2005FIN.pdf](http://www.nihtraining.com/ohsr/site/new/COI-CR_1-4-2005FIN.pdf)
- **National Research Ethics Service, National Patient Safety Agency** – works with colleagues in the UK to maintain a system of ethical review to protect the safety, dignity and well being of research participants. <http://www.nres.npsa.nhs.uk/>
- **National Resource Center on Advancing Emergency Preparedness for Culturally Diverse Communities** – Clearinghouse and information exchange portal to facilitate communication, networking and collaboration to improve preparedness, build resilience and eliminate disparities for racially and ethnically diverse communities in public health emergencies.  
[www.diversitypreparedness.org](http://www.diversitypreparedness.org).
- **National Science Foundation, Interpreting the Common Rule for the Protection of Human Subjects for Behavioral and Social Science Research** - <http://www.nsf.gov/bfa/dias/policy/hsfaqs.jsp>
- **Navajo Nation Human Research Review Board** - Navajo Nation Human Research Code  
<http://www.nnhrrb.navajo.org/pdf/NNHumanResearchCode.pdf>
- **Northwestern University: Student Surveys Planning Group** – page contains a description of survey standards that may be useful for new investigators and policy statements, survey instruments and other resources. <http://www.adminplan.northwestern.edu/ir/sspg.htm>
- **Office for Human Research Protections (OHRP)** – registration, training, publications, consultation, etc. <http://www.hhs.gov/ohrp>
  - **Human Subject Regulations Decision Charts** - <http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm>
  - **IRB Guidebook** - [http://www.dhhs.gov/ohrp/irb/irb\\_guidebook.htm](http://www.dhhs.gov/ohrp/irb/irb_guidebook.htm)
  - **2008 International Compilation of Human Subject Protections** - <http://www.hhs.gov/ohrp/international/>
  - **Policy Guidance (by topic)** - <http://www.hhs.gov/ohrp/policy/index.html>

- **Protecting Human Subjects Videotape Series** - <http://www.hhs.gov/ohrp/references/resource.htm>
- **Office of Research Integrity** - training programs, newsletter, publications, conferences and other resources. <http://ori.dhhs.gov>
- **Oregon Health & Science University** – all forms, policies, procedures, and additional resources are publicly available - <http://www.ohsu.edu/ra/irb/>
- **President's Council on Bioethics** - contains reports, transcripts, background materials and publications related to the advisement of the President on ethical issues related to advances in biomedical science and technology. [www.bioethics.gov](http://www.bioethics.gov)
- **Project TRES (Training in Research Ethics and Standards)** – research ethics training for community health workers conducting studies within the Latino community. <http://www.hhs.gov/ohrp/international/>
- **PRIMR** - training videos, educational seminars, newsletters, conferences, professional certification, ethics (human and animal) resources. Membership required for some services. [www.primr.org](http://www.primr.org)
- **Research Advocacy Network** - connects research advocates to improve patient care and reduce the amount of time for research results to reach community practice. [www.researchadvocacy.org/about.index.php](http://www.researchadvocacy.org/about.index.php)
- **San Francisco State University Office for the Protection of Human & Animal Subjects** - <http://www.sfsu.edu/~protocol/human/review-required.htm>
- **Stanford University** –
  - **Glossary** - medical term definitions for lay audiences. <http://humansubjects.stanford.edu/general/glossary.html>
  - **Research Policy Handbook** - <http://www.stanford.edu/dept/DoR/rph/Chpt7.html>
- **Texas A&M University – Human Subjects Protection Program**
  - **Human Subjects Herald (Newsletter)** - <http://researchcompliance.tamu.edu/irb>
- **The Federal Register** – the official daily publication for rules, proposed rules, and notices of Federal agencies and organizations. <http://www.gpoaccess.gov/fr/index.html>
- **The Hastings Center** – bioethics research institute that explores questions related to healthcare, biotechnology and the environment. [www.thehastingscenter.org](http://www.thehastingscenter.org)
- **Tuskegee University National Center for Bioethics in Research and Health Care** - [www.tuskegee.edu/bioethics](http://www.tuskegee.edu/bioethics)
- **University of California Los Angeles Office for the Protection of Research Subjects** - <http://www.oprs.ucla.edu/>
  - **Investigator's Manual for the Protection of Human Subjects** - <http://www.oprs.ucla.edu/human/manual/TOC>
- **University of California San Francisco Human Research Protection Program** - <http://www.research.ucsf.edu/chr/index.asp>
- **University of Michigan Medical School IRB** - <http://www.med.umich.edu/irbmed/>
- **University of Minnesota Research Subjects' Protection Programs** - <http://www.research.umn.edu/subjects/>
  - **Teaching Ethics for Research, Scholarship & Practice: Human Subjects** - [http://www.research.umn.edu/ethics/curriculum/human\\_subjects.html](http://www.research.umn.edu/ethics/curriculum/human_subjects.html)
- **University of Rhode Island Human Subjects Research site** - <http://www.uri.edu/research/compliance/humansubj.htm>
- **Waianae Coast Comprehensive Health Center** - research and IRB protocols established to protect the community and provide a consistent research framework for a unique population residing on the Waianae Coast of Oahu. [http://www.waianae-comp.org/res\\_irb.htm](http://www.waianae-comp.org/res_irb.htm)
- **Women's Bioethics Project** - public policy think tank for women's issues in health care and biotechnology. <http://womensbioethics.org>
- **World Health Organization**
  - International Clinical Trials Registry Platform <http://www.who.int/ictrp/en/>
  - International ethical guidelines for biomedical research involving human subjects [http://whqlibdoc.who.int/emro/2004/9290213639\\_annex2.pdf](http://whqlibdoc.who.int/emro/2004/9290213639_annex2.pdf)
  - Islamic Viewpoint on the International Ethical Guidelines for Biomedical Research Involving Human Subjects <http://www.emro.who.int/ahsn/Presentations/Day2/Dr-HossamFadel.pdf>
  - Pan American Health Organization – Ethical guidelines for research involving human subjects <http://www.paho.org/common/Display.asp?Lang=E&ReclD=8543>
  - Practical Guide for Health Researchers <http://www.emro.who.int/dsaf/dsa237.pdf>

- Research Ethics Review Committee (ERC) [http://www.who.int/rpc/research\\_ethics/en/](http://www.who.int/rpc/research_ethics/en/)

#### ListSers, Blogs and News Services:

- **CBPR and Research Ethics Listserv**, established to foster dialogue between IRBs about ethical issues in research. Contact Kristine Wong at [Kristine@u.washington.edu](mailto:Kristine@u.washington.edu) or subscribe (free) at <https://mailman1.u.washington.edu/mailman/listinfo/ccph-ethics>
- **Community-Based Participatory Research (CBPR) Listserv**, information for IRBs, compliance and investigators. <https://mailman1.u.washington.edu/mailman/listinfo/cbpr>
- **Institutional Review Blog** by Zachary Schrag, Assistant Professor of History, George Mason University (non-biomedical research focus) – [www.institutionalreviewblog.com](http://www.institutionalreviewblog.com)
- **IRB Forum** (formerly MCWIRB), membership is free. [www.irbforum.org](http://www.irbforum.org)
- **Community IRB Member: Neighbor & Partner**, operated by the US Department of Energy. [www.orau.gov/communityirb/default.htm](http://www.orau.gov/communityirb/default.htm) for information, [www.orau.gov/communityirb/listserv.htm](http://www.orau.gov/communityirb/listserv.htm) to join the discussion group or contact [communityirb@orau.gov](mailto:communityirb@orau.gov)
- **FDAGCPP List**, get up-to-date information on FDA's activities concerning good clinical practice and human subject protection. <https://list.nih.gov/cgi-bin/wa?SUBED1=fdagcpp&A=1>
- **Illuminata, Inc.**: "News in Research with Human Subjects" weekly email news service (subscription required). Contact Sharon Durfy at 866-772-9362 or visit [www.illuminata-inc.com](http://www.illuminata-inc.com).
- **Institute of Medicine**, bi-monthly email newsletter with news, publications, events and online content. <http://www.iom.edu/CMS/3238.aspx>
- **PRIMR Blogspot**, <http://primr.blogspot.com/>

#### Publications:

- **ACME: An International E-Journal for Critical Geographies (Special Thematic Issue: Participatory Ethics)** contains numerous articles such as Bureaucratizing Ethics: Institutional Review Boards and Participatory Research by Deborah Martin and Silenced for Their Own Protection: How the IRB Marginalizes those it Feigns to Protect. <http://www.acme-journal.org/Volume6-3.htm>.
- **Annals of Internal Medicine** Newsletter from the American College of Physicians. Contains numerous articles related to treatment of disease, clinical trial updates and essays on the ethical treatment of human subjects. [www.annals.org](http://www.annals.org)
- **Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research**, National Academies Press [http://www.nap.edu/catalog.php?record\\_id=12458](http://www.nap.edu/catalog.php?record_id=12458)
- **Clinical Trials State of the Industry Report 2006: Market Players, Data, Drug Development and the Future**, BioWorld Today and CenterWatch. Cost is \$499 plus shipping and handling. [www.bioworld.com](http://www.bioworld.com)
- **Conducting Clinical Trials in Europe: an Insider's Analysis and Overview**, Insight Pharma Reports. Cost is \$2,999. [http://www.insightpharmareports.com/reports\\_report.aspx?id=85732&r=639](http://www.insightpharmareports.com/reports_report.aspx?id=85732&r=639). Commentary on report from **Bio-IT World** can be accessed at no charge by clicking <http://www.bio-itworld.com/2009/01/06/european-clinical-trials.html>.
- **Ethical Conduct of Clinical Research Involving Children** Institute of Medicine <http://www.iom.edu/CMS/3740/4864/19422.aspx>
- **Ethical Considerations for Research Involving Prisoners** Institute of Medicine (IOM). <http://www.iom.edu/CMS/3740/24594/35792.aspx>
- **Financial Relationships Between Institutional Review Boards and Industry** by Greg Koski et al. *New England Journal of Medicine* 2006; 355: 2321-9
- (Draft) **Guidance for Clinical Trial Sponsors: On the Establishment and Operation of Clinical Trial Data Monitoring Committees, Food and Drug Administration**. <http://www.fda.gov/ohrms/dockets/98fr/010489gd.pdf>
- **Guiding Good Research: Biomedical Research Ethics and Ethics Review** from the Observatory on Health Research Systems [http://www.rand.org/pubs/documented\\_briefings/2008/RAND\\_DB536.pdf](http://www.rand.org/pubs/documented_briefings/2008/RAND_DB536.pdf)
- **HHS in the 21<sup>st</sup> Century: Charting a New Course for a Healthier America** from the National Academies Press [http://www.nap.edu/catalog.php?record\\_id=12513](http://www.nap.edu/catalog.php?record_id=12513)

- **Human Subjects Protection Resource Book** from the Department of Energy. Free download at <http://www.ornl.gov/community/irb/news.htm>
- **Improving the System for Protecting Human Subjects: Counteracting IRB "Mission Creep"**, The Center for Advanced Study. [www.law.uiuc.edu/conferences/whitepaper/](http://www.law.uiuc.edu/conferences/whitepaper/)
- **Infrequent Flyer: PRIM&R's Calendar of Events**, [announcements@primr.org](mailto:announcements@primr.org)
- **International Compilation of Human Subject Research Protections**, 2007 Edition, Compiled by Office for Human Research Protections, US Department of Health and Human Services. <http://www.hhs.gov/ohrp/international/HSPCompilation.pdf>
- **IRB: Ethics & Human Research**, published by the Hastings Center (subscription charges apply). <http://www.thehastingscenter.org/publications/irb/irb.asp>
- **Journal of Empirical Research on Human Research Ethics (JERHRE)**. [www.csueastbay.edu/JERHRE](http://www.csueastbay.edu/JERHRE)
- **Military Medical Ethics Report**, published by the National Academies Press. Free download (sign in required) or approximately \$20 for paperback copy. [http://www.nap.edu/catalog.php?record\\_id=12478](http://www.nap.edu/catalog.php?record_id=12478)
- **Office of Research Integrity Newsletter**, quarterly newsletter promoting integrity in research. <http://ori.hhs.gov>
- **Outreach Notebook for the Inclusion, Recruitment and Retention of Women and Minority Subjects in Clinical Research**, National Institutes of Health Report number NIH/PUB-03-7036. <http://grants2.nih.gov/grants/policy/emprograms/overview/women-and-mi.htm>
- **Patients and Understanding** (article) by Sandra G. Boodman, The Washington Post. Printed March 5, 2007. An article about low 'health literacy' and the consent process. [http://www.knoxnews.com/kns/health\\_and\\_fitness/article/0,1406,KNS\\_310\\_5391238,00.html](http://www.knoxnews.com/kns/health_and_fitness/article/0,1406,KNS_310_5391238,00.html)
- **Pimatisiwin: A Journal of Indigenous and Aboriginal Community Health** [www.pimatisiwin.com](http://www.pimatisiwin.com)
- **Preserving Public Trust: Accreditation and Human Research Participant Protection Programs** Institute of Medicine, April 17, 2001 [http://www.nap.edu/catalog.php?record\\_id=10085](http://www.nap.edu/catalog.php?record_id=10085)
- **PRIM&R Through the Years: Three Decades of Protecting Human Subjects, compilation of almost 30 years of key talks delivered at past PRIM&R conferences.** Cost: \$65 PRIM&R members or \$80 Non-members. [http://www.primr.org/resources/through\\_the\\_years.html](http://www.primr.org/resources/through_the_years.html)
- **Protecting Human Subjects**, quarterly newsletter by the US Department of Energy, Office of Biological and Environmental Research. To subscribe (free) send name, address and the statement "add new subscriber" with a business card to Michael Viola, MD, SC-72 Germantown Building, US Dept. of Energy, 1000 Independence Ave SW, Washington DC 20585-1290, email [humansubjects@science.doe.gov](mailto:humansubjects@science.doe.gov) or fax to 301-903-8521
- **Public Health Ethics**, a peer-reviewed international journal focusing on systematic analysis of the moral problems that arise in public health and preventative medicine. (Oxford Journals - [http://www.oxfordjournals.org/our\\_journals/phe/](http://www.oxfordjournals.org/our_journals/phe/))
- **Responsible Research: A Systems Approach to Protecting Research Participants** by Daniel D. Federman, Kathi E. Hanna, and Laura Lyman Rodriguez, *Editors*, Committee on Assessing the System for Protecting Human Research Participants (National Academies Press)
- **: Report of the International Bioethics Committee of UNESCO** (United Nations Educational, Scientific and Cultural Organization) **on Consent** <http://unesdoc.unesco.org/images/0017/001781/178124E.pdf>

#### Training and Certification:

- **African Malaria Network Trust (AMANET) Web Based Courses** – free online courses are offered for ethics review boards, IRBs and investigators conducting or overseeing research with African populations. Course titles include Basic and Advanced Research Ethics and Good Clinical Practice. <http://webcourses.amanet-trust.org/>
- **Association of Clinical Research Professionals Online Clinical Courses** – numerous 1-2 contact hour courses in good clinical practices, CRA curriculum, CRC curriculum, investigator curriculum and regulatory affairs. Cost per course is \$175. <http://www.acrpn.net/MainMenuCategory/Education/online/OnlineClinicalCourses.aspx>
- **Centers for Disease Control and Prevention**
  - Scientific Ethics Training – send email to [inquiry@cdc.org](mailto:inquiry@cdc.org) to request access to free, online training curricula
- **Certified IRB Professional** - <http://www.primr.org/Certification.aspx?ID=236>

- **Collaborative Institutional Training Initiative (CITI) Course** – education program for principle investigators and staff consisting of basic, refresher and international online courses. Annual user fee required. [https://www.citiprogram.org/citi\\_information.asp](https://www.citiprogram.org/citi_information.asp)
- **Ethical and Regulatory Aspects of Clinical Research** – The Department of Bioethics at the National Institutes of Health offers this course via webcast and podcast lectures. There is no charge to attend but a textbook is required. <http://www.bioethics.nih.gov/hsrc/index.shtml>
- **Family Health International** - Free 'Research Ethics Training Curriculum for Community Representatives' available in print, CD-ROM and online versions in English, French, Spanish and Portuguese. <http://www.fhi.org/en/RH/Training/trainmat/ethicscurr/RETCCREn/index.htm>
- **Free Research Training** – portal to free online clinical research tutorials. <http://freeresearchtraining.com/>
- **Graduate Certificate in Clinical Research and Regulatory Administration** – Northwestern University, Chicago, IL. <http://www.scs.northwestern.edu/grad/crra/>
- **Healthcare Research Compliance Certification** - [http://www.hcca-info.org/AM/Template.cfm?Section=CHRC\\_Certification](http://www.hcca-info.org/AM/Template.cfm?Section=CHRC_Certification)
- **Human Participant Protections Education for Research Teams** – 2 hour tutorial designed for those involved in conducting research with human participants. Offered by the National Cancer Institute. Free but requires registration. <http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>
- **Human Subject Assurance Training** – OHRP recommends Institutional Officials complete Module 1, IRB administrator and chair should take all three modules. [editorial note: some institutions are using this for community members and other community-based project personnel] <http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp>
- **Northwestern University Clinical and Translational Sciences Institute** - <http://www.nucats.northwestern.edu/>
  - CRC Basic Training Online - <http://www.nucats.northwestern.edu/education/CRPT/CRC%20Basic/onlineCRC.html>
- **Protecting Human Research Participants (PHRP)** – replaces the NCI Human Participant Protections Education for Research Teams course. <http://www.cancer.gov/clinicaltrials/learning/humanparticipant-protections>
- **Research Ethics Training Curriculum for Community Representatives** – free, extensive curriculum developed by Family Health International. A PDF version is available at <http://www.fhi.org/en/RH/Training/trainmat/ethicscurr/retccr.htm> or contact David Borasky at [dborasky@fhi.org](mailto:dborasky@fhi.org) or 919-544-7040 ext. 295.

**Mentorship and Consultation Assistance:**

**Charlotte Shupert, PhD, CIP**; Associate Director, Research Integrity Office, Oregon Health & Science University. 503-494-9644 or [shupertc@ohsu.edu](mailto:shupertc@ohsu.edu) – speaking, consultation, mentoring, etc.

**Institute for Translational Health Sciences Research Bioethics Consult Service** – confidential, advisory consultations on ethical issues related to clinical research studies. Supplemental to the IRBs' responsibility for research oversight, this service is available for research participants, families, communities and IRBs. Consults can be requested by contacting the RSB core office at 206-598-6477 or [rsbcore@u.washington.edu](mailto:rsbcore@u.washington.edu). For urgent issues related to the care of particular research participants, call the Children's paging operator at 206-987-2000 and ask for the Research Bioethicist on call.

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