



Connecting the IRB Community in the Northwest

Published quarterly by the Northwest Association for Biomedical Research (NWABR), the Northwest IRB Fresh Sheet is your communication tool to reach other human subjects programs throughout the region with news and information. Posting announcements and subscriptions are free to members of NWABR. Contact Laurie Hassell at 206-465-4691 or hassell@nwabr.org for newsletter and membership questions.

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News Round-up

BBC News published an article on April 8, 2008 entitled "Halted Drug Trial Safety Concerns" regarding benefits that may be exaggerated in order to halt trials early to support marketing authorization applications. The claim that halting studies with 'good interim results', which speed medications to market and save lives is countered by the argument that 'data on effectiveness and potential side-effects can be missed by stopping a trial early'. Access the article at <http://news.bbc.co.uk/1/hi/health/7336695.stm>.

Chemical & Engineering News printed an article on April 7, 2008 entitled 'Trial Results Roil Drug Companies', which reports criticism from lawmakers against major pharmaceutical companies for withholding negative clinical trial data, allegedly to continue sales of Vytorin and Zetia. The article can be accessed at <http://pubs.acs.org/cen/news/86/i14/8614notw4.html>.

The **Food and Drug Administration** has issued a final ruling about clinical studies not conducted under an Investigational New Drug Application, which will go into effect on October 27, 2008. The final rule replaces the requirement that these studies be conducted in accordance with ethical principles stated in the Declaration of Helsinki, with a requirement that the studies be conducted in accordance with good clinical practice (GCP), including review and approval by an independent ethics committee. Access the complete document at <http://www.fda.gov/cber/rules/forclinstud.htm>.

The **Food and Drug Administration** is proposing to reclassify the Medical Device Data System (MDDS) from class III (premarket approval) to class I (general controls). This action does not include medical device data systems with new diagnostic or alarm functions. FDA is also proposing that the MDDS be exempt from the premarket notification requirements with it is indicated for use only by a healthcare professional and does not perform irreversible data compression. Access the document at <http://www.fda.gov/OHRMS/DOCKETS/98fr/E8-2325.htm>

Google Health (www.google.com/health) began on May 19, 2008 offering personal health records on the web as reported by the **New York Times** on May 20, 2008 (<http://www.nytimes.com/2008/05/20/technology/20google.html?th&emc=th>). [Editorial comment – Identified or de-identified information will not be disseminated without explicit consent, though aggregated information may be published as 'Google Trends'. There are no references to research or clinical trials throughout the web site and related privacy policy or terms of service documents. A limited number of health service providers (pharmacies, clinics, hospitals, etc) are currently available from which to import medical records. Laurie Hassell]

The **Institute of Translational Health Sciences** with core members **University of Washington, Children's Hospital & Regional Medical Center** and the **Fred Hutchinson Cancer Research Center** announce the new Research Bioethics Consult Service. Designed to supplement the IRBs responsibility for research oversight, consultations are confidential and may range from phone conversations, referral services, written reports and in-depth discussion. Topics for analysis may include study development, implementation or analysis, regulatory requirements and review processes. Consults can be requested by contacting the RSB core office at 206-598-6477 or rsbcore@u.washington.edu. For emergencies related to the care of a particular research participant, contact the Children's paging operator at 206-987-2000 and ask for the Research Bioethicist on call.

Oregon Health & Science University, along with local emergency medical services and health system partners, is beginning a 'waiver of consent' study in the Portland/Vancouver metropolitan area that will test methods of resuscitating people who experience cardiac arrest outside of the hospital. The study will be conducted by paramedics and EMTs at the scene of a person's collapse. The ROC PRIMED study is the next in a series of federally funded studies conducted by the Resuscitation Outcomes Consortium (ROC). A related article is available. Contact Liana Haywood at 503-494-8231 or haywoodl@ohsu.edu for more information.

Power point presentations are available from the March 27-28 panel discussion on "Quality Assurance, Quality Improvement and Health Services Activities" at the **Secretary's Advisory Committee on Human Research Protections (SACHRP)** meeting. This discussion addressed the recent controversy over quality improvement studies interpreted as human subjects research, precipitated by the following **New York Times** editorial. Contact Laurie Hassell at lhassell@nwabr.org if you would like copies of the presentations. http://www.nytimes.com/2007/12/30/opinion/30gawande.html?_r=2&scp=108&sq=December+30%2C+2007&st=nyt&oref=slogin&oref=slogin.

The **University of Washington** announces the formation of the Northwest Institute of Genetic Medicine, a collaborative effort with **Seattle Children's Hospital Research Institute**, Group Health and biotechnology companies. This institute, created with a \$5.3 million grant from the Life Sciences Discovery Fund, will facilitate the design, development and execution of translational genetic studies that bridge the gap between basic research and clinical studies. To learn more visit <http://uwnews.org/article.asp?articleID=41170>

The **Washington Post** published an article on April 1, 2008 based on a report by the Chronic Disease Prevention & Control Research Center at Baylor College of Medicine about under-representation of minorities, women, seniors, disabled individuals and rural populations in clinical trials. Access the article (free registration required) at <http://www.washingtonpost.com/wp-dyn/content/article/2008/04/01/AR2008040102092.html?sub=new>.

On April 14, 2008 the **Washington Post** published an article entitled 'Senate Plans Hearing on Sludge' in relating to a study conducted in 2001-2 by the Department of Housing and Urban Development, the Department of Agriculture and the Environmental Protection Agency. Members of the Maryland chapter of the NAACP are calling for an investigation into the circumstances of the research and whether participants from poor, African-American neighborhoods gave informed consent. The Tuskegee Public Health Study is discussed as a reference. A related article can be found on the **Baltimore Sun** website. <http://www.washingtonpost.com/wp-dyn/content/article/2008/04/14/AR2008041400416.html>
<http://www.baltimoresun.com/news/local/bal-md.sludge14apr14,0,3511377.story>

An article entitled 'FDA Faulted for Approving Studies of Artificial Blood' was published on April 29, 2008 in the **Washington Post**. A meta-analysis of 16 studies was conducted and found that artificial blood products increased the risk of death in patients. 'Waiver of consent' studies were particularly noted. Access the article at <http://www.washingtonpost.com/wp-dyn/content/article/2008/04/28/AR2008042801025.html?wpisrc=newsletter>.

Kudos

The **Fred Hutchinson Cancer Research Center** and the **University of Washington** have been awarded \$2.2 million from the Life Sciences Discovery Fund to establish a formal phase I clinical trials program to test new therapies for solid tumors. Initially, the program will use the funding to develop a highly efficient infrastructure for implementing early phase — primarily industry sponsored — cancer clinical trials, and to provide exploratory funds that will allow Consortium researchers to apply their expertise in cancer imaging and biomarkers to cancer drug development. Contact Dean Forbes at 206-605-0311 or dforbes@fhcrc.org for more information.

The **Northwest Association for Biomedical Research** would like to thank Barbara Chamberlain from **Washington State University Spokane** for initiating the creation of the Human Subjects Research Communication Workshop held on May 23, 2008. The efforts of Royce Morrison from **Charles River Clinical Services Northwest**, Dean Forbes and Karen Hansen from the **Fred Hutchinson Cancer Research Center**, Casey Bush from **Legacy Health System**, Linda Coleman from **Quorum Review**, Charlotte Shupert from **Oregon Health & Science University**, Cristy Bledsoe from **Saint Alphonsus Regional Medical Center**, Cathleen Isaacs and Crystal Spencer from **St. Luke's Regional Medical Center**, and Estela Hamblen and Peter Kim from **Swedish Medical Center** on the development of the agenda is much appreciated. Speakers Sharon Smith Elsayed from **University of Washington** and Jim Newman from **Oregon Health & Science University** contributed greatly to the program with their sessions. It is due to their efforts and the willingness of all attendees to openly discuss experiences within their institutions, voice opinions and listen to their peers that we can classify this event as a success. Thank you so much for your support. ~ Laurie Hassell

Classified

Northwest Research and Education Institute is looking for a full-time clinical trials coordinator. Applicants are expected to have a BS degree in a healthcare related field, 2 years of clinical trial experience, proficiency with statistical software, databases, spreadsheets and federal reporting mechanisms, detail oriented with strong organizational skills and CCRP certification. Apply online at <http://www.svh-mt.org> or call 800-237-9008.

Swedish Medical Center is currently hiring a **Neuroscience Research Manager** will oversee and manage all research activities associated with the Swedish Neuroscience Institute. Responsibilities include managing the overall fiscal and staffing functions, developing and growing the program, and allocating resources to support the mission of neuroscience research. To qualify, candidates must have a Master's degree in business management, healthcare, nursing, science, or related field; equivalent experience will be accepted. A minimum of five years experience in healthcare, science, or related field is required with a background in administrative responsibility. Knowledgeable in a research environment, either in a healthcare facility, biomedical company, or as a clinical research coordinator of biomedical research is strongly preferred. Familiarity with laboratory facilities is an asset though not required. Interested

applicants can learn more about the position by reviewing our website at www.swedish.org or contacting Jennifer Hansberry, Director of Research at (206) 215-3100

Swedish Medical Center is also hiring a **Grant and Contract Analyst** for review, negotiation, and oversight of contracts with for-profit and non-profit agencies conducting research under the auspices of Swedish Medical Center. Interested applicants can learn more about the positions by reviewing our website at www.swedish.org or contacting Jennifer Hansberry, Director of Research at (206) 215-3100

Information for Researchers and Investigators

'Protecting the Rights, Safety and Welfare of Study Subjects – Supervisory Responsibilities of Investigators' is available as draft guidance from the **Food and Drug Administration**. Document includes investigator responsibilities for drugs, biologics and device trials, and clarification on supervisory conduct and human subject protection during a clinical trial. Access the document at <http://www.fda.gov/cber/gdlns/studysub.pdf>.

On April 15, 2008 the **New York Times** published an article entitled 'Citing Ethics, Some Doctors are Rejecting Industry Pay', which profiles three clinicians and their decision not to accept payments from food, drug and device companies. Conflict of interest issues and the desire to maintain their objectivity prompted their decisions. Access the article at <http://www.nytimes.com/2008/04/15/health/15conf.html?pagewanted=1&ref=health>.

National Institutes of Health has announced funding opportunities for the Community Clinical Oncology Program and the Minority-Based Community Clinical Oncology Program. Applications are due July 10, 2008. Both provide opportunities to incorporate Community-Based Participatory Research approached into cancer research. <http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-08-015.html> or <http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-08-016.html>

Events Calendar

Compliance Academies

June 2-5, 2008 – Scottsdale, AZ
August 11-15, 2008 – Chicago, IL
November 3-6, 2008 – Orlando, FL
December 1-4, 2008 – San Diego, CA
www.hcca-info.org

NEW 2008 New Frontiers Conference: Propelling Montana Research

June 2, 2008 – Bozeman, MT
www.montanaresearch.org

Clinical Site Management

June 5-6, 2008 – West Toronto, ON
October 23-24, 2008 – Albuquerque, NM
www.socra.org

NEW Mitigating Risk in Early Drug Development: Special ORCA Seminar

June 6, 2008 – Seattle, WA
http://www.orcanw.org/about/about/orca_monthly_mtg_june.htm

CRP Certification, Preparation and Review Course

June 6, 2008 – Toronto, ON
July 25, 2008 – Boston, MA
September 24, 2008 – Vancouver, BC
www.socra.org

Health Care Compliance Association, Pacific Northwest Local Conference

June 6, 2008 – Seattle, WA
www.hcca-info.org

NEW Ethical Issues in International Health Research Workshop

June 9-13, 2008 – Boston, MA
<http://www.hsph.harvard.edu/bioethics/>

Video Conference Series (National Council of University Research Administrators)

June 10, 2008 – Complex Agreements
September 9, 2008 – Good Customer Service for Research Administrators
http://www.ncura.edu/content/educational_programs/ncura_tv/schedule.php

NEW Association of Clinical Research Professionals Webinars

June 11, 2008 – Regulatory & EMEA Inspections in Europe and Progress Update
June 13, 2008 – Next Steps in Clinical Research Billing
June 27, 2008 – Managing Up: How Study Coordinators Get the Best from Their PIs
July 8, 2008 – Introduction to the Core Knowledge Assessment Test (FREE)
August 6, 2008 – Strategies for Improving Site Selection
<http://www.acrpnet.org/MainMenuCategory/Education/webinars.aspx>

NEW Community Partner Conference Call Series

June 13, 2008 – An Environmental Scan of Community Engagement in Health Research
June 24, 2008 – Engaging in CBPR: Tips & Strategies for Community Leaders
<https://catalysttools.washington.edu/webq/survey/ccphuw/54723>

NEW BIO International Convention

June 17-20, 2008 – San Diego, CA
www.bio2008.org

Device Research – Regulations and Guidelines for Device Clinical Research

June 26-27, 2008 – San Diego, CA
www.socra.org

NEW Multi-Center Phase III Clinical Trials and NCI Cooperative Groups

July 1-2, 2008 – Washington, DC
http://www.iom.edu/CMS/26765/52301.aspx?utm_medium=email&utm_source=Institute%20of%20Medicine&utm_campaign=IOMNews+5.15.08&utm_content=IOMNews&utm_term=

Clinical Science Courses

July 14-18, 2008 – Chicago, IL
November 3-7, 2008 – Scottsdale, AZ
www.socra.org

NEW Handling Incidental Finding in Human Subjects Research: Legal and Ethical Perspectives

July 15, 2008 – WEBINAR
www.primr.org

NEW Montana BioScience Alliance Annual Meeting

July 15, 2008 – Missoula, MT
speterson@msubillings.edu

Secretary's Advisory Committee on Human Research Protections (SACHRP)

July 15-16, 2008 – Arlington, VA
<http://www.hhs.gov/ohrp/sachrp/index.html>

Standard Operating Procedures (SOPs) Development and Implementation

July 24-25, 2008 – Boston, MA
www.socra.org

2008 Pediatrics Bioethics Conference – Predicting Our Future: Genetic Testing in Children and Their Families

July 25-26, 2008 – Seattle, WA
<http://bioethics.seattlechildrens.org/>

NEW 20th Annual Native Health Research Conference

August 25-28, 2008 – Portland, OR
<http://www.ihs.gov/MedicalPrograms/Research/conferences.cfm#national>

IRB 101, IRB Administrator 101, IBC Basics, and Essentials of IACUC Administration

September 15-18, 2008 – St. Louis, MO
www.primr.org

Informed Consent and More: Improving Human Research Protections

September 16, 2008 – Richmond, VA
<http://www.hhs.gov/ohrp/education/conference.html#upcoming>

Annual Conference, Society of Clinical Research Associates

September 26-28, 2008 – Vancouver, British Columbia Canada
www.socra.org

Clinical Research Monitoring and GCP Workshop for Monitors, Site Coordinators and Auditors

October 16-17, 2008 – Philadelphia, PA

www.socra.org

Human Subjects Research Regional Conference

October 20, 2008 – Tacoma, WA

lhassell@nwabr.org

Association of Clinical Pharmacology Units Annual Meeting

October 20-22, 2008 – Tacoma, WA

Darci.Helbling@crl.com

NEW American Society for Bioethics & Humanities Annual Meeting

October 23-26, 2008 – Cleveland, OH

<http://www.asbh.org/meetings/annual/index.html>

2008 National Council of University Research Administrators 50th Annual Meeting

November 2-5, 2008 - Washington DC

www.ncura.edu

NEW Building Equitable Partnerships Symposium 2008

November 5-7, 2008 – Toronto, Ontario Canada

Mary_austin@camh.net

UPDATE 2008 Annual Human Research Protection Programs (HRPP) Conference

November 16-19, 2008 - Orlando, FL

www.primr.org

Scholarship applications due June 20, 2008 - http://www.primr.org/Conferences.aspx?id=4245&ekmense=297ded8b_321_0_4245_5

FDA Clinical Trial Requirements Regulations, Compliance and GCP Conference

November 19-20, 2008 – Kansas City, MO

www.socra.org

Clinical Investigator GCP & Trials Management Conference (Clinical Investigators & Key Research Staff

December 4-5, 2008 – Clearwater Beach, FL

www.socra.org

Resource Guide

Articles:

- Anderson EE. A qualitative study of non-affiliated, non-scientist institutional review board members. *Account Res.* 2006 Apr-Jun;13(2):135-55.
- Bauer PE. A few simple truths about your community IRB members. *IRB.* 2001 Jan-Feb;23(1):7-8.
- Beversdorf S, Ahmed S, Beck B. Community-Academic Partnerships and Institutional Review Board Insights. *Partnership Perspectives.* 2007 IV, Issue 1:95-104
- Brugge D, Missaghian M. Protecting the Navajo People through tribal regulation of research. *Sci Eng Ethics.* 2006 Jul;12(3):491-507.
 - Colwell-Chanthaphonh C. Self-governance, self-representation, self-determination and the questions of research ethics--commentary on "Protecting the Navajo People through tribal regulation of research". *Sci Eng Ethics.* 2006 Jul;12(3):508-10.
 - Navajo Nation IRB: a unique human research review board has three primary concerns: protecting its community, its people, and its heritage. *Prot Hum Subj.* 2003 Spring;(8):1-2 (www.science.doe.gov/ober/humansubj/spring03.pdf)
 - Schrag B. Research with groups: group rights, group consent, and collaborative research commentary on "Protecting the Navajo People through tribal regulation of research". *Sci Eng Ethics.* 2006 Jul;12(3):511-21.
- "Academic Health Centers' Clinical Research Efforts Buoyed". *CenterWatch.* 2008 Jan;15(1)
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- Chene R, Garcia L, Goldstrom M, et al. Mental health research in primary care: mandates from a community advisory board. *Ann Fam Med.* 2005 Jan-Feb;3(1):70-2.
- De Vries R, Forsberg CP. Who decides? A look at ethics committee membership. *HEC Forum.* 2002 Sep;14(3):252-8.
- Flicker S, Travers R, Guta A, et al. Ethical Dilemmas in Community-Based Participatory Research: Recommendations for Institutional Review Board. *J Urban Health.* 2007. e-pub (DOI 10.1007/s11524-007-9165-7)
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- Malone RE et al. "It's like Tuskegee in reverse": A case study of ethical tensions in institutional review board review of community-based participatory research. *American Journal of Public Health*. 2006;96(11):1914-9
- **NEW** Mather John H, Hartnett Terry. HSP and Accreditation: Growing Pains and Successes Mark First Seven Years. Medical Research Law & Policy Report. 2008;7(4)
- Ness Roberta E. Influence of the HIPAA Privacy Rule on Health Research. *JAMA*. 2007;298(18):2164-70
- **NEW** Pinto, R. M., McKay, M. M. & Escobar, C. "You've gotta know the community": Minority women make recommendations about community-focused health research. *Women and Health*, 47, 83-104.
- Quinn SC. Ethics in public health research: protecting human subjects: the role of community advisory boards. *Am J Public Health*. 2004 Jun;94(6):918-22.
- Sengupta S, Lo B. The roles and experiences of nonaffiliated and non-scientist members of institutional review boards. *Acad Med*. 2003 Feb;78(2):212-8.
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- Travers R, et al. Proposal for an ethics review board of community-based HIV/AIDS research in Ontario, an OHTN position paper. *Ontario HIV Treatment Network: Toronto, ON*. 2006
- Westin AF. How the Public Views Privacy and Health Research. Institute of Medicine. 2007 Nov.

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 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
- ***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 XXVth 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 Neurobiological Research with Human Subjects*** by Adil E. Shamoo
- ***Ethics of Research Involving Human Subjects: Facing the 21st 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
- ***NEW 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
- ***NEW 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

Historical and regulatory reference:

- **Belmont Report** - <http://hhs.gov/ohrp/humansubjects/guidance/belmont.htm>
- **Declaration of Helsinki** - www.wma.net/e/policy/b3.htm
- **Nuremberg Code** - www.hhs.gov/ohrp/references/nurcode.htm

- **Title 45 Public Welfare, Department of Health and Human Services, Part 46 Protection of Human Subjects -** 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>
- **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
- **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>
- **Citizens for Responsible Care and Research -** List of IRBS registered with the Office for Human Research Protections. www.circare.org/info/researchbythenumbers1.htm
- **Community-Campus Partnerships for Health (CCPH), Ethics & IRBs -** multiple links, useful resources. www.ccph.info, <http://depts.washington.edu/ccph/links.html#ethics> or http://depts.washington.edu/ccph/pdf_files/resources_CBPR_108.pdf
- **UPDATE Department of Energy**
 - Protection of Human Subjects - <http://humansubjects.energy.gov/>
- **Department of Social & Health Services, Human Research Review Section/Washington State Institutional Review Board -** <http://www1.dshs.wa.gov/rda/hrs/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
- **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>
 - IRB Information sheets - <http://www.fda.gov/oc/ohrt/irbs/default.htm>
 - IRB - <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/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>
- **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
- **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
- **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>
- **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.
- **Navajo Nation Human Research Review Board -** Navajo Nation Human Research Code <http://www.nnhrb.navajo.org/pdf/NNHumanResearchCode.pdf>

- **Office for Human Research Protections (OHRP)** – registration, training, publications, consultation, etc.
<http://www.hhs.gov/ohrp>
 - **IRB Guidebook** - http://www.dhhs.gov/ohrp/irb/irb_guidebook.htm
 - **2008 International Compilation of Human Subject Protections** - <http://www.hhs.gov/ohrp/international/>
- **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
- **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
- **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
- **Stanford University** – medical term definitions for lay audiences. <http://humansubjects.stanford.edu/general/glossary.html>
- **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
- **Tuskegee University National Center for Bioethics in Research and Health Care** - www.tuskegee.edu/bioethics
- **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
- **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
 - 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/

ListSers:

- **CBPR and Research Ethics Listserv**, established to foster dialogue between IRBs about ethical issues in research. Contact Kristine Wong at 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>
- **IRB Forum** (formerly MCWIRB), membership is free. www.irbforum.org
- **Community IRB Member: Neighbor & Partner**, operated by the US Department of Energy. www.orau.gov/communityirb/default.htm for information, www.orau.gov/communityirb/listserv.htm to join the discussion group or contact 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>
- **Institute of Medicine**, bi-monthly email newsletter with news, publications, events and online content.
<http://www.iom.edu/CMS/3238.aspx>

News Service:

- **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.

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
- **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
- **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>
- **Human Subjects Protection Resource Book** from the Department of Energy. Free download at
<http://www.ora.gov/communityirb/news.htm>
- **Improving the System for Protecting Human Subjects: Counteracting IRB "Mission Creep"**, The Center for Advanced Study. www.law.uiuc.edu/conferences/whitepaper/
- **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
- **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/emprogrms/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
- **NEW Pimatisiwin: A Journal of Indigenous and Aboriginal Community Health** 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
- **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
- **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 or fax to 301-903-8521
- **NEW 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/)
- **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)

Training:

- **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.org/MainMenuCategory/Education/online/OnlineClinicalCourses.aspx>
- **Centers for Disease Control and Prevention**
 - Scientific Ethics Training – send email to inquiry@cdc.org to request access to free, online training curricula
- **CORRECTION 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
- **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/>
- **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>
- **NEW 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>

- **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 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 – speaking, consultation, mentoring, etc.

NEW 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. 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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