

Northwest IRB Fresh Sheet – Resource Guide

April 2009 through December 2009

Articles:

- Adamis D, Treloar A, et al. Ethical research in delirium: arguments for including decisionally incapacitated subjects. *Sci Eng Ethics*. 2009.
- AHC Media. Keep informed consent interactive, avoid misconception. *Clin Trials Admin*. Mar 1, 2009.
- Allen J, McNamara B. Reconsidering the value of consent in biobank research. *Bioethics* 2009
- Annas GJ. Globalized Clinical Trials and Informed Consent. *N Engl J Med*. 2009;360(20):2050-3.
<http://content.nejm.org/cgi/content/full/360/20/2050>
- Appelbaum P, Lidz C, Klitzman R. Voluntariness of Consent to Research: A conceptual Model. *The Hastings Center*. 2009.
- Altavilla A, Giaquinto C, Ceci A. European survey on ethical and legal framework of clinical trials in paediatrics: results and perspectives. *J Int Bioethique*. 2008;19(3):17-48, 121-2.
- Barrett JR. Double Protection: reaching accord on the ethical conduct of child observational research. *Environ Health Perspective*. 2009;117(8):A354-7.
- Berger JT. Patients' concerns for family burden: a nonconforming preference in standards for surrogate decision making. *J Clin Ethics*. 2009;20(2):158-61.
- Birmingham K, Doyle A. Ethics and governance of a longitudinal birth cohort. *Paediatr Perinat Epidemiol*. 2009;23 Suppl 1(39-50).
- Biros MH, Baren JM. The Ethics of Observation. *Acad Emerg Med*. 2009
- Bozeman B, Slade C, Hirsch P. Understanding bureaucracy in health science ethics: toward a better institutional review board. *Am J Public Health*. 2009;99(9):1549-56.
- Boxall K, Ralph S. Research ethics and the use of visual images in research with people with intellectual disability. *J Intellect Dev Disabil*. 2009;34(1):45-54.
- Brink M, Deunk J, et al. Observational research in trauma radiology: should patients be informed? *J Am Coll Radiol*. 2009;6(1):51-7.
- Brody JL, Annett RD, Scherer DG, et al. Enrolling adolescents in asthma research: adolescent, parent and physician influence in the decision-making process. *J Asthma*. 2009;46(5):492-7.
- Buchanan EA, Hvizdak EE. Online survey tools: ethical and methodological concerns of human research ethics committees. *J Empir Res Human Res Ethics*. 2009;4(2):37-48.
- Bustillos D. Limited English proficiency and disparities in clinical research. *J Law Med Ethics*. 2009;37(1):28-37.
- Califf RM. Clinical Research Sites – The underappreciated Component of the Clinical Research System. *JAMA*. 2009;302(18):2025-7.
- Carter B. Tick box for child? The ethical positioning of children as vulnerable, researchers as barbarians and reviewers as overly cautious. *Int J Nurs Stud*. 2009.
- Chamberlain JM, Lillis K, Vance C, et al. Perceived challenges to obtaining informed consent for a time-sensitive emergency department study of pediatric status epilepticus results of two focus groups. *Acad Emerg Med*. 2009;16(8):763-70.
- Chassany O, Bernard-Harlaut M, Guy G, et al. Information sheets and informed consent forms for clinical study participants: towards standardized recommendations? *Therapie*. 2009;64(3):179-86.
- Chawla Sahota P. Research Regulation in American Indian/Alaska Native Communities
 - Policy and Practice Considerations -
<http://www.ncaiprc.org/files/Research%20Regulation%20in%20AI%20AN%20Communities%20-%20Policy%20and%20Practice.pdf>
 - A Guide to Reviewing Research Studies -
<http://www.ncaiprc.org/files/Research%20Regulation%20in%20AI%20AN%20Communities%20-%20Guide%20to%20Reviewing%20Research%20Studies.pdf>
- Chretien KC, Greysen SR, Chretien JP, et al. Online Posting of Unprofessional Content by Medical Students. *JAMA*. 2009;302(12):1309-15.
- Chong SA, Huxtable R, Campbell A. Authorizing Psychiatric Research: Principles, Practices and Problems. *Bioethics* 2009
- Clark AL, Lammiman MJ, Goode K, Cleland JGF. Is taking part in clinical trials good for your health? A cohort study. *Eur J of Heart Failure*. 2009;11(11):1078
- Coleman C. Vulnerability as a Regulatory Category in Human Subject Research. *Journal of Law, Medicine & Ethics: Vulnerability in Biomedical Research*. Spring 2009
- Collier R. Rapidly rising clinical trial costs worry researchers. *Can Med Assoc J*. Feb 2009;180:277-8.

- Cook D, Lauzier F, et al. Serious adverse events in academic critical care research. *Can Med Assoc J.* Apr 2008;178:1181-4.
- Coors ME, Raymond KM. Substance use disorder genetic research: investigators and participants grapple with ethical issues. *Psychiatr Genet.* 2009;19(2):83-90.
- Davidson AJ, O'Brien M. Ethics and medical research in children. *Paediatr Anaesth.* 2009
- Dawson L, Zarin DA, Emanuel EJ, et al. Considering Usual Medical Care in Clinical Trial Design. *PLoS Med.* 2009;6(9): <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000111>
- Day JG, Stacey GN. Biobanking. *Mol Biotechnol.* 2008;40(2):202-13.
- Dresser R. First-in-human trial participants: not a vulnerable population, but vulnerable nonetheless. *J Law Med Ethics.* 2009;37(1):38-50.
- Druml C, Wolzt M, Pleiner J, et al. Research ethics committees in Europe: trials and tribulations. *Intensive Care Med.* 2009;35(9):1636-40.
- Dyer S, Demeritt D. Un-Ethical Review? Why it is wrong to apply the medical model of research governance to human geography? *Progress in Human Geography.* 2009.
- Eggertson L. Ethics guidelines strengthened but reach remains limited. *Can Med Assoc J.* Feb 2009;180:379-80.
- Elger B. Research involving prisoners: consensus and controversies in International and European Regulations. *Bioethics.* May 2008.
- Elger BS, Hofner MC, Mangin P. Research involving biological materials from forensic autopsies: legal and ethical issues. *Pathobiology.* 2009;76(1):1-10.
- Elger BS. Factors influencing attitudes towards medical confidentiality among Swiss physicians. *J Med Ethics.* 2009;35(8):517-24.
- Ellison JA, Hennekens CH, Wang J, et al. Low rates of reporting commercial bias by physicians following online continuing medical education activities. *Am J Med.* 2009;122(9):875-8.
- Epstein RS, Frueh FW, Geren D, et al. Payer perspectives on pharmacogenomics testing and drug development. *Pharmacogenomics* 2009;10(1):149-51.
- Eskew S, Meyers C. Religious belief and surrogate medical decision making. *J Clin Ethics.* 2009;20(2):192-200.
- Eth S, Leong GB. Toward revising the ethical boundaries of research with noncompetent subjects. *Am J Psychiatry.* 2009;166(2):131-4.
- Fedor C, Yaussy CF, Cola PA. Development and Progression of a Model: Prospective Research Compliance Monitoring. *J Res Admin.* Fall 2008.
- Flicker S, Travers R, Guta A, et al. Ethical Dilemmas in Community-Based Participatory Research: Recommendations for Institutional Review Boards. *J of Urban Health: Bulletin of the New York Academy of Medicine.* 2007;84(4):469-71.
- Folan et al. Participating in Biomedical Research. *JAMA.* 2009;302:2201-2.
- Ford PJ. Vulnerable brains: research ethics and neurosurgical patients. *J Law Med Ethics.* 2009;37(1):73-82.
- Frimpong-Mansoh A. Culture and voluntary informed consent in African health care systems. *Dev World Bioeth.* 2008;8(2):104-14.
- Garattini S, Bertele V. Ethics in clinical research. *J Hepatol.* 2009
- Garattini S, Chalmers I. Patients and the Public Deserve Big Changes in Evaluation of Drugs. *BMJ.* April 2009.
- Gelijns AC, Ascheim DD, Parides MK, et al. Randomized trials in surgery. *Surgery.* 2009;145(6):581-7.
- Gershon A, Tu J. The effect of privacy legislation on observational research. *Can Med Assoc J.* Mar 2008;178:871-3.
- Gilbert GH, Qvist V, Moore SD, et al. Institutional review board and regulatory solutions in The Dental PBRN. *J Public Health Dent.* 2009.
- Glickman SW, McHutchinson JG, et al. Ethical and scientific implications of the globalization of clinical research. *N Engl J Med.* 2009;360(8):816-23.
- Goldenberg AJ, Chandros Hull S, Botkin JR, et al. Pediatric biobanks: approaching informed consent for continuing research after children grow up. *J Pediatr.* 2009.
- Gostin LO, Nass S. Reforming the HIPAA Privacy Rule: Safeguarding Privacy and Promoting Research. *JAMA.* Apr 2009;301(13):1373-5.
- Griffin JM, Struve JK, Collins D, et al. Long term clinical trials: how much information do participants retain from the informed consent process? *Contemp Clin Trials.* 2006;27(5):441-8.
- Gurwitz D, Fortier I, Lunshof JE, et al. Research ethics. Children and population biobanks. *Science.* 2009;325(5942):818-9.
- Hall M, et al. Community Hospital Oversight of Clinical Investigators' Financial Relationships. *Eth Hum Res.* January-February 2009.
- Hausman D. Protecting Groups from Genetic Research. *Bioethics.* 2008;22(3):157-65,
- Haylett WJ. Ethical considerations in pediatric oncology phase 1 clinical trials according to the Belmont Report. *J Pediatr Oncol Nurs.* 2009.
- Hebert P, Saginur R. Research ethics review: do it once and do it well. *Can Med Assoc J* Mar 2009;180:597.

- Henry J, Palmer BW, et al. Reformed Consent: Adapting to New Media and Research Participant Preferences. *IRB: Ethics & Human Research*. Mar-Apr 2009;31(2):1-8.
- Hens K, Nys H, et al. Biological sample collections from minors for genetic research: a systematic review of guidelines and position papers. *Eur J Hum Genet*. 2009.
- Hens K, Nys H, Cassman JJ, et al. Genetic research on stored tissue samples from minors: a systematic review of the ethical literature. *Am J Med Genet A*. 2009;149A(10):2346-58.
- Herrera C. In praise of undercover research. *Can Med Assoc J*. Mar 2008;178:723-4.
- Hug K. Banks, repositories and registries of stem cell lines in Europe: regulatory and ethical aspects. *Stem Cell Rev*. 2009.
- Hutson S. A change is in the wind as 'adaptive' clinical trials catch on. *Nature Medicine*. 2009;15:977.
- Hyatt RR, Gute DM, Pirie A, et al. Transferring knowledge about human subjects protections and the role of the institutional review boards in a community-based participatory research project. *Am J Public Health*. 2009;99:S526-31.
- Iltis AS. Payments to normal healthy volunteers in phase 1 trials: avoiding undue influence while distributing fairly the burdens of research participation. *J Med Philos*. 2009;34(1):68-90.
- Jagsi R, et al. Under-representation of women in high-impact published clinical cancer research. *Cancer* 2009
- Jansen LA, Wall S. Paternalism and fairness in clinical research. *Bioethics*. 2009;23(3):172-82.
- Jesus JE, Michael GE. Ethical considerations of research in disaster-stricken populations. *Prehosp Disaster Med*. 2009;24(2):109-14.
- Jha AK, DesRoches CM, Campbell EG, et al. Use of Electronic Health Records in US Hospitals. *NEJM*. 2009;360(16):1628-38.
- Joffe S, Miller FG. Bench to Bedside: Mapping the Moral Terrain of Clinical Research. *Hastings Center Report* 2008;38(2):30-42.
- Kass NE, Sugarman J, Medley AM, et al. An Intervention to Improve Cancer Patients' Understanding of Early-Phase Clinical Trials. The Hastings Center. May-June 2009
<http://www.thehastingscenter.org/Publications/IRB/Detail.aspx?id=3420>
- Kim SY, Kim HM, et al. Surrogate consent for dementia research: a national survey of older Americans. *Neurology*. 2009;72(2):149-55.
- Kim SYH, Schrock L, Wilson RM, et al. An Approach to Evaluating the Therapeutic Misconception. *IRB: Ethics & Human Research*. 2009;31(5):7-14. <http://www.thehastingscenter.org/Publications/IRB/Detail.aspx?id=3894>
- Lansimies-Antikainen H, Laitinen T, Rauramaa R, et al. Evaluation of informed consent in health research: a questionnaire survey. *Scand J Caring Sci*. 2009.
- Lavery JV, Singer PA, Ridzon R, et al. In Global Health Research, Is It Legitimate to Stop Clinical Trials Early on Account of their Opportunity Cost? *PLoS Medicine*. June 2009; 6(6)
- Lazzarini Z, Case P, Thomas CJ. A walk in the park: a case study in research ethics. *J Law Med Ethics*. 2009;37(1):93-103.
- Lema VM, Mbondo M, Kamau EM. Informed consent for clinical trials: a review. *East Afr Med J*. 2009;86(3):133-42.
- Lidz CW, Appelbaum PS, Joffe S, et al. Competing Commitments in Clinical Trials. *IRB: Ethics & Human Research*. 2009;31(5):1-6. <http://www.thehastingscenter.org/Publications/IRB/Detail.aspx?id=3890>
- Lo B, Kriegstein A, Grady D. Clinical trials in stem cell transplantation: guidelines for scientific and ethical review. *Clin Trials*. 2008;5(5):517-22.
- Luce BR, Kramer JM, Goodman SN, et al. Rethinking Randomized Clinical Trials for Comparative Effectiveness Research: The Need for Transformational Change. *Annals of Int Med*. 2009;151(3)
<http://www.annals.org/cgi/content/full/0000605-200908040-00126v1>
- Lyerly, A, Little M, Faden R. The Second Wave: Toward Ethical Inclusion of Pregnant Women in Clinical Research. *Intl J Fem Approaches to Bioeth* 2008;1(2):5-22.
- Lynoe N, Juth N, Helgesson G. How to reveal disguised paternalism. *Med Health Care Philos*. 2009.
- Marshall J, Hadskis MR. Canadian Research ethics boards, MRI research risks and MRI risk classification. *IRB*. 2009;31(4):9-15.
- Mathieu S, Boutron I, Moher D, et al. Comparison of Registered and Published Primary Outcomes in Randomized Controlled Trials. *JAMA*. 2009;302(9):977-84.
- McDonald KE, Keys CB, Henry DB. Gatekeepers of science: attitudes toward the research participation of adults with intellectual disability. *Am J Ment Retard*. 2008;113(6):466-78.
- McMahan AD, Conway DI, MacDonald TM, McInnes GT. *PLoS Medicine*. 2009.
<http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000131>
- McNutt LA, Gordon EJ, Uuskula A. Informed recruitment in partner studies of HIV transmission: an ethical issue in couples research. *BMC Med Ethics*. 2009;10(1):14.
- Menikoff J. The Vulnerability of the Very Sick. *J Law Med Eth*. Spring 2009.

- Miller F. The Randomized Controlled Trial as a Demonstration Project: An Ethical Perspective. *Am J Psychiatry*. July 2009.
- Miller F. Research on Medical Records without Informed Consent. *Journal of Law, Medicine & Ethics: Race Pharmaceuticals, and Medical Technology*. Fall 2008.
- Miller S, Selgelid M. Ethical and Philosophical Consideration of the Dual-use Dilemma in the Biological Sciences. *Sci Eng Ethics*. 2007;13:523-580.
- Milliez J. Just inclusion of women of reproductive age in research FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. *Int J Gynaecol Obstet*. 2009.
- Mullard A. Willing subjects live longer but blur clinical trial results. *Nature Medicine*. 2009;15:1338.
- Murphy J, Scott J, et al. Public expectations for return of results from large-cohort genetic research. *Am J Bioeth*. 2008;8(11):36-43.
- Navarro R. An ethical framework for sharing patient data without consent. *Inform Prim Care*. 2008;16(4):257-62.
- Nelson M, Schmidt TA, et al. Community consultation methods in a study using exception to informed consent. *Prehosp Emerg Care*. 2008;12(4):417-25.
- Oliver-Africano P, Dickens S, Ahmed Z, et al. Overcoming the barriers experienced in conducting a medication trial in adults with aggressive challenging behavior and intellectual disabilities. *J Intellect Disabil Res*. 2009.
- Opel DJ, Wilfond BS, Brownstein D, et al. Characterization of organizational issues in paediatric clinical ethics consultation: a qualitative study. *J Med Ethics*. 2009;35(8):477-82.
- Orticio LP. Protecting human subjects in research. *Insight*. 2009;34(3):14-6.
- Pehboeck D, Hohlieder M, et al. Submission of clinical studies to ethics committees or clinical trial registers: the author's point of view. *Intensive Care Med*. 2009.
- Perlman D. Public Health Practice vs. Research: Implications for Preparedness and Disaster Research Review by State Health Department IRBs. *Disaster Medicine and Public Health Preparedness*. 2008.
- Permut-Wey J, Borenstein AR. Financial remuneration for clinical and behavioral research participation: ethical and practical considerations. *Ann Epidemiol*. 2009.
- Pietzsch J, Shluzas L, Pate-Cornell M, et al. State-Gate Process for the Development of Medical Devices. *J Med Devices*. 2009;3(2)
- Pietzsch JB, Aquino LM, Yock PG, et al. Review of US Medical Device Regulation. *J Med Devices*. 2007;1(4):283
- Pincus HA. Challenges and pathways for clinical and translational research: Why is this research different from all other research? *Academic Medicine*. 2009;84(4):411-2
- Reid J. Conducting qualitative research with advanced cancer patients and their families: ethical considerations. *Int J Palliat Nurs*. 2009;15(1):30-3.
- Ridley RT. Assuring Ethical Treatment of Students as Research Participants. *J Nurs Educ*. 2009:1-5.
- Riviello C, Ottanelli S, Di Tommaso MR, et al. Ethical issue and consent form in the management of high-risk pregnancy. *J Matern Fetal Neonatal Med*. 2009:1-5.
- Rutherford BR, Sneed JR, Roose SP. Does Study Design Influence Outcome? *Psychother Psychosom*. 2009;78:172-81.
- Sachs B. Going from principles to rules in research ethics. *Bioethics* 2009
- Saginur R, Dent SF, Schwartz L, et al. Ontario Cancer Research Ethics Board: Lessons Learned from Developing a Multicenter Regional Institutional Review Board. *J Clin Oncol*. 2008;26(9):1479-1482.
- Sammons HM. Ethical issues of clinical trials with children, a European perspective. *Arch Dis Child*. 2009.
- Schaefer GO, Emanuel EJ, Wertheimer A. The Obligation to Participate in Biomedical Research. *JAMA* 2009;302(1):67-72.
- Schluger NW. Improving protection for human research subjects: better oversight, not just more oversight. *Am J Bioeth*. 2008;8(11):13-5.
- Schmaling KB, Blume AW. Ethics instruction increases graduate students' responsible conduct of research knowledge but not moral reasoning. *Account Res*. 2009;16(5):268-83.
- Schopper D, Upshur R, Matthys F, et al. Research ethics review in humanitarian contexts: the experience of the independent ethics board of Medecins Sans Frontieres. *PLoS Med*. 2009;6(7):e1000115.
- Schrag ZM. How Talking Became Human Subjects Research: The Federal Regulation of the Social Sciences, 1965-1991. *J Public Policy*. 2009;21(1):3-37.
- Schunemann JH, Osborne M, Moss J, et al. An official American Thoracic Society Policy statement: managing conflict of interest in professional societies. *Am J Respir Crit Care Med*. 2009;180(6):564-80.
- Serrano-Delgado M, Novellow-Garza BI, Valdez-Martinez E. Ethical issues relating to the banking of umbilical cord blood in Mexico. *BMC Med Ethics*. 2009;10(1):12
- Shamoo AE, Schwartz J. Universal and uniform protections of human subjects in research. *Am J Bioeth*. 2008;8(11):3-5.
- Shuchman M. Clinical trials regulation – how Canada compares. *Can Med Assoc J*. Sep 2008;179:635-8.

- Shuchman M. Clinical Trials: the balance between protecting participants and promoting drug and product development. *Can Med Assoc J.* Mar 2009;180(6). <http://www.cmaj.ca/cgi/content/full/180/6/603>
- Silversides A. Clinical trials: the muddled Canadian landscape. *Can Med Assoc J.* Jan 2009;180:20-22.
- Silversides A. Clinical trials: chasing recruits. *Can Med Assoc J.* Feb 2009;180:375-8
- Silversides A. Clinical trial participation poses ethical, practical issues. *Can Med Assoc J.* Mar 2009;180:500-2.
- Sood A, Prasad K, Chhatwani L, et al. Patients' Attitudes and Preferences about Participation and Recruitment Strategies in Clinical Trials. *Mayo Clin Proc.* 2009;84(3):243-7.
- Sterkel R, Banister C, Bruns J, et al. Collaboration with pediatric call centers for patient recruitment. *Arch Pediatr Adolesc Med.* 2009;163(6):588-9.
- Stewart PM, Stears A, Tomlinson JW, Brown MJ. Regulation – the real threat to clinical research. *BMJ.* 2008;337:a1732.
- Taljaard M, Weijer C, Grimshaw JM, et al. Ethical and policy issues in cluster randomized trials: rationale and design of mixed methods research study. *Trials.* 2009;10(61)
- Tanne JH. European and US agencies will cooperate to ensure ethical conduct of trials. *BMJ.* 2009;339(3):234.
- Tarini BA, Goldenberg A, Singer D, et al. Not without my Permission: Parents' Willingness to Permit Use of Newborn Screening Samples for Research. *Public Health Genomics.* 2009; DOI: 10.1159/000228724
- Tekola F, Bull SJ, Farsides B, et al. Tailoring consent to context: designing an appropriate consent process for a biomedical study in a low income setting. *PLoS Negl Trop Dis.* 2009;3(7):e482.
- Trommelmans L, Dierickx K. Standard of care in clinical research with human engineered products (HEPs). *Am J Bioeth.* 2009;9(3):44-5.
- Trommelmans L, Selling J, Dierickx K. The importance of the values attached to cells for a good informed consent procedure in cell donation for tissue engineering purposes. *Cell Tissue Bank.* 2009.
- Ursin LO. Biobank research and the right to privacy. *Theor Med Bioeth.* 2008;29(4):267-85.
- van der Graaf R, van Delden JJ. What is the best standard for the standard of care in clinical research? *Am J Bioeth.* 2009;9(3):35-43.
- Venkatapuram S, Marmot M. Epidemiology and social justice in light of social determinants of health research. *Bioethics.* 2009;23(2):79-89.
- Wagman J, Francisco L, et al. Ethical challenges of research on and care for victims of intimate partner violence. *J Clin Ethics.* 2008;19(4):371-80.
- Wagner TH, Murray C, Goldberg J, et al. Costs and Benefits of the National Cancer Institute Central Institutional Review Board. *J Clin Oncol.* 2009; 0: JCO.2009.23.2470v1
- Walkup J, Bock E. What do prospective research participants want to know? What do they assume they know already? *J Empir Res Hum Res Ethics.* 2009;4(2):59-63.
- Wall A. Including persons with Alzheimer disease in research on comorbid conditions. *IRB.* 2009;31(1):1-6.
- Wang O, Krumholz HM. Clinical trial participation: are we studying the patients we are trying to treat? *Eur J Heart Failure.* 2009;11(11):1021.
- Watson LF, Lumley J, et al. Recruitment to research studies in maternity hospitals: an example from the Early Births Study. *Midwifery.* 2008;24(4):509-20.
- Wazaify M, Khalil S, Silverman H. Expression of Therapeutic Misconception amongst Egyptians: A Qualitative Pilot Study. *BMC Medical Ethics.* June 2009
- Weijer C, Goldsand G, Emanuel E. Protecting Communities in Research: Current Guidelines and Limits of Extrapolation. *Nature Genetics.* 1999;23(3):275-80.
- Weinfurt KP, Hall MA, King NMP, et al. Disclosure of Financial Relationships to Participants in Clinical Research. *JAMA* 2009;361(9):916-21.
- Wendler D. Minimal risk in pediatric research as a function of age. *Arch Pediatr Adolesc Med.* 2009;163(2):115-8.
- Whicher D, Currie P, Taylor HA. Factors that Influence Institutional Review Board Members' Commitment to Their Role Responsibilities. *IRB: Ethics & Human Research.* 2009;31(5):15-19. <http://www.thehastingscenter.org/Publications/IRB/Detail.aspx?id=3896>
- Wilson JM. A History Lesson for Stem Cells. *Science.* 8May09;324(5928):727-8.
- Wilson S, Draper H, Ives J. Ethical issues regarding recruitment to research studies within the primary care consultation. *Fam Pract.* 2008;25(6):456-61.
- Wolf L. IRB Policies Regarding Finder's Fees and Role Conflicts in Recruiting Research Participants. *IRB: Ethics & Human Research.* Jan-Feb 2009.
- Yap TY, Yamokoski A, Noll R, et al. A Physician-Directed Intervention: Teaching and Measuring Better Informed Consent. *Academic Medicine.* 2009;84(8):1036-42.

Blogs:

- **Institutional Review Blog** - <http://www.institutionalreviewblog.com/>

- **Social Science Research News** - <http://ssresearchnews.blogspot.com/>

Books:

- **Chasing Medical Miracles: The Promise and Perils of Clinical Trials** by Alex O'Meara - http://www.amazon.com/Chasing-Medical-Miracles-Promise-Clinical/dp/0802716962/ref=sr_1_1?ie=UTF8&s=books&qid=1247525099&sr=1-1
- **Clinical Trials Handbook** by John Wiley and Sons Ltd. - http://www.researchandmarkets.com/research/484571/clinical_trials_ha
- **Examining Tuskegee, The Infamous Syphilis Study and its Legacy** by Susan Riverby - http://uncpress.unc.edu/browse/book_detail?title_id=1672
- **On Being a Scientist: A Guide to Responsible Conduct in Research** by the Committee on Science Engineering and Public Policy, National Academy of Sciences, National Academy of Engineering and Institute of Medicine - http://www.nap.edu/catalog.php?record_id=12192

Clinical Trial Volunteer Registries:

- **Army of Women** – specific to breast cancer studies. www.armyofwomen.org
- **International Spinal Muscular Atrophy Patient Registry** - <https://smaregistry.iu.edu/>
- **Michigan Institute for Clinical & Health Research** - <https://www.umms.med.umich.edu/registry/index.htm>
- **Oklahoma Diabetes Center** - <http://www.ouhsc.edu/odc/Clinical%20Trials/Clinical%20Trials.asp>
- **ResearchMatch** – www.researchmatch.org
- **Vanderbilt Clinical Trials** - <https://www.vanderbilthealth.com/clinicaltrials/13133>
- **Washington University School of Medicine** - <https://vfh.wustl.edu/>

Internet resources:

- **2009 International Compilation of Human Research Protections** – from the Office for Human Research Protections. <http://www.hhs.gov/ohrp/international/HSPCompilation.pdf>
- **Agency for Healthcare Research and Quality** –
 - **Informed Consent and Authorization Toolkit for Minimal Risk Research.** <http://www.ahrq.gov/fund/informedconsent/>
 - **Research Activities Online Newsletter.** <http://www.ahrq.gov/research/resact.htm>
- **Catholic Health Institutional Review Board** – research checklist for physicians detailing elements the IRB will consider in protocols, consent forms and related documents. <http://www.chsbuffalo.org/PhysicianRecruitment/Education/InstitutionalReviewBoard>
- **Center for Information & Study on Clinical Research Participation** – www.ciscrp.org information for research participants including educational materials, statistics, surveys, and more.
 - **African Americans and Clinical Research brochure** - <http://www.ciscrp.org/e-store/brochure-aa.asp> **Education Before Participation** (Hispanic Version) - http://www.ciscrp.org/e-store/brochures/ciscrp_hispanic_brochure.pdf
 - **Children and Clinical Studies brochure** - <http://ciscrp.org/e-store/brochure-childrens.asp>
 - **Educational DVDs** - <http://www.ciscrp.org/e-store/dvd.asp>
 - **Hispanics and Clinical Research Brochure** - <http://ciscrp.org/e-store/brochure-latin.asp>
 - **Medical Heroes Membership Packet** – information for research participants designed to enhance connections to research. http://ciscrp.org/e-store/medhero_memberpack.asp **The Participant Newsletter – August 2009 Edition** <http://ciscrp.org/quarterlyupdate/aug2009/Participant0809-all4.pdf>
 - **Posters** – “Behind every new medicine are the volunteers who take part in clinical research studies” (English and Spanish). <http://ciscrp.org/e-store/poster1.asp>
 - **What is a Placebo Controlled Trial Brochure** - http://ciscrp.org/e-store/brochures/placebo_english_web.pdf
- **Clinical Research Ethics – Education Materials** – Resources compiled for the purpose of responsible conduct of research teaching practices. <http://twiki.library.ucsf.edu/do/view/ResearchEthics/WebHome>
- **Coast IRB informational website** – created and compiled by the Citizens for Responsible Care and Research. <http://www.circare.org/info/coastirb.htm>
- **Cognitive Science Network** – announcements, job postings, research paper service, etc by the Social Science Research Network <http://www.ssrn.com/csn/index.html>

- **Consent form templates** from the Hastings Center - <http://www.thehastingscenter.org/Publications/IRB/Detail.aspx?id=3744>
- **Ethics Share** – research and collaboration web site for scholars working in the field of ethics. <https://www.ethicshare.org/>
- **How Grantees Manage Financial Conflicts of Interest in Research Funding by the National Institutes of Health** – report from the Office of Inspector General, Department of Health and Human Services <http://www.oig.hhs.gov/oei/reports/oei-03-07-00700.pdf>
- **Human Tissue Guidance** – Generated by the University of British Columbia Research Ethics Policy Advisory Board. http://www.ors.ubc.ca/ethics/forms/UBC%20REPAB%20Human%20Tissue%20Guidance_Version%201_March_2005.pdf
- **Informed Consent and Authorization Toolkit for Minimal Risk Research** – Developed by the Agency for Healthcare Research and Quality. <http://www.ahrq.gov/fund/informedconsent/>
- **Institute of Translational Health Sciences** – resources for investigators. www.iths.org
- **Introduction to the Principles and Practice of Clinical Research** – video and handout archive for NIH Clinical Center courses in 2009 and 2008. <http://ippcr.nihtraining.com/>
- **“Jerry Notes”** – teaching resources from the Journal of Empirical Research on Human Research Ethics. <http://www.csueastbay.edu/JERHRE/notes/>
- **Juvenile Diabetes Research Foundation Clinical Trials Connection** – a web site designed to help patients with Type 1 Diabetes access and evaluate clinical trials. <https://jdrf.optimalcare.com/patient/index.cfm>
- **Lab Management Video Vignettes** – by the Office for Research Integrity for development of management skills regarding authorship, stolen methodologies, ethics and more. <http://learning.ucdavis.edu/LabAct/>
- **Lupus Foundation of America** – www.lupus.org
 - **Center for Clinical Trials Education** - <http://www.lupus.org/clinicaltrials/>
 - **FAQ on Participating in Clinical Trials** - <http://www.lupus.org/clinicaltrials/media/docs/faq-clinical-trials.pdf>
- **Medical Research: A Consumer’s Guide for Participation** – Health Lawyers’ Public Information Series. <http://www.healthlawyers.org/Resources/PI/InfoSeries/Documents/MedicalResearch09.pdf>
- **National Cancer Institute** - Clinical Trials Promotional and Educational Materials including pins, handouts, print ads, PowerPoint presentations, etc. <http://ncipoet.cancer.gov/CTES/promoTools.cfm>
- **A Patient’s Guide to Clinical Trials** – 16 page guide from curetoday.com. http://www.curetoday.com/assets/documents/pocketguide_clintrialweb.pdf
- **Principles on Conduct of Clinical Trials: Communication of Clinical Trial Results** – principles of conduct from the Pharmaceutical Research and Manufacturers of America (PhRMA). http://www.phrma.org/files/042009_Clinical%20Trial%20Principles_FINAL.pdf
- **Readability Toolkit** – from the Project to Review and Improve Study Materials (PRISM) from the Group Health Center for Health Studies. http://www.centerforhealthstudies.org/capabilities/readability/readability_home.html
- **Report of the Public Responsibility in Medicine and Research (PRIM&R) Human Tissue/Specimen Banking Working Group: Part 1, Assessment and Recommendations** - http://www.primr.org/uploadedFiles/PRIMR_Site_Home/Public_Policy/Recently_Files_Comments/Tissue%20Banking%20White%20Paper%203-7-07%20final%20combined.pdf
- **Research Conflicts of Interest Training** – Online course by the University of Texas Health Science Center at Houston. <https://apache.hsc.uth.tmc.edu/rcoi/index.jsp>
- **Research that Benefits Native People: A Guide for Tribal Leaders** – from the National Congress of American Indians Policy Research Center. <http://www.ncaiprc.org/research-curriculum-guide>
- **Research Toolkit** – developed to help researchers create and sustain multisite research collaborations. www.researchtoolkit.org
- **State of Research Integrity and Misconduct Policies in Canada** – commissioned by the Canadian Research Integrity Committee. <http://www.hal.ca/HAL%207807%20State%20of%20Research%20Integrity%20Policies%20in%20Canada.pdf>
- **Understanding Consent in Research Involving Children** – from the Murdoch Children’s Research Institute (Australia). Includes case studies, handbook for researchers and human research ethics committees (Australian IRB equivalent), international guidelines, etc. <http://www.mcri.edu.au/projects/consentinresearch/>

- **You Want to be an IRB Community Member... Now What?** – provided by the University of Southern California.
http://www.usc.edu/admin/provost/oprs/private/docs/oprs/brochures/community_member_web.pdf

Publications:

- **AAHRPP Advance Newsletter** – Quarterly newsletter from the Association for the Accreditation of Human Research Protection Programs. [http://www.aahrpp.org/www.aspx?PageID=142\\$7](http://www.aahrpp.org/www.aspx?PageID=142$7)
- **Association of Academic Health Centers** – www.aahcdc.org
 - Report – Clinical Trials Offices: What's New in Research Administration by Elaine Rubin, PhD and Danielle Lazar, MA.
http://www.aahcdc.org/policy/reddot/AAHC_Clinical_Trials_Offices_Whats_New.pdf
 - Clinical Trials Administration Toolkit - <http://www.aahcdc.org/toolkit/>
- **Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research** – from the National Academies Press. http://www.nap.edu/catalog.php?record_id=12458
- **Conflict of Interest in Medical Research, Education and Practice** – Institute of Medicine committee report to examine COI and recommend steps to identify, limit and manage COI.
http://www.iom.edu/CMS/3740/47464/65721.aspx?utm_medium=email&utm_source=Institute%20of%20Medicine&utm_campaign=05.09+IOM+News&utm_content=IOMNews&utm_term=
- **Investigator Conflict of Interest: An IRB Case Study** – FDA News, June 4, 2009, Vol. 6(108)
<http://www.fdanews.com/newsletter/article?articleId=117636&issueId=12715> (subscription required)
- **Public Health: Ethical Issues** by the Nuffield Council on Bioethics – while not strictly about institutional review boards or clinical trials, case studies examine issues of consent, risk and vulnerable populations.
http://www.nuffieldbioethics.org/fileLibrary/pdf/Public_health_-_ethical_issues.pdf
- **Report of the International Bioethics Committee of UNESCO (United Nations Educational, Scientific and Cultural Organization) on Consent** – report contains general information about the consent process, situational consent categories, applications and conclusions.
<http://unesdoc.unesco.org/images/0017/001781/178124E.pdf>
- **The Participant** – Center for Information and Study on Clinical Research Participation (CISCRP) newsletter.
<http://www.ciscrp.org/information/participant.asp>
- **Understanding Clinical Trials: Why They are Done and What is Learned** by Gary Cutter, PhD and Brian Waldersen, BS – reference for multiple sclerosis patients and their families considering enrollment in a clinical trial. Includes descriptions of controls, placebos, randomization, inclusion/exclusion criteria, etc.
<http://www.unitedspinal.org/msscene/2009/08/27/understanding-clinical-trials-why-they-are-done-and-what-is-learned/>

Training and Certification:

- **Association of Clinical Research Professionals** – online clinical courses
 - **CRA Curriculum** -
<http://www.acrpnet.org/MainMenuCategory/Education/online/OnlineClinicalCourses/CRACurriculum.aspx>
 - **CRC Curriculum** -
<http://www.acrpnet.org/MainMenuCategory/Education/online/OnlineClinicalCourses/CRCCurriculum.aspx>
 - **GCP Curriculum** –
<http://www.acrpnet.org/MainMenuCategory/Education/online/OnlineClinicalCourses/GoodClinicalPractice.aspx>
 - **Investigator Curriculum** -
<http://www.acrpnet.org/MainMenuCategory/Education/online/OnlineClinicalCourses/InvestigatorCurriculum.aspx>
 - **Regulatory Affairs Curriculum** -
<http://www.acrpnet.org/MainMenuCategory/Education/online/OnlineClinicalCourses/RegulatoryAffairsCurriculum.aspx>
 - **Leadership Courses** -
<http://www.acrpnet.org/MainMenuCategory/Education/online/OnlineLeadershipCourses.aspx>
- **Your Role in Cancer Clinical Trials** – Free, online interactive courses for patient advocates, community leaders, primary care providers and cancer clinical trials staff. <http://www.enacct.org/our-programs/your-role-cancer-clinical-trials>