

## Resource Archive January 2010 – April 2010

### Articles:

- Anderson JR, Schonfeld TL. Data-sharing dilemmas: allowing pharmaceutical company access to research data. *IRB*. 2009;31(3):17-9.
- Angell E, Tarrant C, Dixon-Woods M. Research involving storage and use of human tissue: how did the Human Tissue Act 2004 affect decisions by research ethics committees? *J Clin Pathol*. 2009;62(9):825-9.
- Ashton CM, Wray NP, Jarman AF, et al. Ethics and methods in surgical trials. *J Med Ethics*. 2009;35(9):579-83.
- Banja JD, Dunlop B. Enhancing informed consent in clinical trials and exploring resistances to disclosing measures in a pandemic. *Am J Bioeth*. 2009;9(8):39-41.
- Barakat-Haddad CP, Elliott SJ, Eyles J, Pengelly D. Predictors of locating children participants in epidemiological studies 20 years after last contact: internet resources and longitudinal research. *Eur J Epidemiol*. 2009;24(8):397-405.
- Barclay L. Exploitation and double standards in research in developed countries. *Monash Bioeth Rev*. 2008;27(4):37-44.
- Barsky AE. The legal and ethical context for knowing and using the latest child welfare research. *Child Welfare*. 2009;88(2):69-92.
- Bastida EM, Tseng TS, McKeever C, et al. Ethics and community-based participatory research: perspectives from the field. *Health Promot Pract*. 2009;11(1):16-20.
- Bathe OF, McGuire AL. The ethical use of existing samples for genome research. *Genet Med*. 2009.
- Bell WC, Sexton KC, Grizzle WE. How to efficiently obtain human tissues to support specific biomedical research projects. *Cancer Epidemiol Biomarkers Prev*. 2009;18(6):1676-9.
- Bellieni CV, Buonocore G. Recommendations for an ethical treatment of newborns involved in clinical trials. *Acta Paediatr*. 2009;99(1):30-2.
- Bennett B, Deakin C, Australian Gender Equity in Health Research G. Registration of clinical trials: challenges for global regulation. *J Law Med*. 2009;17(1):82-94.
- Berlan ED, Bravender T. Confidentiality, consent and caring for the adolescent patient. *Curr Opin Pediatr*. 2009;21(4):450-6.
- Beskow LM, Grady C, Iltis AS, et al. Points to consider: the research ethics consultation service and the IRB. *IRB*. 2009;31(6):1-9.
- Boers M. The time has come to limit the placebo period in rheumatoid arthritis trials to 3 months: A systematic comparison of 3- and 6-month response rates in trials of biologic agents. *Ann Rheum Dis*. 2009.
- Brostrom L, Johansson M. Surrogates have not been shown to make inaccurate substituted judgments. *J Clin Ethics*. 2009;20(3):266-73.
- Bueno M, Brevideilli MM, Cocarelli T, et al. Reasons for resubmission of research projects to the Research Ethics Committee of a university hospital in Sao Paulo, Brazil. *Clinics (Sao Paulo)*. 2009;64(9):831-6.
- Burris S, Davis C. Assessing social risks prior to commencement of a clinical trial: due diligence or ethical inflation? *Am J Bioeth*. 2009;9(11):48-54.
- Cegala DJ, Post DM. The impact of patients' participation on physicians' patient-centered communication. *Patient Education and Counseling*. 2009;77:202-8.
- Chervenak FA, McCullough LB. Ethics of research in perinatal medicine. *Semin Perinatol*. 2009;33(6):391-6.
- Cheung WY, Pond GR, Heslegrave RJ, et al. The contents and readability of informed consent forms for oncology clinical trials. *Am J Clin Oncol*. 2009.
- Choonara I. Ethical and safety aspects of clinical trials in neonates. *Early Hum Dev*. 2009.
- Chwang E. Against risk-benefit review of prisoner research. *Bioethics*. 2009;24(1):14-22.
- Cook D, Burns K, Finfer S, et al. Clinical research ethics for critically ill patients: A pandemic proposal. *Crit Care Med*. 2009.
- Cryder CE, London AJ, Volpp KG, Loewenstein G. Informative inducement: study payment as a signal of risk. *Social Science & Medicine*. Feb 2010
- Dawson L, Zarin D, Emanuel E, et al. Considering usual medical care in clinical trial design. *PLoS Medicine*. September 2009.  
<http://newsmanager.commpartners.com/primrd/downloads/RED%20Dec%2009/Considering%20Usual%20Medical%20Care%20in%20Clinical%20Trial%20Design.pdf>
- Deakin CT, Alexander IE, Kerridge I. Accepting risk in clinical research: is the gene therapy field becoming too risk-averse? *Mol Ther*. 2009.
- Dhruva SS, Bero LA, Redberg RF. Strength of study evidence examined by the FDA in premarket approval of cardiovascular devices. *JAMA*. 2009;302:2679-85.
- Dickert N, Wendler D. Ancillary care obligations of medical researchers. *JAMA*. 2009;302(4):424-8.
- Diekema DS. Ethical issues in research involving infants. *Semin Perinatol*. 2009;33(6):364-71.

- Dolgin E. African networks launch to boost clinical trial capacity. *Nature Med.* 2010;16(8).
- Duncan RE, Drew SE, Hodgson J, Sawyer SM. Is my mum going to hear this? Methodological and ethical challenges in qualitative health research with young people. *Soc Sci Med.* 2009.
- Egleston BL, Dunbrack RL, Hall MJ. Clinical trials that explicitly exclude gay and lesbian patients. *NE J Med.* 2010;362(11):1054-5.
- Elger BS, Spaulding A. Research on prisoners – a comparison between the IOM Committee recommendations (2006) and European regulations. *Bioethics.* 2009;24(1):1-13.
- European Society of Human Genetics. Genetic testing in asymptomatic minors: recommendations of the European Society of Human Genetics. *Eur J Hum Genet.* 2009;17(6):720-1.
- Fadare JO, Porter C. Informed consent in human subject research: a comparison of current international and Nigerian Guidelines. *J Emp Res on Hum Res Ethics.* 2010;5(1): 67-74.
- Fassassi S, Bianchi Y, Stiefel F, Waeber G. Assessment of the capacity to consent to treatment in patients admitted to acute medical wards. *BMC Med Ethics.* 2009;10(15).
- Feiring E. Reassessing insurers' access to genetic information: genetic privacy, ignorance and injustice. *Bioethics.* 2009;23(5):300-10.
- Finch SA, Barkin SL, Wasserman RC, et al. Effects of local institutional review board review on participation in national practice-based research network studies. *Arch Ped Adol Med.* 2009;163(120):1130-1134.
- Finder SG. Is consent necessary for ethics consultation? *Camb Q Healthc Ethics.* 2009;18(4):384-96.
- Foddy B. A duty to deceive: placebos in clinical practice. *Am J Bioeth.* 2009;9(12):4-12.
- Freeman BD, Kennedy CR, Frankel HL, et al. Ethical considerations in the collection of genetic data from critically ill patients: what do published studies reveal about potential directions for empirical ethics research? *Pharmacogenomics J.* 2009.
- Friedman Ross L, Loup A, Nelson RM, et al. Human subjects protections in community-engaged research: a research ethics framework. *J Emp Res on Hum Res Ethics.* 2010;5(1): 5-18.
- Friedman Ross L, Loup A, Nelson RM, et al. Nine key functions for a human subjects protection program for community-engaged research: points to consider. *J Emp Res on Hum Res Ethics.* 2010;5(1): 33-48.
- Frith L. The use of clinical ethics committees in infertility clinics. *Hum Fertil (Camb).* 2009;12(2):89-94.
- Frizelle F. Consent for case reports and medical images. *N Z Med J.* 2009;122(1300):8-10.
- Fry-Revere S, Malmstrom DB. More regulation of industry-supported biomedical research: are we asking the right questions? *J Law Med Ethics.* 2009;37(3):420-30.
- Frye RL, Simari RD, Gersh BJ, et al. Ethical issues in cardiovascular research involving humans. *Circulation.* 2009;120(21):2113-21.
- Goebel JW, Pickardt T, Bedau M, et al. Legal and ethical consequences of international biobanking from a national perspective: the German MBM-EU Coop project. *Eur J Hum Genet.* 2009.
- Goldacre B. Is conflict of interest unacceptable when drug companies conduct trials on their own drugs? Yes. *BMJ.* 2009;339(b4949).
- Goldenberg AJ, Chandros Hull S, Botkin JR, et al. Pediatric biobanks: approaching informed consent for continuing research after children grow up. *J Pediatrics.* In press.  
<http://newsmanager.commpartners.com/primrd/downloads/RED%20Dec%2009/Pediatric%20Biobanks.pdf>
- Gordijn B, Dekkers W. Ethics and regulation. *Med Health Care Philos.* 2009.
- Gordon MP. A legal duty to disclose individual research findings to research subjects? *Food Drug Law J.* 2009;64(1):225-60.
- Halpern SD, Randolph AG, Angus DC. No child left behind: Enrolling children and adults simultaneously in critical care randomized trials. *Crit Care Med.* 2009;37(9):2638-41.
- Hansson SO. Do we need a special ethics for research? *Sci Eng Ethics.* 2009.
- Hansson SO. Should we protect the most sensitive people? *J Radiol Prot.* 2009;29(2):211-8.
- Hartling L, Ospina M, Liang Y, et al. Risk of bias versus quality assessment of randomized controlled trials: cross sectional study. *BMJ.* 2009;339:b4012.
- Hebert PC, Fergusson DA. Are we keeping research participants safe enough? *CMAJ.* 2010; DOI: [10.1503/cmaj.100404](http://dx.doi.org/10.1503/cmaj.100404)
- Hemmings A. Ethnographic research with adolescent students: situated fieldwork ethics and ethical principles governing human research. *J Empir Res Hum Res Ethics.* 2009;4(4):27-38.
- Hicks SC, James RE, Wong N, et al. Australasian gastro-intestinal trials: a case study evaluation of ethics review systems for multicentre clinical trials. *Med J Aust.* 2009;191(5):280-2.
- Hoeyer K. Donors' perceptions of consent to and feedback from biobank research: time to acknowledge diversity? *Public Health Genomics.* 2009.
- Hoffman RJ, Farcy D, Scalea T. Ethics, equipoise, and evidence: when should investigators decide to not test their hypothesis. *Am J Emerg Med.* 2009;27(8):983-5.
- Hoglund AT, Helgesson G, Eriksson S. Ethical dilemmas and ethical competence in the daily work of research nurses. *Health Care Anal.* 2009.

- Hollands P, McCauley C. Private cord blood banking: current use and clinical future. *Stem Cell Rev.* 2009;5(3):195-203.
- Holm S. Protecting children in clinical research – need for a rethink? *Crit Care Med.* 2009;37(9):2673-4.
- Holubkov R, Dean JM, Berger J, et al. Is “rescue” therapy ethical in randomized controlled trials? *Pediatr Crit Care Med.* 2009;10(4):431-8.
- Howard DL, Boyd CL, Nelson DK, Godley P. Getting from A to IRB: developing an institutional review board at a historically black university. *J Emp Res on Hum Res Ethics.* 2010;5(1): 75-82.
- Howick J. Questioning the methodologic superiority of ‘placebo’ over ‘active’ controlled trials. *Am J Bioeth.* 2009;9(6-7):11-3.
- Hrynaskiewicz et al. Preparing raw clinical data for publication: guidance for journal editors, authors and peer reviewers. *BMJ.* 2010;340:c181.
- Huang H, Coker A. Examining issues affecting African American participation in research studies. *J Black Studies.* March 2010.
- Humphreys S. Paying the phase 1 volunteer: proposed ‘lottery’ or deferred payment model aims to resolve undue inducement. *Applied Clinical Trials.* April 2010.
- Hyatt RR, Gute DM, Pirie A, et al. Transferring knowledge about human subjects protections and the role of institutional review boards in a community-based participatory research project. *Am J Public Health.* 2009;99 Suppl 3(S526-31).
- Isasi RM, Knoppers BM. Governing stem cell banks and registries: emerging issues. *Stem Cell Res.* 2009;3(2-3):96-105.
- Isidor JM, Kaltman SP. Is the Coast clear? Managing the expected increased scrutiny of IRBs. *Medical Research Law & Policy Report.* November 2009.
- Ivashkov Y, Van Norman GA. Informed consent and the ethical management of the older patient. *Anesthesiol Clin.* 2009;27(3):569-80.
- Jansen LA. The ethics of altruism in clinical research. *Hastings Center Rep.* 2009;39(4):26-36.
- Jegede AS. Understanding informed consent for participation in international health research. *Dev World Bioeth.* 2009;9(2):81-7.
- Kahn J. Informed consent barriers deter trial enrollment. *TCTMD.* Jan 2010
- Kaktins NM. Faculty Guide to the Institutional Review Board Process. *Nurse Educator.* 2009;34(6):244-8.
- Kass NE, Sugarman J, Medley AM, et al. An intervention to improve cancer patients’ understanding of early-phase clinical trials. *IRB.* 2009;31(3):1-10.
- Kaushik J. Organ transplant and presumed consent: towards an “opting-out” system. *Indian J Med Ethics.* 2009;6(3):149-52.
- Kaye J, Boddington P, de Vries J, et al. Ethical implications of the use of whole genome methods in medical research. *Eur J Hum Genet.* 2009.
- Khin-Maung-Gyi FA, Schwarzhoff A. Informed consent forms: are we writing them for subjects? *SoCRA Source.* November 2009.  
[http://newsmanager.commpartners.com/primrd/downloads/RED%20Dec%202009/Informed%20Consent%20Forms%20Are%20We%20Writing%20Them%20for%20Subjects\\_CR.pdf](http://newsmanager.commpartners.com/primrd/downloads/RED%20Dec%202009/Informed%20Consent%20Forms%20Are%20We%20Writing%20Them%20for%20Subjects_CR.pdf)
- Kim SY, Schrock L, Wilson RM, et al. An approach to evaluating the therapeutic misconception. *IRB.* 2009;31(5):7-14.
- Knapp P, Raynor DK, Silcock J, Parkinson B. Performance-based readability testing of participant materials for a phase 1 trial: TGN1412. *J Med Ethics.* 2009;35(9):573-8.
- Knowles RL, Bull C, Wren C, Dezateux C. Ethics, governance and consent in the UK: implications for research into longer-term outcomes of congenital heart defects. *Arch Dis Child.* 2009.
- Kowalski CJ, Hewett JL. Data and safety monitoring boards: some enduring questions. *J Law Med Ethics.* 2009;37(3):496-506.
- Koyfman SA, McCabe MS, Emanuel EJ, Grady C. A consent form template for phase I oncology trials. *IRB.* 2009;31(4):1-8.
- Kozanczyn C, Collins K, Fernandez CV. Offering results to research subjects: US institutional review board policy. *Accountability in Research.* 2007;14(4):255-267.
- Lawton V. Is the conflict of interest unacceptable when drug companies conduct trials on their own drugs? *No. BMJ.* 2009;339(b4953).
- Layman EJ. Human experimentation: historical perspective of breaches of ethics in US health care. *Health Care Manag (Frederick).* 2009;28(4):354-74.
- Leggett Dugosh K, Festinger DS, Croft JR, Marlowe DB. Measuring coercion to participate in research within a doubly vulnerable population: initial development of the coercion assessment scale. *J Emp Res on Hum Res Ethics.* 2010;5(1): 93-102.
- Lemke AA, Trinidad SB, Edwards KL, et al. Attitudes toward genetic research review: results from a national survey of professionals involved in human subjects protection. *J Emp Res on Hum Res Ethics.* 2010;5(1): 83-92.

- Liao SM, Sheehan M, Clarke S. The duty to disclose adverse clinical trial results. *Am J Bioeth.* 2009;9(8):24-32.
- Liao SM, Sheehan M, Clarke S. Disclosing clinical trial results: publicity, significance and independence. *Am J Bioeth.* 2009;9(8):W3-5.
- Lidz CW, Appelbaum PS, Joffe S, et al. Competing commitments in clinical trials. *IRB.* 2009;31(5):1-6.
- Lipworth W, Morrell B, Irvine R, Kerridge I. An empirical reappraisal of public trust in biobanking research: rethinking restrictive consent requirements. *J Law Med.* 2009;17(1):119-32.
- Lo B, Grady D. Strengthening institutional review board review of highly innovative interventions in clinical trials. *JAMA.* 2009;302(24):2697-8.
- Lockshin et al. Clinical trial registration and publication of randomized controlled trials. *JAMA.* 2010;303:517-8.
- Lowenstein PR, Lowenstein ED, Castro MG. Challenges in the evaluation, consent, ethics and history of early clinical trials – implications of the Tuskegee ‘trial’ for safer and more ethical clinical trials. *Curr Opin Mol Ther.* 2009;11(5):481-4.
- Lucassen A. Ethicolegal aspects of genetics in surgical practice. *Ann R Coll Surg Engl.* 2009;91(6):451-5.
- Luo J, Logan C, Long TP, et al. Cyberdermatology I: ethical, legal, technologic, and clinical aspects of patient-physician e-mail. *Clin Dermatol.* 2009;27(4):359-66.
- Lyerly AD, Little MO, Faden R. The second wave: toward responsible inclusion of pregnant women in research. *Int J Fem Approaches Bioeth.* 2008;1(2):5-22.
- Mack R, Giarelli E, Bernhardt BA. The adolescent research participant: strategies for productive and ethical interviewing. *J Pediatr Nurs.* 2009;24(6):448-57.
- Massimo LM, Calcagno A, Battaglia T, Pistorio A. A project for the evaluation of awareness of under-aged patients involved in clinical trials. Development of the IGG – Awareness Scale. *Minerva Pediatr.* 2009;61(5):483-8.
- Matutina RE. Ethical issues in research with children and young people. *Paediatr Nurs.* 2009;21(8):38-44.
- McNett M, Lawry K. Research and quality improvement activities: when is institutional review board review needed? (Ethicolegal Perspectives). *J Neurosci Nurs.* 2009;41(6):344-8.
- McGrath M, et al. The limits of collaboration: a qualitative study of community ethical review of environmental health research. *Am J Pub Health.* August 2009.
- Miller VA, Reynolds WW, Ittenbach RF, et al. Challenges in measuring a new construct: perception of voluntariness for research and treatment decision making. *J Empir Res Hum Res Ethics.* 2009;4(3):21-31.
- Morrison CA, Horwitz IB, Carrick MM. Ethical and legal issues in emergency research: barriers to conducting prospective randomized trials in an emergency setting. *J Surg Res.* 2009.
- Munthe C, Radovic S, Anckarsater H. Ethical issues in forensic psychiatric research on mentally disordered offenders. *Bioethics.* 2009;24(1):35-44.
- Murphy J, Scott J, Kaufman D, et al. Public perspectives on informed consent for Biobanking. *Am J Pub Health.* 2009;99(2):2128-34.
- Nakkash R, Makhoul J, Afifi R. Obtaining informed consent: observations from community research with refugee and impoverished youth. *J Med Ethics.* 2009;35(10):638-43.
- Nunn R. Preparing for a post-placebo paradigm: ethics and choice of control in clinical trials. *Am J Bioeth.* 2009;9(9):51-2.
- Osrin D, Azad K, Fernandez A, et al. Ethical challenges in cluster randomized controlled trials: experiences from public health interventions in Africa and Asia. *Bull World Health Organ.* 2009;87(10):772-9.
- Owen Schaefer G, Emanuel E, Wertheimer A. The obligation to participate in biomedical research. *JAMA.* 2009;302(1):67-72.
- Parker M, Bull SJ, de Vries J, et al. Ethical data release in Genome-Wide Association Studies (GWAS) in developing countries. *PLoS Med.* Dec 2009.
- Penn C, Evans M. Assessing the impact of a modified informed consent process in a South African HIV/AIDS research trial. *Patient Educ Couns.* 2009.
- Petrini C. Ethical Issues in the difference between placebo-controlled and active-controlled trials. *Am J Bioeth.* 2009;9(9):56-8.
- Petrini C. “Broad” consent, exceptions to consent and the question of using biological samples for research purposes different from the initial collection purpose. *Soc Sci Med.* 2009.
- Pitak-Arnnop P, Sader R, Herve C, et al. Reporting of ethical protection in recent oral and maxillofacial surgery research involving human subjects. *Int J Oral Maxillofac Surg.* 2009;38(7):707-12.
- Rachlin J. Biobanking: if, when and how to return research results. *ACRP Monitor.* April 2010.
- Rasmussen LM. Problems with minimal-risk research oversight: a threat to academic freedom? *IRB.* 2009;31(3):11-6.
- Resnik DB. Re-consenting human subjects: ethical, legal and practical issues. *J Med Ethics.* 2009;35(11):656-7.
- Resnik DB, Patrone D, Peddada S. Evaluating the quality of information about alternatives to research participation in oncology consent forms. *Contemp Clin Trials.* 2009.

- Ries NM. Growing up as a research subject: ethical and legal issues in birth cohort studies involving genetic research. *Health Law J.* 2007;15:1-41.
- Roche PA. Ethical challenges encountered in genomic research. *Circ Cardiovasc Genet.* 2009;2(3):293-7.
- Rothstein MA. Currents in contemporary ethics. Improving privacy in research by eliminating informed consent. IOM Report misses the mark. *J Law Med Ethics.* 2009;37(3):507-12.
- Rubbert-Roth A, Burmester GR. Clinical trials: how to cope with medical needs, ethics and timelines. *Ann Rheum Dis.* 2009;69(1):1-3.
- Sachs B. The exceptional ethics of the investigator-subject relationship. *J Med Philos.* 2009.
- Schuklenk U, Lowry C. Terminal illness and access to Phase 1 experimental agents, surgeries and devices: reviewing the ethical arguments. *Br Med Bull.* 2009;89:7-22.
- Selgelid MJ. Governance of dual-use research: an ethical dilemma. *Bull World Health Organ.* 2009;87(9):720-3.
- Shelton AK, Fish AF, Cobb JP, et al. Surrogate consent for genomics research in intensive care. *Am J Crit Care.* 2009;18(5):418-26; quiz 427.
- Shore N. Student research projects and the institutional review board. *J Teaching in Social Work.* 2009;29(3):329-45.
- Siegel A, Anderson MW, Schmidt TC, Youngner SJ. Informed consent to tissue donation: policies and practice. *Cell Tissue Bank.* 2009;10(3):235-40.
- Simon C, Mosavel M. Community members as recruiters of human subjects: ethical considerations. *Am J Bioethics.* March 2010.
- Smith VJ. Ethical and effective ethnographic research methods: a case study with Afghan refugees in California. *J Empir Res Human Res Ethics.* 2009;4(3):59-72.
- Smoyer AB, Blankenship KM, Belt B. Compensation for incarcerated research participants: Diverse state policies suggest a new research agenda. *Am J Pub Health.* Oct 2009
- Sokol DK. Informed consent is more than a patient's signature. *BMJ.* 2009;339(b3400).
- Swartling U, Helgesson G, Hansson MG, Ludvigsson J. Split views among parents regarding children's right to decide about participation in research: a questionnaire survey. *J Med Ethics.* 2009;35(7):450-5.
- Truyers C, Kellen E, Arbyn M, et al. The use of human tissue in epidemiological research: ethical and legal considerations in two biobanks in Belgium. *Med Health Care Philos.* 2009.
- Tweddle F. Covert medication in older adults who lack decision-making capacity. *Br J Nurs.* 2009;18(15):936-9.
- Ulrich CM, Zhou Q, Grady C. Recommending research participation to patients: an ethical imperative? *Clinical Scholars Review.* 2009.
- Unger S, Lesley W, Shafagh F, et al. Motivated by Money? The impact of financial incentive for the research team on study recruitment. *IRB: Ethics and Human Research.* Jan-Feb 2010.
- van der Vorm A, van der Laan AL, Borm G, et al. Experts' opinions on ethical issues of genetic research into Alzheimer's disease: results of a Delphi study in the Netherlands. *Clin Genet.* 2009.
- Vermeulen E, Schmidt MD, Aaronson NK, et al. A trial of consent procedures for future research with clinically derived biological samples. *Br J Cancer.* 2009;101(9):1505-12.
- Wall LL, Brown D. "Commercial pressures and professional ethics: troubling revisions to the recent ACOG Practice Bulletins on surgery for pelvic organ prolapse": response to Lawrence. *Int Urogynecol J Pelvic Floor Dysfunct.* 2009.
- Weinfurt KP, Hall MA, King NM, et al. Disclosure of financial relationships to participants in clinical research. *N Engl J Med.* 2009;361(9):916-21.
- Wertheim HF, Farrar J, Horby P. Online video sharing and patients' privacy. *BMJ.* 2009;339(b3391).
- West SL, Blake C, Zhiwen L, et al. Reflections on the use of electronic health record data for clinical research. *Health Informatics J.* 2009;15(2):108-21.
- Whicher D, Curry P, Taylor H. Factors that influence institutional review board members' commitment to their role responsibilities. *IRB: Ethics & Human Research.* September-October 2009
- White DB, Malvar G, Karr J, et al. Expanding the paradigm of the physician's role in surrogate decision-making: An empirically derived framework. *Crit Care Med.* 2009.
- Womack C, Gray NM. Banking human tissue for research: vision to reality. *Cell Tissue Bank.* 2009;10(3):267-70.
- Wynia M, Boren D. Better regulation of industry-sponsored clinical trials is long overdue. *J Law Med Ethics.* 2009;37(3):410-9.
- Yawn BP, Graham DG, Bertram SL, et al. Practice-based research network studies and institutional review boards: two new issues. *J Am Board Fam Med.* 2009;22:453-60.
- Yoram U, Sill AM, Kamani N. The experiences of children enrolled in pediatric oncology research: implications for assent. *Pediatrics.* April 2010.

**Books:**

- **Examining Tuskegee: The Infamous Syphilis Study and its Legacy**, by Susan Reverby
- **The Immortal Life of Henrietta Lacks** by Rebecca Skloot
- **Institutional Review Board: Member Handbook, Third Edition** by Robert J Amdur, MD and Elizabeth A Bankert, MA. <http://www.jblearning.com/catalog/9780763780005/>
- **Making Data Talk: Communicating Public Health Data to the Public, Policy Makers and the Press** by David E Nelson, Bradford W Hesse and Robert T Croyle, Oxford University Press 2009
- **Study Guide for Institutional Review Board Management and Function, Second Edition** by Amy Davis, Elizabeth Bankert, Karen Hansen, Susan Kornetsky and Helen McGough. <http://www.jblearning.com/catalog/0763738662/>

#### Clinical Trial Volunteer Registries and Information:

- **Coalition of Cancer Cooperative Groups** - [http://www.cancertrialshelp.org/lcare\\_content/icMainContent.aspx?intAppMode=1](http://www.cancertrialshelp.org/lcare_content/icMainContent.aspx?intAppMode=1)
- **ResearchMatch** – [www.researchmatch.org](http://www.researchmatch.org)

#### Internet resources:

- **Award for Excellence in Human Research Protection** – Offered by the Health Improvement Institute. <http://www.hii.org/>
- **Canadian Association of Research Ethics Boards (CAREB)** - <http://www.careb-accor.org/>
- **Center for Information & Study on Clinical Research Participation** - <http://cisrcp.org/index.html>
  - **Poster** – “Behind Every New Medicine are the Volunteers who take part in Clinical Research Studies” [http://cisrcp.org/professional/store/posters\\_volunteers\\_spanish.html](http://cisrcp.org/professional/store/posters_volunteers_spanish.html)
  - **Catalogue of Programs and Resources** - [http://cisrcp.org/downloads/CISCRP\\_Catalog.pdf](http://cisrcp.org/downloads/CISCRP_Catalog.pdf)
- **Children and Clinical Studies website** – resources from the National Heart Lung and Blood Institute at the NIH. <http://www.nhlbi.nih.gov/childrenandclinicalstudies/index.php>
- **Clinical Trial Magnifier** - <http://www.clinicaltrialmagnifier.com/default.aspx>
- **Council for Certification of IRB Professionals** – handbook, practice exams and testing schedules. <http://www.ptcny.com/clients/CCIP/>
- **Human Research Report** – [www.humansubjects.com](http://www.humansubjects.com)
- **Institute for Translational Health Services** – online training programs. <https://www.iths.org/training/online>
- **Institutional Review Board Member Handbook** – by Robert Amdur and Elizabeth Bankert <http://ethics.iit.edu/eelibrary/?q=node/3157>
- **Journal of the American Medical Association**
  - Randomized controlled trial page for patients and prospective research participants - <http://jama.ama-assn.org/cgi/content/full/303/12/1216>
- **National Cancer Clinical Trials System for the 21<sup>st</sup> Century: Reinvigorating the NCI Cooperative Group Program** – a report from the Institute of Medicine. <http://www.iom.edu/Reports/2010/A-National-Cancer-Clinical-Trials-System-for-the-21st-Century-Reinvigorating-the-NCI-Cooperative.aspx>
- **Office for Human Research Protections** - educational videos <http://www.hhs.gov/ohrp/education/#materials>
- **StaR Child Health** – International Forum of Standards for Research with Children. <http://www.ifsrc.org/>
- **Translational Researcher Toolkit** – includes IRB contacts, reference materials, training links, funding sources, form templates, community-based participatory research materials, research partners and dissemination contacts. <http://healthlinks.washington.edu/index.jsp?id=E0C106FD-997D-4E61-85B3-E56E4EFAEB16>
- **UC Davis Guidance for IRBs** - [http://www.research.ucdavis.edu/home.cfm?id=OVC\\_1,2000](http://www.research.ucdavis.edu/home.cfm?id=OVC_1,2000)

#### Publications:

- **ADVANCE Newsletter**, from the Association for the Accreditation of Human Research Protections Programs, Inc. Winter 2010 Edition - <http://www.aahrpp.org/Documents/D000242.PDF>
- **Clinical Research Times** – newsletter from Boston University's IRB, and Office of Clinical Research. <http://www.bu.edu/crtimes/>
- **Oral History: a Viable Methodology for 21<sup>st</sup> Century Educational Administration Research: National Impact**, from Articles Hub. - <http://articles-hub.net/2010/03/oral-history-a-viable-methodology-for-21st-century-educational-administration-research-national-impact/>

- **Registries for Evaluating Patient Outcomes: A User's Guide, 2<sup>nd</sup> Edition** – from the Agency for Healthcare Research and Quality. Chapter 8 contains a discussion of human subjects protection in research registries.
- **Reviewing Clinical Trials: A Guide for the Ethics Committee** - <http://www.clinicaltrials.com/default.aspx>