



TUSKEGEE
UNIVERSITY

*National Center for Bioethics
in Research and Health Care*



**Community-Campus
Partnerships for Health**
Transforming Communities & Higher Education



Resource List for Conference Call Series on Institutional Review Boards (IRBs) and Ethical Issues in Research

If you have recommended resources to add to this list, please email them to CCPH graduate research assistant Jessica Grignon at jgrignon@u.washington.edu

Call #6: IRB Reform: Changing Policy and Practice to Protect Communities

Selected articles:

- Beversdorf, S., Ahmed, S., & Beck, B. (2007). Community-Academic Partnerships and Institutional Review Board Insights. *Partnership Perspectives*. 2007; IV, Issue I: 95-104. Available at <http://ccph.info/>.
- Flicker, S., Travers, R., Guta, A., McDonald, S. & Meagher, A. Ethical Dilemmas in Community-Based Participatory Research: Recommendations for Institutional Review Boards. *Journal of Urban Health*; 2007. e-pub (DOI 10.1007/s11524-007-9165-7).
- Glass KC, Kaufert J. Research Ethics Review and Aboriginal Community Values: Can the Two be Reconciled? *Journal of Empirical Research on Human Research Ethics*. 2007; 2(2): 25-40.
- King, N., Henderson, G., & Stein, J. (1999). *Beyond Regulations: Ethics in Human Subjects Research*. Chapel Hill: University of North Carolina Press.
- Macaulay AC, Hickner J, Sherwood RA. Protecting participants in family medicine research: a consensus statement on improving research integrity and participants' safety in educational research, community-based participatory research, and practice network research. *Family Medicine*. 2006;38(2):116-20.
- Shore, N. Re-conceptualizing the Belmont Report: A community-based participatory research perspective. *Journal of Community Practice*. 2006;14(4), pp. 5-26.
- Shore, N. Community Based Participatory Research and the Ethics Review Process. *Journal of Empirical Research on Human Research Ethics*. 2007; 2(1): 31-41.
- Travers, R., et al. Proposal for an ethics review board of community-based HIV/AIDS research in Ontario, an OHTN position paper. 2006, Ontario HIV Treatment Network: Toronto, ON.

Call #5: Beyond the University IRB: Understanding Alternative Models for Human Protection, Part II: Creating an Independent Community IRB — When is it Right for You?

Selected articles on community IRBs and building community research capacity:

- 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. Retrieved on May 21, 2007 from <http://www.science.doe.gov/ober/humsubj/spring03.pdf>

- Braun KL, Tsark JU, Santos L, Aitaoto N, Chong C. Building Native Hawaiian capacity in cancer research and programming. A legacy of 'Imi Hale. *Cancer*. 2006 Oct 15;107(8 Suppl):2082-90.
- 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.
- Hernandez JAA. Blood, lies, and Indian rights: tribal colleges and universities (TCUs) becoming gatekeepers for research. 2004; 16(2). Retrieved on May 21, 2007 from <http://tribalcollegejournal.org/themag/backissues/winter2004/winter2004hernandez.html>
- Kagawa-Singer M, Park Tanjasiri S, Lee SW, Foo MA, Ngoc Nguyen TU, Tran JH, Valdez A. Breast and cervical cancer control among Pacific Islander and Southeast Asian Women: participatory action research strategies for baseline data collection in California. *J Cancer Educ*. 2006 Spring;21(1 Suppl):S53-60. Retrieved on May 21, 2007 from http://www.leaonline.com/doi/pdf/10.1207/s15430154jce2101s_11
- Oneha MF; Beckham S. Re-examining community based research protocols. *Pacific Public Health* 2.11:1;2004.
- 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.

Selected examples of independent community IRBs:

- Orange County Asian and Pacific Islander Community Alliance: <http://www.ocapica.org> in collaboration with Special Services for Groups: <http://www.ssgmain.org/>
 - About the IRB: http://www.cbcrp.org/publications/newsletters/2006/page_17.php
 - American Public Health Association conference audio-recorded presentation: *A community perspective of CBPR methods: The Promoting Access to Health for Pacific Islander and Southeast Asian women program*: http://apha.confex.com/apha/134am/techprogram/paper_131797.htm
- Waianae Coast Comprehensive Health Center: <http://www.wcchc.com/>
 - Research and Institutional Review Board Protocols: http://www.waianae-comp.org/Res_IRB.htm
- Papa Ola Lokahi: <http://www.papaolalokahi.org>
 - Native Hawaiian Health Care System (NHHCS) – Institutional Review Board (IRB): http://www.papaolalokahi.org/hoe2/index.cfm?wwa_ID=93B99296-EF41-4D27-9ECEB62C082DD382&sub=yes
- Navajo Nation Human Research Review Board: <http://www.nnhrrb.navajo.org/>

Call # 4 – Beyond the University IRB: Understanding Alternative Models for Human Protection, Part I: Supplementing the IRB for Community Protection with a Community Advisory Board

Selected Articles on community advisory boards or similar entities:

- Burrus BB, Liburd LC, Burroughs A. Maximizing participation by black Americans in population-based diabetes research: the Project DIRECT pilot experience. *J Community Health*. 1998 Feb;23(1):15-27.

- Cargo M, Levesque L, Macaulay AC, et al. Kahnawake Schools Diabetes Prevention Project (KSDPP) Community Advisory Board. Community governance of the Kahnawake Schools Diabetes Prevention Project, Kahnawake Territory, Mohawk Nation, Canada. *Health Promot Int.* 2003 Sep;18(3):177-87.
- 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.
- Galea S, Factor SH, Bonner S, et al. Collaboration among community members, local health service providers, and researchers in an urban research center in Harlem, New York. *Public Health Rep.* 2001 Nov-Dec;116(6):530-9.
- Gilbert SG. Supplementing the traditional institutional review board with an environmental health and community review board. *Environ Health Perspect.* 2006 Oct;114(10):1626-9.
- Horowitz CR, Arniella A, James S, et al. Using community-based participatory research to reduce health disparities in East and Central Harlem. *Mt Sinai J Med.* 2004 Nov;71(6):368-74.
- Macaulay AC, Cross EJ, Delormier T, et al. Developing a Code of Research Ethics for research with a Native community in Canada: a report from the Kahnawake Schools Diabetes Prevention Project. *Int J Circumpolar Health.* 1998;57 Suppl 1:38-40.
- 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
- Strauss RP, Sengupta S, Quinn SC, Goepfinger J, Spaulding C, Kegeles SM, Millett G. The role of community advisory boards: involving communities in the informed consent process. *Am J Public Health.* 2001 Dec;91(12):1938-43.

Organizations with Supplementary Models of Protections:

- Kanhawake Schools Diabetes Prevention Project, Community Advisory Board: <http://www.ksdpp.org/whatcab.html>
- University of Pittsburgh Center for Minority Health, Community Research Advisory Board (CRAB): http://www.cmh.pitt.edu/research_crab.asp
 - CRAB guidelines: http://www.cmh.pitt.edu/pdf/crabguidelines_dates.pdf
- Yakima Valley Farm Workers' Clinic, Community Advisory Board: http://www.farmworkerhealth.org/newsletters/10934vol6_Newsletter.pdf
- Access Alliance: Multicultural Community Health Center: http://www.accessalliance.ca/index.php?option=com_content&task=view&id=37&Itemid=56
- University of California San Francisco, Positive Health Program Community Advisory Board: http://www.communityconsortium.org/about/about_cab.html
- HIV/AIDS research network community advisory boards: <http://www.thebody.com/content/policy/art4866.html>

Call # 3 – Community-Based Participatory Research (CBPR) Proposals and the Human Subjects Review Process: Methods for Working with University IRBs

Selected Articles on IRB Review and Community-based Participatory Research or Participatory Action Research:

- Flicker S, Travers R, Guta A, McDonald S, Meagher A. Ethical Dilemmas in Community-Based Participatory Research: Recommendations for Institutional Review Boards. *J Urban Health.* 2007 Apr 10.

- Khanlou N and Peter E. Participatory action research: considerations for ethical review. *Social Science & Medicine*. 2005; 60: 2333-2340.
- 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): 1914-1919.

Call # 2 – Highlighting the Importance of the Nonaffiliated (Community) IRB Member

Resources for Non-affiliated/Non-Scientific Community IRB Members:

- The Community IRB Member: Neighbor and Partner, U.S. Department of Energy website: <http://www.ornl.gov/communityirb/default.htm>. Join their listserv at: <http://www.ornl.gov/communityirb/listserv.htm>
- Research Ethics Training Curriculum for Community Representatives, Family Health International. Available at: <http://www.fhi.org/en/RH/Training/trainmat/ethicscurr/retccr.htm>
- Citizens for Responsible Care and Research’s listing of IRBs registered with the Office for Human Research Protections. Available at: <http://www.circare.org/info/researchbythenumbers1.htm>
- Research Advocacy Network is a non profit organization working to bring together all participants in the medical research process with the focus on education, support and connecting patient advocates with the research community to improve patient care. To learn more about the network and how to get involved, please visit: <http://www.researchadvocacy.org/about/index.php>

Recent Past Conferences and Presentations on Community IRB Members

- Public Responsibility in Medicine and Research (PRIM&R) pre-conference workshop in 2006 entitled, “What does It Mean to Represent the Community?” Description available at: http://www.primr.org/education/2006_HRPP/Community_Participation.pdf
- PRIM&R’s educational session on recruitment and retention of non-affiliated members. Available at: http://www.primr.org/education/2006_Webinar/overview_webinar06.htm
- Southeast Community Research Center & Tuskegee University Center for Bioethics in Research and Health Care presented a workshop in 2003 entitled, “Science By the People: Promoting Community Participation on Institutional Review Boards” Description available at: http://www.cbpr.org/index.php?option=com_content&task=view&id=18

Selected Articles on Community IRB Members:

- 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.
- De Vries R, Forsberg CP. Who decides? A look at ethics committee membership. *HEC Forum*. 2002 Sep;14(3):252-8.
- 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.

Regulations on IRB Membership:

- Code of Federal Regulations, 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/45cfr46.htm#46.107>

Call #1 - What is an Institutional Review Board (IRB) and What Purpose does it Serve?**Code of Federal Regulations:**

- Title 45 Public Welfare, Department of Health and Human Services, Part 46 Protection of Human Subjects: www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

Historical Events & Ethical Codes:

- Nuremberg Code: www.hhs.gov/ohrp/references/nurcode.htm
- Declaration of Helsinki: www.wma.net/e/policy/b3.htm
- U.S. Public Health Service Syphilis Study background: <http://www.tuskegee.edu/Global/story.asp?S=1207512>
- Belmont Report: <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>
- Washington, Harriet A. *Medical Apartheid: The Dark History of Medical Experimentation on Black Americans from Colonial Times to the Present*. New York: Doubleday, 2007.

Educational Materials & Resources on IRBs:

- Office for Human Research Protections IRB Guidebook: http://www.dhhs.gov/ohrp/irb/irb_guidebook.htm
- Public Responsibility in Medicine and Research (PRIM&R) offers a course called IRB 101sm: http://www.primr.org/education/2007_IRB_FUND/overview_FUND_0207.html
- Research Ethics and IRB Resources for Tribes and Researchers – by Aberdeen Area Tribal Chairmen’s Health Board: <http://www.aatchb.org/epi/docs/ResearchEthics.htm>
- IRB: Ethics & Human Research Journal Available at: <http://www.thehastingscenter.org/publications/irb/irb.asp>

Relevant Websites:

- Community-Campus Partnerships for Health (CCPH) Ethics & IRBs Links Page: <http://depts.washington.edu/ccph/links.html#Ethics>
- Department of Health and Human Services, Office of Human Research Protections: <http://www.dhhs.gov/ohrp/>
- Tuskegee University National Center for Bioethics in Research and Health Care: www.tuskegee.edu/bioethics
- Public Responsibility in Medicine and Research (PRIM&R): www.primr.org