

**INSTITUTIONAL REVIEW BOARD
NEW JERSEY DEPARTMENT OF HEALTH & SENIOR SERVICES**

MEETING AGENDA

10 January 2007

2:30 PM – 4:30 PM

Health & Agriculture Building, First Floor Boardroom

I. New Business

- A. Opening Remarks – Cynthia Kirchner, M.P.H., Senior Policy Advisor to the Commissioner
- B. Introductions
- C. Draft Membership Roster
- D. Monthly Meeting Schedule
- E. Recording of IRB meetings
- F. Discussion of IRB Chairperson
- G. Transition Process from UMDNJ IRB
- H. Presentation:
 - 1. History of Department's former IRB
 - 2. IRB Mission & Authority
 - 3. The Nuremberg Trial & Code
 - 4. The Declaration of Helsinki
 - 5. Henry Beecher's *Ethics & Clinical Research*
 - 6. The Tuskegee Syphilis Study
 - 7. Ethical Principles of The Belmont Report
 - 8. Determinations Required for IRB Approval (45 CFR Part 46.111)
- I. IRB Member Resource Binders:
 - 1. The Belmont Report
 - 2. Federal Regulations on the Protection of Human Subjects (45 CFR Part 46)
 - 3. Slide Presentation Handout
 - 4. Department's *Policy on the Protection of Human Research Subjects*
 - 5. HREP's *Guidance on Federal Certificates of Confidentiality*
 - 6. Emanuel, E., Wendler, D, Grady, C. (2000). What Makes Clinical Research Ethical? *Journal of the American Medical Association*. 283(20): 2701-2711
 - 7. Koocher, G. (2002). Using the CABLES Model to Assess and Minimize Risk in Research: Control Group Hazards. *Ethics & Behavior*. 12(1): 75-86

8. Wendler, D. Rackoff, J. (2001). Informed Consent and Respecting Autonomy: What's a Signature Got to Do with It? *IRB: Ethics & Human Research*. 23(3): 1-4
9. Wendler, D., Belseky, L., Thompson, K, Emanuel, E. (2005). Quantifying the Federal Minimal Risk Standard: Implications for Pediatric Research Without a Prospect of Direct Benefit. *Journal of the American Medical Association*. 294(7): 826-832
10. Dickert, N, Grady, C. (1999). What's the Price of a Research Subjects? Approaches to Payment for Research Participation. *New England Journal of Medicine*. 341(3): 198-202
11. Kipnis, K. (2001). Vulnerability in Research Subjects: A Bioethical Taxonomy. In: Ethical and Policy Issues in Research involving Human Participants: National Bioethics Advisory Commission.
12. Beskow, L., Sandler, R., Weinberger, M. (2006). Research Recruitment through Central Cancer Registries: Balancing Privacy and Scientific Issues. *American Journal of Public Health*. 96(11): 1920-1926
13. Botkin, J. (2001). Protecting the Privacy of Family Members in Survey and Pedigree Research. *Journal of the American Medical Association*. 285(2): 207-211
14. Beskow, L., Burker, W., Merz, J, et al. (2001). Informed Consent for Population-based Research involving Genetics. *Journal of the American Medical Association*. 286(18): 2315-2321
15. Beskow, L. Botkin, J., Daly, M., et al. (2004). Ethics Issues in Identifying and Recruiting Participants for Familial Genetic Research. *American Journal of Medical Genetics*. 130A: 424-431
16. Cooper, Z., Nelson, R., Ross, L. (2006). Informed Consent for Genetic Research Involving Pleiotropic Genes. *IRB: Ethics & Human Research*. 28(5): 1-10

J. Journal Club Proposal

II. Tentative Meeting Agenda:

A. February 2007:

1. Informed Consent Requirements (45 CFR Part 46.116(a-b))
2. Assent Requirements (45 CFR Part 46.408)
3. Waiver of Informed Consent & Assent (45 CFR Part 46.116(c-d))
4. Waiver of Documentation of Informed Consent & Assent (45 CFR Part 46.117(c))
5. Review Draft IRB Application [Will send prior to meeting, come with feedback.]
6. Review Draft IRB Reviewer Forms [Will send prior to meeting, come with feedback.]

B. March 2007:

1. Mock IRB Review
2. Overview of IRB E-Archive
3. Overview of IRB Website

C. April 2007:

1. Conduct Reviews of IRB Applications
2. Review Federal Regulations on Pregnant Women as Subjects (45 CFR Part 46.201-207)
3. Review Federal Regulations on Prisoners as Subjects (45 CFR Part 46.301-306)
4. Review Federal Regulations on Children as Subjects (45 CFR Part 46.401-409)