

***Stanford Center for Biomedical Ethics***

***Classic Readings in Bioethics* Seminar Syllabus**

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| **Session 1 - *Grimes vs. Kennedy Krieger Institute***Mastroianni, A. C., & Kahn, J. P. (2002). Risk and responsibility: ethics, Grimes v Kennedy Krieger, and public health research involving children*. American Journal of Public Health 92*(7):1073-1076.Buchanan, D. R., & Miller, F. G. (2006). Justice and fairness in the Kennedy Krieger Institute lead paint study: the ethics of public health research on less expensive, less effective interventions. *American Journal of Public Health 96*(5): 781-787.*Grimes vs. Kennedy Krieger Institute* <http://www.columbia.edu/itc/hs/pubhealth/p9740/readings/grimes-krieger.pdf> |
| **Session 2 - *Vulnerable Subjects*** |
| Kipnis, K., P. King, N. M., & Nelson, R. M. (2006). Response to Open Peer Commentaries on “An Open Letter to Institutional Review Boards Considering Northfield Laboratories' PolyHeme® Trial”: The Emergency Exception and Unproven/Unsatisfactory Treatment. *The American Journal of Bioethics*, *6*(3), W49-W50.Levine, C., Faden, R., Grady, C., Hammerschmidt, D., Eckenwiler, L., & Sugarman, J. (2004). The limitations of “vulnerability” as a protection for human research participants. *The American Journal of Bioethics*, *4*(3), 44-49.**Session 3 - *Emergency Research***Watters, D., Sayre, M. R., & Silbergleit, R. (2005). Research conditions that qualify for emergency exception from informed consent. *Academic emergency medicine*, *12*(11), 1040-1044.C. Holloway, K. F. (2006). Accidental communities: Race, emergency medicine, and the problem of PolyHeme®. *The American Journal of Bioethics*, *6*(3), 7-17.Kipnis, K., King, N. M., & Nelson, R. M. (2006). An open letter to institutional review boards considering Northfield Laboratories' PolyHeme® trial. *The American Journal of Bioethics*, *6*(3), 18-21.Magnus, David. (2006). Blood, Sweat and Tears. *The American Journal of Bioethics*, *6*(3), 1-2.Optional: Mann, H. (2006). How Confidential Trial Negotiations and Agreements between the Food and Drug Administration and Sponsors Marginalize Local Institutional Review Boards, and What to Do About It. *The American Journal of Bioethics*, *6*(3), 22-24. |
| **Session 4 - *Conflicts of Interest***Thompson, D. F. (1993). Understanding financial conflicts of interest. *New England Journal of Medicine*, *329*, 573-573.Rodwin, M. (2007). Physicians' conflicts of interest: the limitations of disclosure. *Available at SSRN 1012156*. AAMC.  (February 2008) Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research.  *[https://services.aamc.org/Publications/showfile.cfm?file=version107.pdf&prd\_id=220&prv\_id=268&pdf\_id=107](https://services.aamc.org/Publications/showfile.cfm?file=version107.pdf&prd_id=220&prv_id=268&pdf_id=107" \t "_blank)*. |
| **Session 5 – *Tuskegee***Jones, J. H. (2008). The Tuskegee syphilis experiment. *The Oxford textbook of clinical research ethics*, 1681.Brandt, A. M. (1978). Racism and research: the case of the Tuskegee syphilis study. *Hastings Center Report*, *8*(6), 21-29.Pence, G. E. (2007). “Chapter 9: Human Subjects: The Tuskegee Syphilis Study” in *Medical ethics: Accounts of the cases that shaped and define medical ethics.* |
| **Session 6 - *Moore vs. Regents of UC****Moore vs. Regents of UC****.*** (1990). [***http://law.justia.com/cases/california/cal3d/51/120.html***](http://law.justia.com/cases/california/cal3d/51/120.html)Lavoie, J. (1989). Ownership of human tissue: Life after Moore v. Regents of the University of California. *Virginia Law Review*, 1363-1396.Charo, R. A. (2006). Body of research—ownership and use of human tissue. *New England journal of medicine*, *355*(15), 1517-1519. |
| **Session 7 - *Placebo Controls***Hill, A. B. (1994). The continuing unethical use of placebo controls. *N Engl J Med*, *331*, 394-398.Emanuel, E. (2001). THE ETHICS OF PLACEBO-CONTROLLED TRIALS—AMiddle GROUND. *N Engl J Med*, *345*(12).Beecher, H.K. (1966). Ethics and clinical research. *N Engl J Med*, 274: 1354–1360. |
| **Session 8 - *45 CFR 46****45 CFR 46.*[***http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html***](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html)Moreno, J., Caplan, A. L., & Wolpe, P. R. (1998). Updating protections for human subjects involved in research. *JAMA: the journal of the American Medical Association*, *280*(22), 1951-1958.Beecher, H. K. (1966). Consent in clinical experimentation: myth and reality. *JAMA: the journal of the American Medical Association*, *195*(1), 34-35.Emanuel, E. J., Wendler, D., & Grady, C. (2000). What makes clinical research ethical?. *JAMA: the journal of the American Medical Association*, *283*(20), 2701-2711. |
| **Session 9 - *Tarasoff vs. Regents of UC****Tarasoff vs. Regents of UC.* [*http://www.stanford.edu/group/psylawseminar/Tarsoff%20I.htm*](http://www.stanford.edu/group/psylawseminar/Tarsoff%20I.htm)Appelbaum, P. S. (1985). Tarasoff and the clinician: Problems in fulfilling the duty to protect. *The American journal of psychiatry*.Appelbaum, P. S., & Rosenbaum, A. (1989). Tarasoff and the researcher. *American Psychologist*, *44*, 219-228. |
| **Session 10 – *Autoexperimentation***Jonas, H. (1969). Philosophical reflections on experimenting with human subjects. *Daedalus*, *98*(2), 219-247.Caplan, A. L. (1984). Is there a duty to serve as a subject in biomedical research?. *IRB: Ethics and Human Research*, *6*(5), 1-5. |
| **Session 11 - *Innovative Research***McKneally, M. F., & Daar, A. S. (2003). Introducing new technologies: protecting subjects of surgical innovation and research. *World journal of surgery*, *27*(8), 930-934.Eaton, M. L., & Kennedy, D. (2007). *Innovation in medical technology: Ethical issues and challenges*. JHU Press. |
| **Session 12 - *Undue Inducement***Emanuel, E. J. (2005). Undue inducement: Nonsense on stilts?. *The American Journal of Bioethics*, *5*(5), 9-13.Grady, C. (2001). Money for research participation: does it jeopardize informed consent?. *American Journal of Bioethics*, *1*(2), 40-44.Open Peer Commentaries to C. Grady’s 2010 Paper: <http://cirge.stanford.edu/Jun%2020%20-%20Undue%20inducement/Grady%20Money%20Open%20Peer%20Commentary.pdf>  |
| **Session 13 - *Therapeutic Misconception***Appelbaum, P. S., Roth, L. H., & Lidz, C. (1982). The therapeutic misconception: informed consent in psychiatric research. *Int J Law Psychiatry*, *5*(3-4), 319-329.Henderson, G. E., Churchill, L. R., Davis, A. M., Easter, M. M., Grady, C., et al. (2007). Clinical trials and medical care: defining the therapeutic misconception. *PLoS medicine*, *4*(11), e324. |
| **Session 14 - *Gelsinger v. University of Pennsylvania***Steinbrook, R. (2008). The Gelsinger case. *The Oxford Textbook of Clinical Research Ethics*, 110-120.Walters, L. (2000). The oversight of human gene transfer research. *Kennedy Institute of Ethics Journal*, *10*(2), 171-174. |
| **Session 15 - *Incidental Findings***Ravitsky, V., & Wilfond, B. S. (2006). Disclosing individual genetic results to research participants. *The American Journal of Bioethics*, *6*(6), 8-17.Wolf, S. M., Lawrenz, F. P., Nelson, C. A., Kahn, J. P., Cho, M. K., Clayton, E. W. et al. (2008). Managing incidental findings in human subjects research: analysis and recommendations. *The Journal of law, medicine & ethics*, *36*(2), 219-248. |
| **Session 16 – *Equipoise***Freedman, B. (1987). *Equipoise and the ethics of clinical research*. Massachusetts Medical Society.Miller, F. G., & Brody, H. (2003). A critique of clinical equipoise: therapeutic misconception in the ethics of clinical trials. *Hastings Center Report*, *33*(3), 19-28. |
| **Session 17 - *Informed Consent***Faden, R. R., Beauchamp, T. L., & King, N. M. (1986). *A history and theory of informed consent*. Oxford University Press on Demand.Robinson III, S. W. (1988). Opinion in Canterbury v. Spence. *US Court of Appeals, District of Columbia Circuit*, *464*. |
| **Session 18 - *Declaration of Helsinki***Declaration of Helsinki. <http://www.wma.net/en/20activities/10ethics/10helsinki/> Kimmelman, J., Weijer, C., & Meslin, E. M. (2009). Helsinki discords: FDA, ethics, and international drug trials. *The Lancet*, *373*(9657), 13-14.Rid, A., & Schmidt, H. (2010). The 2008 Declaration of Helsinki—First among Equals in Research Ethics?. *The Journal of Law, Medicine & Ethics*, *38*(1), 143-148. |
| **Session 19 - *Forensics*** |
| Greely, H. T., Riordan, D. P., Garrison, N. A., & Mountain, J. L. (2006). Family ties: the use of DNA offender databases to catch offenders' kin. *The Journal Of Law, Medicine & Ethics*, *34*(2), 248-262Cho, M. K., & Sankar, P. (2004). Forensic genetics and ethical, legal and social implications beyond the clinic. *Nature genetics*, *36*, S8-S12.Ossorio, P., & Duster, T. (2005). Race and genetics: controversies in biomedical, behavioral, and forensic sciences. *American Psychologist*, *60*(1), 115.**Session 20 – Part 1: *US Dept of Energy Radiation Experiments*** Advisory Committee on Human Radiation Experiments Final Report, (1995). **Part 2: *Willowbrook State School Hepatitis Studies*** |

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Stephen Goldby, Saul Krugman, M. H. Pappworth, and Geoffrey Edsall. 1971. “The Willowbrook Letters.” *The Lancet.* <http://philosophy.tamucc.edu/readings/ethics/willowbrook-letters>

Robinson, W. M., & Unruh, B. T. (2008). The Hepatitis Experiments at the Willowbrook State School. *The Oxford Textbook of Clinical Research Ethics*, 80.