

Readings

for

"Social, Ethical and Legal Considerations for
Cardiovascular Research"

A Research Ethics Course
of the
Cardiovascular Research Ethics Program
(CADRE)

(NIH, National Heart, Lung, and Blood Institute Grant No.
HL075759)

The enclosed readings are provided primarily as background material related to faculty presentations in the course. Completion of the readings is not required in advance of the course. Please note that *paper* copies of the enclosed readings will not be distributed at the course, so registered course participants are encouraged to read these materials online, or to print out copies at their convenience. Course faculty may distribute additional materials or late reading materials on-site.

The enclosed readings include the following:

Faculty Presenter	Course Topic	Background Reading	starts page no.*
Vanderpool	<i>Module 1: Overview of research ethics</i>	The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research (also available at http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm)	1
Carter	<i>Module 2: Data and safety monitoring for cardiovascular research</i>	Brass, E.P. 2001. Implementation of a data and safety monitoring program in a General Clinical Research Center. <i>Journal of Investigative Medicine</i> 49(6): 479-485.	13
Doukas	<i>Module 3: Medical directives in cardiovascular research</i>	Crane, M.K., and Wittink, M. 2005. Respecting end-of-life treatment preferences. <i>American Family Physician</i> 72(7): 1263-1268.	20
		King, S.B. <i>et al.</i> 1998. Task Force 2: Application of medical and surgical interventions near the end of life. <i>Journal of the American College of Cardiology</i> 31(5): 933-942.	26
Hornung	<i>Module 4: Study endpoints and statistical analysis in cardiovascular disease research</i>	No readings	--
Morreim	<i>Module 5: Conflicts of interest in cardiovascular research</i>	Martinson, B.C. <i>et al.</i> 2005. Scientists behaving badly. <i>Nature</i> 435(7043): 737-738.	36
		Armstrong, D. 2005. Delicate operation: How a famed hospital invests in device it uses and promotes. <i>The Wall Street Journal Online</i>	38

* refer to center pagination on each page

		(http://online.wsj.com/article_print/SB113435097142119825.html).	
		Mathews, A.W. 2005. Ghost story: At medical journals, writers paid by industry play big role. The Wall Street Journal Online http://online.wsj.com/article_print/SB113443606745420770.html).	43
Heitman	<i>Module 6: The History of the Concept of Race in Medicine and its Role in Cardiovascular Research</i>	Heitman E, Wells AL. 2004. Ethical issues and unethical conduct: Race, racism, and the abuse of human subjects in research. In B Beech, V Setlow, & MF Goodman (eds). Race and research: Perspectives on minority participation in health studies. Washington, DC: American Public Health Association.	48
Stone	<i>Module 7: Bench to bedside: moving cardiovascular research to a community standard of care: the case of stroke</i>	Hurwitz, B. 1999. Clinical guidelines: Legal and political considerations of clinical practice guidelines. BMJ 318: 661-664.	61