

**Description:**

Given the existing regulatory structure and focus on continuing education in ethical research practices, the likelihood of demonstrating responsible conduct in research should be greatly improved. In practice, numerous challenges occur when conducting research that may compromise the process. This session will highlight challenges in human subjects research with an emphasis on application of the ethical principles of respect, beneficence and justice described within the [Belmont Report](#). In addition, participants will receive an overview of the [federal regulations](#) for human research protections and gain a better understanding of the roles and responsibilities of stakeholders in the research process (participant, community, researcher, IRB, regulatory agencies). A case study will be used to discuss controversial research practices from the perspective of the regulations, IRB, investigator, and participant.

**Objectives:**

- 1) Historical background
- 2) Federal Regulations
- 3) Ethical Principles
- 4) Stakeholder Roles/Responsibilities
- 5) Evaluating ethical challenges – PolyHeme Case

**PolyHeme Blood Substitute Clinical Trial:** In 2003, a multi-site study to test a new blood substitute was approved by the FDA to be conducted in several major U.S. cities, including San Diego, CA. The purpose of the study is to determine if the blood substitute is superior to saline in the field and superior to typed-matched blood in the hospital which is routinely given to individuals suffering from severe bleeding. This blood substitute is carried in ambulances or Life-flight helicopters in areas of the city that have the highest trauma rates – which includes a disproportionate number of individuals from socially and economically disadvantaged neighborhoods. Adult victims are randomly assigned to either saline or the blood substitute. Those who are on saline receive type-matched blood as soon as possible after arriving to the hospital. Those assigned to receive the blood substitute continue to receive this substitute after arriving at the hospital for up to 12 hours (or 6 units) before receiving type-matched blood. The requirement for informed consent was waived for this study through an application of the regulations for research involving emergency treatment. Individuals who live in the study catchment area must wear a specially issued bracelet if they wish to opt out of the study.

**Study Sponsor URL:** [http://www.northfieldlabs.com/amb\\_trial.html](http://www.northfieldlabs.com/amb_trial.html)

**Study Information:** <http://www.clinicaltrials.gov/ct/show/NCT00076648?order=1>

**Letter:** Kipnes, K., N. King, and R.M. Nelson, 2006. "An Open Letter to IRBs Considering Northfield Laboratories' PolyHeme Trial." *The American Journal of Bioethics*, 6(3): 1-4.

**Editorial:** Magnus, D., 2006. "Blood, Sweat and Tears." *The American Journal of Bioethics*, 6(3): 1-4.

**Article:** Moore, E.E., Frederick A. Moore, Timothy C. Fabian, Andrew C. Bernard, Gerard J. Fulda, David B. Hoyt, Therese M. Duane, Leonard J. Weireter Jr, Gerardo A. Gomez, Mark D. Cipolle, George H. Rodman Jr, Mark A. Malangoni, George A. Hides, Laurel A. Omert, Steven A. Gould and PolyHeme Study Group. "Human Polymerized Hemoglobin for the Treatment of Hemorrhagic Shock when Blood is Unavailable: The USA Multi-center Trial." *Journal of the American College of Surgeons*, Volume 208, Issue 1, January 2009, Pages 1-13

**Symposium:** Bioethics in Scientific Research: Conflicts between Subject's Equitable Access to Participate in Research and Current Regulation. *Informed Consent in the Context of Communities*, Jeffrey Kahn  
<http://jn.nutrition.org/cgi/content/full/135/4/918>

**Public Media:** "Fake Blood, Real Controversy. An artificial blood product, possibly better than the real stuff, may land in your body without your permission. Not surprisingly, watchdogs are barking." By Randy Dotinga.  
[http://www.wired.com/news/medtech/0,1286,62955,00.html?tw=wn\\_story\\_mailer](http://www.wired.com/news/medtech/0,1286,62955,00.html?tw=wn_story_mailer)

**Informed Consent Regulations:**

Federal Regulations (45 CFR 46.116) on the informed consent process and documentation.

(<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116>).

21 CFR 50.24 FDA exception from informed consent requirements for emergency research

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm>