



## **Implementation and Outcomes of a Research Ethics Education Program for Cardiovascular Investigators**

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Topic: Special Populations

Alternative Topic: Research Ethics Education

### **Problem/Issue Statement**

Human subjects protection education that is tailored to specialized researchers and suited to their particular interests or research context may serve to improve their ability at addressing human subject protection issues that arise in their practice. However, there is a dearth of literature that describes specialized human subjects protection education, including issues related to development, delivery or evaluation. In 2004 we conducted a needs assessment among scientific members of a large health professional society with interests in cardiovascular health to determine their need for and interest in human subjects protection education, and preferred educational delivery method. Our study demonstrated significantly greater interest in some human subject protections topic compared to others, and that some interest differed by respondents' professional affiliation or training. Subsequently, we used data from our needs assessment to develop a program of research ethics training for cardiovascular investigators, which was subsequently funded by NIH through 2010.

### **Description of Program**

Our program consisted of fifteen educational modules on different topics, including, for example, statistical analysis, emergency research, subject advocacy, pediatric research, genetic research, and subject recruitment. Each module included reading materials distributed online, a didactic presentation, a related case study for discussion and problem-solving, and handouts. Topics were contextualized to cardiovascular research, but framing principles are widely applicable. For each course, course and speaker evaluations were collected, and a debriefing session conducted. Our intended outcome was a transportable, modular program of research ethics education that met the expressed needs of prospective constituents comprised of cardiovascular researchers and others (e.g., IRB members) with interests in cardiovascular research ethics and human subjects protection.

To date, eight courses each consisting of up to six modules have been delivered across the U.S., held on or near to major centers of cardiovascular research. Through our debriefings as well as evaluations, course participants expressed a high degree of satisfaction with our educational content, our delivery methods, and having met our educational objectives. Our methods and instruments are easily replicated by others who are interested in developing specialized educational programs in human subjects protection. Our educational materials are currently being prepared for online dissemination at no cost to end-users.

### **Additional Information**

The goals of the proposed session are to (1) improve understanding of the challenges of human subject protection education environment for cardiovascular investigators; (2) describe development, evaluation, and instructional methodology of a cardiovascular disease research ethics educational program; and (3)



provide an opportunity for sharing human subject protection education ideas and discussing related issues.