

PROBLEMS FACING RESEARCHERS IN
SELF-CARE: INFORMED CONSENT AND THE
AFFECTIVE DOMAIN

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ABSTRACT

Studies involving children in self-care activities are likely to be met with negative “reflexive responses” by parents. This may be true even when children have demonstrated competencies in making decisions about caring for themselves. The affective domain often colors adults’ responses to self-care studies for children.

One of the issues that anyone who proposes research in “self-care” must overcome is the possible attitudinal biases of members of an Institutional Review Board—that is—those who serve on a Human Subjects Protection Committee (HSPC). Members of HSPC’s are mandated by the federal government to protect subjects involved in most types of research from deception, or unanticipated adverse reactions leading to physical or psychological injury. The individuals who perform these thankless jobs are scientists, who are peers, as well as members of the lay community. While most members of HSPC discharge their reviews of requests for approval totally objectively, occasionally there is an aspect of a proposal that “grabs” a scientist in his/her affective domain, and presents a barrier to approval.

We said “most” types of research require review because there are types of studies in which informed consent is not required. These do not relate to the source of funds (government/private) or size of the endeavor; they relate to the

degree to which subject's identification can be linked to data about them. Thus, analysis of existing data sets in which the identity of subjects is unknown, surveys in which respondents are not personally identified, and educational research on groups are exempt from informed consent. However, with the passage of time (and presumably litigation), the consent forms that subjects must sign get longer, and the exemptions fewer.

In addition to anticipating how to protect subjects in the study from injury, a more difficult and less visible problem for researchers submitting an application related to the practice of self-care, especially by children, is addressing the personal attitudes/beliefs of members of HSPC committees. Some adults have difficulty trusting children's judgment, regardless of their stage of cognitive development. Thus, they use a protective device known as denial, when confronted with the competence of children. Recently, Hillary Clinton spoke eloquently of the competency of children which is somewhat easier for adults to deal with if the children are not their own.

In 1984, we published the results of a randomized trial of a self-care educational program for children seven to twelve years old and their parents (Lewis et al., 1984). In this program, "A.C.T. (Asthma Care Training) for Kids," which is disseminated by the Asthma and Allergy Foundation of America, children learn to recognize symptoms of asthma at an early stage, use peak flow meters to document the presence of bronchospasm, and with their parent's prior consent, take appropriate medications as prescribed by their physicians. Asthma aggravators, symptoms, and medications are labeled/coded using a traffic light analogy: Red (stop), Yellow (slow down), and Green (go). The study was quite successful! The intervention significantly reduced the utilization of emergency care of children in the treatment group. It saved Kaiser Permanente-Sunset in Los Angeles, California, the site of the intervention trial, over \$400 per child per year (the program at Kaiser Permanente-Sunset continues to be offered to children and their families 13 years later).

Although the outcomes for the self-care program "A.C.T. for Kids" was successful, it took almost as long to obtain clearance from the UCLA Medical Human Subjects Committee, as it did to conduct the study. It was subsequently learned that the Chair of that committee, a well-respected Professor of Pharmacology, had a child with asthma. He was convinced that the "A.C.T. for Kids" Program would place children at risk for medication overdoses due to their lack of competency.

Fortunately "Act for Kids" has been used throughout the world for over ten years without difficulty. It has also been adapted for Spanish-speaking children (Lewis et al., 1994), and with this version as well, there has been no evidence of the adverse consequences that were predicted earlier.

The moral of this story is: self-care is loaded with values—don't presume everyone will act rationally when asked to comment on it.

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