

The CABLES Model

Assessing and Minimizing Risk in Research

Abstract:

CABLES is both an acronym and metaphor for conceptualizing research participation risk by considering 6 distinct domains in which risks of harm to research participants may exist: cognitive, affective, biological, legal, economic, and social/cultural. These domains are described and illustrated, along with suggestions for minimizing or eliminating the potential hazards to human participants in biomedical and behavioral science research. Adoption of a thoughtful ethical analysis addressing all 6 CABLES strands in designing research provides a strong protective step toward safeguarding and promoting the well-being of study participants. (Koocher, 2002)

The CABLES Model

COGNITIVE RISKS

are threats to the participant's intellectual functioning, learning, academic achievement, and the underpinnings of self-esteem.

Examples of research in this category might include comparative analyses of teaching strategies, remediation of learning disabilities, or problem-solving tasks.

AFFECTIVE and EMOTIONAL RISKS

are the hazards of emotional distress both during and following participation in the research.

Risks of participation can reveal sides of oneself that they would rather not see. Emotional risks may occur in research tests, where the treatment may seem worse than the symptoms to some participants. Some participants in placebo control trials where they are not in an intervention, or on a waiting list because they are not symptomatic, may lead to experience distress or give up hope while waiting.

They may also be inherent in studies that involve collection of sensitive data; such studies may not be fully prepared to deal with the consequences of testing positive for something.

Such discoveries can have legal risks (e.g., liability and discrimination claims) and economic hazards as well (e.g., loss of employment, inability to obtain insurance). An example would be if one is found not eligible for a potentially lifesaving clinical trial, or guilt distress if genetic testing reveals that one individual is unaffected by a gene that is present in other of their family members.

BIOLOGICAL RISKS

refer to the hazards of physical injury or illness as a result of delayed, ineffective, or absent treatment, as a direct or side effect of the intervention, or as a result of investigator negligence.

A good example of control-group risk potential occurred 20 years ago. A research model suggested that a briefer 12- to 18- month course of noxious chemotherapy might be as effective as the lengthy standard course of 36 months, in treating a form of bone cancer. A randomized clinical trial was deemed necessary; however, there was some risk that the shorter course of treatment might result in early relapse by a chemotherapy-resistant tumor cell line.

LEGAL RISKS

might include adverse consequences, such as disclosure of sensitive identifiable confidential information, mandated reporting of abuse or neglect, or even litigation begun as the result of self-discoveries made in the course of one's participation in research).

A number of sensitive areas of medical research, such as including people infected with HIV/AIDS and predictive genetic testing, may lead to significant legal risks. Psychosocial research in areas such as child neglect or abuse, child or caregiver substance abuse, and domestic violence can pose similar risk, especially if confidentiality and data access are inadequately protected.

Source: Koocher, G. P. (2002). Using the CABLES Model to Assess and Minimize Risk in Research: Control Group Hazards. *Ethics & Behavior*, 12, 75-86.

ECONOMIC RISKS

are actual financial hazards associated with actual incurred costs (e.g., transportation to experimenter's laboratory) or lost opportunity costs (e.g., time and revenue lost from paid employment to enable participation), and remediation of iatrogenic or damages associated with participation in the research.

This may involve people suffering from symptoms of depression or anxiety who are recruited into a drug study, and may already have difficulty as a result of their symptoms. Participants may be asked to take off time from work, arrange child care, pay their own transportation costs, and attend sessions that contain no active treatment components. Economic inducements may also raise ethical economic issues.

SOCIAL and CULTURAL RISKS

Are risks resulting in social rejection or stigmatization(AIDS, genetic disorders). All too often, investigators fail to consider special factors related to race, culture, or ethnicity that may complicate the validity of their research or adequately respect the participants.

Even relatively benign studies can lead to a degree of stigmatization, with some members of a group excluded based on study criteria while their friends/ classmates are included. Such research often fails to consider the potential consequences of being labeled in this category, especially when the participant at risk becomes known as such to others and assigned to a control group that offers no direct benefit.