Ethical Considerations in Research Studies

In every study, authors are required to report on the ethical considerations of their research. Most readers determine if the study was approved by a review board and if there was participant consent. Readers should understand these two important issues, but they also should be aware of other ethical considerations when reviewing a research article. In this column, I will give an overview of the ethical considerations readers should consider.

Institutional Review Boards

The purpose of an institutional review board (IRB) review is to protect human subjects; there are also procedures for protecting animals used in research. Most of these boards are called IRBs, but they can have other names (U.S. Department of Health & Human Services [HHS], 2009). Review of proposals prior to beginning research and ongoing oversight are requirements for all institutions receiving federal funding. The main purpose of the IRB is to protect human subjects by weighing any possible harm against any benefit. Members also are responsible to ensure study participation is voluntary and potential subjects have all the information they need to make an informed decision concerning study participation. IRBs include at least five members, usually a diverse group of individuals knowledgeable about research and also about protecting subjects. In addition, at least one member is external to the institution. In addition, the ongoing monitoring of research includes any complications that occur due to research (Blessing & Niebuhr, 2008).

Consent

Informed consent is an essential part of the research process, and the consent form is reviewed by the IRB. In some cases, such as with surveys, consent may be implied if participants complete the survey. Nonetheless, information about the conduct of the study is shared with the participants, often as part of the survey instructions. Consent consists of the following: consent should be given freely (voluntary), subjects should understand what is being asked of them, and involved persons must be competent to consent. Disclosure of any alternatives to treatment must be provided. Subjects have the right to withdraw from the research at any time. Particular care is required of vulnerable people, such as children, older adults, and prisoners (Fouka & Mantzorou, 2011). For children, parents provide consent; however, the child, if old enough, assents (or not) to be involved (Polit & Beck, 2014).

Other Ethical Considerations

Researchers

Investigators should be competent to conduct the research. If the study is complex, a team of researchers with various expertise and competence may be necessary. Usually this is not outlined in the text of the article, but it can be assessed by reviewing information about the authors (e.g., their credentials and organizational affiliation). Researchers also must be culturally competent to conduct research with diverse groups (Papadopoulos & Lees, 2002). If the research involves clinical nurses who will collect data or are involved in patient recruitment, approval from nursing management should be obtained and staff education described.

Another ethical issue may stem from researchers’ multiple roles, such as clinician and researcher. In these cases, usually a separate individual will recruit patients to decrease the likelihood they will feel coerced into participation. This situation must be handled carefully and reported honestly (Smith, 2003).

Any conflicts of interest should be reported, such as in the conflict of interest statement in the study by Oermann, Kardong-Erdgren, Odom-Maryon, and Roberts (2014) in this issue. The statement is located on the first page of the article under the listing of the authors, their credentials, and affiliations. This statement is written clearly as to what was involved and how the conflict was addressed ethically in the study.

Recruitment

In addition to consent, recruiting methods for the study must not use coercion. Potential subjects should not believe they have to participate in the research because a physician or nurse asked them to be involved. Researchers should make it clear that people can refuse to participate without any adverse effect on their care or education. In an article, it should be clear how potential subjects were approached; if incentives were given, they

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should not be excessive. An excessive incentive can be a form of coercion for some people (Polit & Beck, 2014).

Another important aspect of subject recruitment is the need for fairness. Information about risks, benefits, and burdens of the research should be distributed fairly with no discrimination based on sex, ethnicity, or other factors. No one group of people should be exclusively included or excluded from the research unless there is a valid scientific reason to do so and it is described in the article (HHS, 2009).

**Research Procedures**

Research procedures need to be developed carefully and deception generally should be avoided. On rare occasions, deception may be necessary to conduct research, but this must be justified fully and reported clearly. Possible harm to patients should be minimized and explained fully to them. Research procedures should not create an excessive burden for patients. Research data should be kept confidential and protected. In research reports, procedures should be outlined concisely but clearly so readers know any harm was minimized or subjects were informed fully of the possibility of harm (Drew, Hardman, & Hosp, 2008).

**Open and Honest Reporting**

Research reporting should be clear and honest, without deception to readers. This is one reason that research reports are peer reviewed prior to publication. However, readers should review the report for vagueness that may suggest a problem. For example, data and statistics should be reported clearly. In addition, information needed to interpret them should be included. In addition, negative results should be reported rather than omitted. Researchers should not report conclusions not supported by the data (Marco & Larkin, 2000). This is represented clearly in the study by Oermann and colleagues (2014) in this issue. Data are reported thoroughly throughout the findings section, with a table of data also included. In addition, researchers were clear which parts of their findings were statistically significant and which were not. In qualitative research, quotations should be used honestly and clearly to support the researcher’s interpretation of the categories and themes, such as in the article in this issue by Barrere and Durkin (2014).

To protect research subjects, information about subjects generally is reported in the aggregate for quantitative research. In qualitative research, pseudonyms generally are used. If the group that is studied is a small well-known group, researchers should take care to protect their identity (Polit & Beck, 2014).

In this column, I cannot address all ethical considerations involved in the conduct of research and many other issues are difficult to discern from a report. When writing a proposal for research, researchers should be knowledgeable about many ethical aspects of research; institutions usually require training in ethical standards for research. If more information is needed, the references and other readings can be reviewed. In addition, the members of the IRB can be a good resource. 

**REFERENCES**


