Ethics of Clinical Research

The profession of occupational therapy is experiencing a growth in the amount and type of research being executed to expand its knowledge base. The initiation and funding of numerous research projects by the American Occupational Therapy Foundation and the American Occupational Therapy Association and the continued success of the Research Forum at the Association’s Annual Conference are clear signs of the surge in occupational therapy research.

A significant and necessary part of that research is clinical in nature. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research defines clinical research as any clinical action executed with the primary intent of creating generalizable knowledge (1); that is, the performance and systematic study of any clinical technique or intervention in an effort to support or discover its therapeutic effectiveness constitutes clinical research.

The novice to clinical research may, in his or her zeal and naiveté, overlook ethical considerations that are morally and legally mandated. This article discusses major ethical considerations that must characterize all sound research. A more in-depth knowledge of ethics in research may be gained by referring to the list of related readings.

Clinical Research Regulations

Numerous codes of ethics exist to provide guidelines for the performance of clinical research, for example, the ethical codes of the American Medical Association (AMA) and the American Psychological Association (APA). In addition, the Department of Health and Human Services provides regulations that are used in many facilities as a guide for clinical research. These regulations require that an institutional review board, made up of experts in the field, review the proposed research to determine the possible risks and benefits of the research procedures. Based on that review, the board can recommend approval or disapproval of the research project (2).

These regulations also require that all participants (subjects) in the research provide informed consent; that is, any competent subject must be notified as much as possible of the details, risks, and benefits to self and society of his or her participation in the research. In the case of incompetent subjects, informed consent must be obtained from those persons’ guardians (2, 3, 4). These signed informed consents must be kept by the researcher as evidence of the subjects’ voluntary participation in the study (3).

Denial of Treatment

Random clinical trials are necessary for the development of effective and safe therapy (2). This characteristic of research design allows for statistical comparisons of the effectiveness of the clinical procedure being studied. However, every effort must be taken to ensure that subjects are not denied possible beneficial therapy or randomized to an inferior therapeutic procedure. Hence, the researcher must be certain to design the study to avoid such ethical wrongdoing. For the novice researcher it is important to seek guidance from an experienced colleague for it is imperative that no harm befall any patient participating in a research program.

Right to Privacy

The right to privacy refers to the subject’s right to prevent researcher access to certain information about himself or herself. Such information could be one’s religious preference, one’s feelings toward certain others, and so forth. Researchers must take into consideration this right and take steps to ensure that this right is respected. Further, the researcher must always realize that subjects have the right to withdraw from participation at any time without reprimand if they are so inclined (3). The solicitation of information considered too personal by the subject may precipitate such a withdrawal.

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**Right to Anonymity**

Subjects have the right to remain anonymous; that is, they have the right to require that their personal identities not be a feature of the research. To ensure anonymity, the researcher may report data as groups or averages. Also, subjects may be identified by a number rather than by name.

**Right to Confidentiality**

Subjects have the right to expect that information obtained about them be used only for the expressed purposes of the study and not for other purposes. To ensure confidentiality, data can be listed by number rather than by name; it is also recommended that original test protocols be destroyed at the completion of the study (4).

**Researchers’ Rights**

It is the ethical task of any researcher to credit fully and respect the integrity of other researchers’ works contributing to the study. Hence, any reports made of a study must credit the contributions of that study’s predecessors. A researcher must respect the copyright laws governing the reproduction and use of any tests or evaluations that may be involved in the research. Finally, if a researcher wishes to modify an existing evaluation, he or she must obtain permission of the necessary persons to do so. Numerous evaluations exist in occupational therapy that have not been copyrighted. It is professionally and ethically required that the researcher obtain permission from the authors of the tests before modifying them for the purposes of research.

**Summary**

The clinical researcher has certain obligations to subjects and theorists associated with the research being proposed. This article has identified some of the major ethical considerations that characterize “good” research. The related readings will give more information regarding ethics of clinical research.

**REFERENCES**


**RELATED READINGS**


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**Correction**

In the March 1985 issue of *AJOT*, an editing error was made in a sentence on page 203 of the article entitled “Ritual, Rigor, and Relevance: The Design of Clinical Research” by Kenneth J. Ottenbacher, PhD, OTR. As published, the sentence read, “Studies that can approximate the strict requirements of true experiments are often not representative of everyday clinical practice or do not provide statistical information on the average performance of individuals in a group.” The correct sentence should read, “Studies that are able to approximate the strict requirements of true experiments are often not representative of everyday clinical practice or provide statistical information on the average performance of individuals in a group but little information directly relevant to the therapist treating a specific patient.”

In addition, as a result of a flaw in the editorial policy for The Foundation page, this article was printed without Dr. Ottenbacher’s final review and approval of editorial changes. This policy has now been changed.