

<p><u>Information Sheet</u></p> <p>Guidelines for Avoiding Use of the Term “Experiment(al)” in Human Subject Research</p>	<p>Advocate Health Care Institutional Review Board</p> <p>205 W. Touhy, Suite 203, Park Ridge, IL 60068-4202 Voice: 847-384-3534; Fax: 847-384-3537 E-Mail: IRBMail@AdvocateHealth.com</p>
Version: 1.0; Date: October 2006	

The Advocate Health Care Institutional Review Board (AHC IRB) office is presenting the following guidelines to provide clarification on the usage of terms “experimental” and “investigational” in human subject research.

NOTE

A person who participates in a research study is called a “subject.”

“**Investigational** is the term used by the FDA for test articles that have not yet been approved for marketing” (Amdur and Speers, p. 119). “Although research on human subjects may have a study design that involves an experiment, the meaning of the term **experimental** in the context of a discussion of research standards is so unclear that it usually serves to confuse rather than enlighten the reader. Some experts consider **experimental** to be unacceptable terminology” (Amdur and Speers, p. 120). (See also RJ Levine, Ethics and Regulation of Clinical Research, Edition 2. Baltimore, MD: Urban and Schwarzenberg, 1986).

“The Belmont Report provides an authoritative and articulate explanation of the boundaries between practice and research” (Amdur and Speers, p. 120). National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, The Belmont Report: Ethical Principles and Guidelines of the Protection of Human Subjects of Research (DHEW Publication No. (OS) 78-0012, 18 April 1979):

. . . The distinction between research and practice is blurred partly because both often occur together (as in research designed to evaluate a therapy) and partly because notable departures from standard practice are often called experimental when the terms experimental and research are not carefully defined.

. . . When a clinician departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research. The fact that a procedure is experimental, in the sense of new, untested, or different, does not automatically place it in the category of research. Radically new procedures of this description should, however, be made the object of formal research at an early stage in order to determine whether they are safe and effective. Thus, it is the responsibility of medical practice committees, for example, to insist that a major innovation be incorporated into a formal research protocol.

Example

Dr. Vincent is treating Mr. Casey for high blood pressure. The standard dose of medication seems to have no effect on Mr. Casey. Dr. Vincent has good reason to believe that Mr. Casey has atypical physiology so he increases the dosage above standard of care and combines it with another medication not typically prescribed for high blood pressure. This is an **experiment**, but it is not **investigational** since it is not Dr. Vincent’s intent to generalize the outcome; his sole intent is to enhance Mr. Casey’s wellbeing. If Dr. Vincent noticed that several patients’ conditions parallel Mr. Casey’s, thus raising the question of whether a new standard of care should be developed, he is seeking generalizable knowledge. What began as an **experiment** has now become **investigational**, and Dr. Vincent should write a research plan and proceed accordingly.

References

- ▶ RJ Amdur and MA Speers, “Identifying Research Intent,” in *Institutional Review Board Management and Function*, eds. R Amdur and E Bankert, (Jones and Bartlett: Sudbury, MA, 2002), pp. 118-124.
- ▶ RJ Levine, “Ethics and Regulation of Clinical Research, Edition.” (Baltimore, MD: Urban and Schwarzenberg, 1986).
- ▶ National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research: *The Belmont Report: Ethical Principles and Guidelines of the Protection of Human Subjects of Research* (DHEW Publication No. (OS) 78-0012, 18 April 1979); <http://ohsr.od.nih.gov/guidelines/belmont.html>.