Dynamic Chiropractic

PERSONAL INJURY / LEGAL

The Protection of Research Subjects

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At the December 1989 meeting in Los Angeles, a motion was unanimously approved by members of the "Pacific" Consortium for Chiropractic Research to officially adopt the Helsinki/NIH regulations regarding protection of human subjects. These regulations, also endorsed by the World Health Organization, most governments, funding agencies, hospitals, educational and research institutions in the world, document in detail all the various ways that human rights should be protected within the context of research.

Most people are surprised to learn that these regulations do not actually prohibit any particular experimental treatments. There are several pages of specific protections, but most of them are variations on the theme of disclosure, either to the subject for the purposes of informed consent, or about the subject, after the fact. Whatever the risks or costs, a research subject must be adequately and completely informed. The subject must not be deceived or misled about what he is getting into. What is learned about subjects must not be used in ways that will violate their right to privacy. If it is likely that there will be costs to them -- physical, psychological or financial -- subjects must be informed of exactly what and how much those costs will be.

These disclosure issues in the Helsinki Accords are particularly relevant to programs which purport to be research but are, in fact, primarily designed to recruit patients. The violations of subjects' rights in such programs are not subtle or difficult to see; the subject is simply not told the whole truth as to the purpose of their being recruited. After participating, their right to privacy is violated by using their "research data" to convert them into "patients." Ultimately, as a direct result of participating, a certain percentage of the "subjects" sustain treatment costs which they were not informed about beforehand.

It is important to realize that in such recruiting programs, even if the research which is being done is well-designed and scientifically valid (which may be open to question), the human rights of the subject are violated, nevertheless, twice before the fact by being misinformed as to the purpose and possible costs, and once after the fact by the violation of confidentiality.

Although it is not likely to happen, if recruiting programs such as these wanted to conform to the Helsinki/NIH code of ethics, prospective subjects would have to be given a completely honest "informed consent" document which would include the following statement:

"If you agree to participate in this research study, the diagnostic and other personal information which will be obtained from you as a part of that research will be used to convince you to accept chiropractic care from this office. On average, about --% of the subjects who have participated in this research in the past have subsequently become our chiropractic patients and have incurred costs for chiropractic care ranging from $--- to $---, with an average expenditure of $---- per month."

In the last analysis, research subjects' rights are not really very different from patients' rights; confidentiality and honesty are of paramount importance in either case. It is easy to get confused, however, when the good of the patient is at stake. In fact, it might seem that the ethical obligation of a clinician to treat those who appear to require it, is at odds with the ethical obligations of the

researcher not to disclose or otherwise use confidential subject information. The conflict-of-interest problem is created by the researchers being the same people as the clinicians, and by their benefiting financially from the patient receiving treatment.

The solution to this ethical dilemma is as obvious as it is unlikely to be used: if the subject's diagnosis indicates it, inform them of their condition, but specifically exclude referral to any doctor directly or indirectly associated with the research project, even if, indeed, especially if the patient chooses such an involved doctor because they have gotten to know them during the research project.

Ethical issues aside, recruiting patients by violating their rights as research subjects could do serious damage to the credibility of legitimate chiropractic research efforts, and ultimately to chiropractic itself, should someone in the media (Geraldo?) decide to make a feature out of it. Greshams Law in economics states that bad currency in circulation drives out good. In the public mind, one scandal in chiropractic research could "drive out" or overshadow years of legitimate work. At the Consortium for Chiropractic Research, we are concerned that the shortsightedness of a few could actually cause this to happen.

The (Pacific) Consortium for Chiropractic Research is a dynamic, interactive research organization composed of the research departments of eight chiropractic colleges (Palmer, Palmer-West, Northwestern, Logan, LACC, Cleveland-Los Angeles, Western States, and Life-West), a number of state and national chiropractic associations, other chiropractic research institutions, and hundreds of individual doctors. Dues for individuals include the consortium newsletter and are $65 per year. Mail your check to: (Pacific) Consortium for Chiropractic Research, 1095 Dunford Way, Sunnyvale, CA 94087; or call 800-327-2289 and charge it on your Mastercard or Visa. (Organizations please call the executive director at 408-983-4067).

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