

## Alabama Proposes Strict Regulations Governing Research Recruitment

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On June 22, 1990, the Alabama State Board of Chiropractic Examiners issued a "cease and desist" letter to all Alabama chiropractors who were involved in research recruitment. The letter specifically stated that: "If you are currently involved with the Outreach 2000 Program (or any other form of research that may be considered uninvited communication that requires an oral response from the recipient), you should cease and desist this activity immediately." (Please see "Alabama Outlaws VSRI" in the August 1, 1990 issue of Dynamic Chiropractic)

The Alabama State Board was unable to enforce its decision due to a previous decision in May 1989, relating to a chiropractor who was using the Vertebral Subluxation Research Institute program. Because the board did not find the DC guilty, dropping the investigation on the basis that he would discontinue using the program, a precedent was established. This precedent forced the Alabama Board to form a committee to examine the issue and develop a new rule that would address the problem. (Please see "VSRI Gains Temporary Reprieve in Alabama" in the September 26, 1990 issue of "DC").

At approximately the same time, three malpractice insurance companies, the National Chiropractic Mutual Insurance Company (NCMIC), the OUM Insurance Group and the National Chiropractic Council (NCC) set policy against their policyholders participating in research for the purpose of recruiting patients. The International Chiropractors Association (ICA) and the American Chiropractic Association (ACA) also followed suit with policy statements of their own.

After much discussion, investigation and consideration, the Alabama Board has proposed the following rule regarding research:

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### Proposed Rule: Rule 190-X-5-.14 Research Activities

#### Statement of Policy

It is the policy of the board that legitimate scientific research is important to the advancement of the chiropractic profession, and should be supported. The board, however, recognizes the dangers inherent in research activities which seek, directly or indirectly, to convert research subjects into the private chiropractic patients of any licensee participating in such research activities. Such patient recruitment or practice building under the auspices of research undermines the integrity of the chiropractic profession and endangers the health, safety and welfare of the public because:

It promotes the use of inappropriate advertising or patient solicitation practices by chiropractors;

It creates an environment which fosters the use of unnecessary or excessive treatments;

It undermines critical informed consent considerations inherent in the physician/patient

relationship; and

It unnecessarily increases the malpractice exposure of chiropractors who participate in such activities.

Accordingly, in order that the state of Alabama may protect the health, safety and welfare of its citizens, while not abridging any rights guaranteed to chiropractic practitioners or the public by the Constitution of the United States, or the Constitution of the state of Alabama, as construed by the United States Supreme Court, or the Alabama Supreme Court, the board finds that research activities which do not comply with the following requirements shall constitute immoral, unprofessional, or dishonorable conduct by a chiropractor in violation of code of Alabama 1975 34-24-166(b)(2) and rule 190-X-5-.05.

#### Approval by Board

Any activity undertaken by a licensee involving chiropractic research must be pre-approved by the board in accordance with rule 190-X-5-.06(5)

#### Requirements for Approval

Research activities must be conducted under the auspices and direction of an accredited college of chiropractic or board recognized national or state organization, or satisfy the following requirements, in order to be approved by the board.

#### Subject Recruitment

Research subjects may be recruited or otherwise selected from a licensee's pre-existing, established patients. For the purposes of this rule, "pre-existing established patients" shall be defined as those patients who have had an established doctor/patient relationship with the licensee participating in research activities for a period of six months or more, or who have been treated six or more times by the licensee participating in research activities as a paying patient, either by health insurance benefit assignment, cash or cash equivalent, or otherwise, prior to the commencement of the research activities. A research subject who is not a pre-existing, established patient may participate in a licensee's research activities, but may not later become a private patient of any licensee participating in research activities or any other licensee affiliated or associated with the licensee participating in research activities for a period of one year from the completion of the research activities.

#### Records

All records, x-rays, or other materials pertaining to any research subject must be maintained separately from those of a licensee's other patients, and shall be preserved for a period of five years from the completion of the research activities. On request, any and all original medical records for a research subject shall be transferred to the board by a licensee participating in research activities within five working days for the purpose of patient referral.

#### Licensee/Research Subject Communications

No report of research findings, diagnosis, or other disclosure of medical condition shall be made to a research subject by any licensee participating in research activities, or any other licensee affiliated or associated with the licensee participating in research activities.

#### Referral Requirements

Where required by emergency medical necessity, direct referral of a research subject to an emergency medical facility by a licensee participating in research activities is permitted. Otherwise, any other referral for treatment, including chiropractic treatment, shall be made as provided herein and accompanied by a research subject disclosure form completed by the licensee participating in research activities.

#### Referral Procedure, Research Subject Disclosure Forms

Referrals of research subjects for further treatment, including chiropractic treatment, shall be accomplished by the completion of a research subject disclosure form by the licensee participating in research activities. Regardless of whether a referral is made, a research subject disclosure form for each research subject shall be forwarded by the licensee participating in research activities to the executive secretary of the board no later than 30 days from the completion of the research activities.

#### Prohibited Acts

Any attempt by a licensee to circumvent the research subject selection requirements (record keeping requirements; communications restrictions; referral and research subject disclosure requirements; and research rule disclosure requirements or any other provision of this rule) shall constitute immoral, unprofessional or dishonorable conduct by a chiropractor in violation of code of Alabama 1975, 34-24-166(b)(2) and rule 190-X-5-.05.

#### Disclosure

A copy of this rule shall be read, signed and dated by all research subjects prior to their participating in any research activity and shall be maintained in that research subject's records by any licensee participating in research activities.

#### Effective Date

The provisions of this rule apply to any research activities which may be ongoing in the state of Alabama on the effective date of the rule, and any and all future research activities.

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It is interesting to note the extent that a state board has been forced to go to in order to insure that chiropractors in that state will not use research to recruit patients. It is obvious that under this regulation, most chiropractors would see little value in paying VSRI the \$2,500 fee it charges for its "research" program.

While this proposed rule must still go through the regulatory process, which may or may not include a public hearing, there are a number of other state boards that have requested copies of the rule as a possible basis for a similar regulation in their state.

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