EXPERIMENTAL TREATMENTS

Mark W. Stafford, General Counsel
Kansas State Board of Healing Arts

I. The Basics
II. The Thought Process
III. The Position of the Profession
IV. The Question: What Does This Mean for Regulators?
V. The Attachments:
   Sample Statutes
   Canadian Federation of Chiropractic Regulatory and Educational Accrediting Boards: Research Ethics Review Policy
   Tri-Agency Policy Statement
   Logan Speaks
   Letter from Dr. Carl Cleveland, III
   Selected ACA Policies
   Sample 510K Letter: DRX9000
   Sample Rule for Institutional Review Board Membership

Please accept my sincere appreciation for the opportunity to spend time with you and to discuss how we, as regulators, might improve our service to the public.
65-2836.  Revocation, suspension, limitation or denial of licenses; censure of licensee; grounds; consent to submit to mental or physical examination or drug screen, or any combination thereof, implied.  A licensee’s license may be revoked, suspended or limited, or the licensee may be publicly or privately censured, or an application for a license or for reinstatement of a license may be denied upon a finding of the existence of any of the following grounds:
   * * *
   (b) The licensee has committed an act of unprofessional or dishonorable conduct or professional incompetency.  
   * * *

65-2837.  Professional incompetency, unprofessional conduct; definitions.  As used in K.S.A. 65-2836, and amendments thereto, and in this section:
   (a) “Professional incompetency” means:
      (1) One or more instances involving failure to adhere to the applicable standard of care to a degree which constitutes gross negligence, as determined by the board.
      (2) Repeated instances involving failure to adhere to the applicable standard of care to a degree which constitutes ordinary negligence, as determined by the board.
      (3) A pattern of practice or other behavior which demonstrates a manifest incapacity or incompetence to practice medicine.
   (b) “Unprofessional conduct” means:
      * * *
      (27) Using experimental forms of therapy without proper informed patient consent, without conforming to generally accepted criteria or standard protocols, without keeping detailed legible records or without having periodic analysis of the study and results reviewed by a committee or peers.
Research Ethics Review Policy
(Approved by the Board of Directors March 31, 2007)

The Canadian Federation of Chiropractic Regulatory and Educational Accrediting Boards (The Federation) has a mandate to assist provincial and territorial regulatory boards protect the public interest.

The Federation is also committed to promoting health research that meets the highest standards of excellence and ethics. As such, the Federation adopts the Tri-Agency (CIHR, NSERC & SSHRC) Policy Statement: Ethical Conduct for Research Involving Humans.

In particular, the Federation believes that all research that involves living human subjects should require review and approval by a Research Ethics Board (REB) in accordance with the Tri-Agency Policy Statement, before the research is undertaken.

A registered chiropractic practitioner shall, before engaging in a research project involving human subjects, obtain the written approval either of a Canadian Research Ethics Board conducted under the jurisdiction of an accredited chiropractic programme, a University, an Affiliated Research Institute, or Hospital, or where available, of the Research Ethics Review Committee of the respective provincial/territorial chiropractic regulatory board.

CIHR – Canadian Institutes for Health Research
NSERC – National Sciences and Engineering Research Council of Canada
SSHRC – Social Sciences and Humanities Research Council of Canada

(Note: The Tri-Agency Policy Statement: Ethical Conduct for Research Involving Humans is appended to this policy.)
TRI-COUNCIL POLICY STATEMENT

Ethical Conduct for Research Involving Humans

Canadian Institutes of Health Research
Natural Sciences and Engineering Research Council of Canada
Social Sciences and Humanities Research Council of Canada

The fundamental ethical principles and practices in research involving human subjects are common across the social sciences and humanities, the natural sciences, and the health sciences. They reflect shared fundamental values that are expressed in principles, rights, and norms of those involved in research. Research subjects reasonably expect that their rights shall be equally recognized and respected, regardless of the researcher's discipline. Similarly, Canadian society legitimately expects that the benefits and harms of research shall be fairly distributed.
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On behalf of the:
Canadian Institutes of Health Research: http://www.cihr-irsc.gc.ca
Social Sciences and Humanities Research Council of Canada: http://www.sshrc-crsh.gc.ca

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Ethical Conduct for Research Involving Humans

Canadian Institutes of Health Research
Natural Sciences and Engineering Research Council of Canada
Social Sciences and Humanities Research Council of Canada

August 1998
(with 2000, 2002, 2005 amendments)

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Note: For the most recent information on amendments, please consult the official online version of the TCPS at www.pre.ethics.gc.ca.

Permission is granted to photocopy this material.
CONTENTS

INTRODUCTION ............................................................................................................. i.1

GOALS OF THE POLICY ................................................................................................. i.2
   A. Mandate of the Agencies ......................................................................................... i.2
   B. Goals and Rationale of the Policy ........................................................................... i.2

CONTEXT OF AN ETHICS FRAMEWORK ....................................................................... i.4
   A. The Need for Research .......................................................................................... i.4
   B. A Moral Imperative: Respect for Human Dignity .................................................. i.4
   C. Guiding Ethical Principles ..................................................................................... i.5
   D. A Subject-Centred Perspective ............................................................................. i.7
   E. Academic Freedoms and Responsibilities ............................................................... i.8
   F. Ethics and Law ......................................................................................................... i.8
   G. Putting Principles into Practice ............................................................................... i.9

SECTION 1 – ETHICS REVIEW ...................................................................................... 1-1
   A. Research Requiring Ethics Review ......................................................................... 1-2
   B. Research Ethics Boards (REBs) ............................................................................ 1-2
       B1. Authority of the REB ....................................................................................... 1-2
       B2. Membership of the REB ................................................................................ 1-3
       B3. Number of REBs Within an Institution, and Relationships Among REBs .......... 1-4
   C. Analysis, Balance and Distribution of Harms and Benefits .................................... 1-5
       C1. Minimal Risk .................................................................................................... 1-5
       C2. Scholarly Review as Part of Ethics Review ......................................................... 1-6
   D. Review Procedures ................................................................................................ 1-7
       D1. A Proportionate Approach to Ethics Assessment .............................................. 1-7
       D2. Meetings and Attendance ............................................................................... 1-8
       D3. Record Keeping ............................................................................................... 1-9
       D4. Decision Making ............................................................................................ 1-9
       D5. Reconsideration .............................................................................................. 1-10
       D6. Appeals .......................................................................................................... 1-10
   E. Conflicts of Interest ............................................................................................... 1-10
   F. Review Procedures for Ongoing Research ............................................................ 1-10
   G. Review of Multicentred Research ......................................................................... 1-11
   H. Review of Research in Other Jurisdictions or Countries ......................................... 1-12
SECTION 8 – HUMAN GENETIC RESEARCH ................................................................. 8.1
A. The Individual, Families and Biological Relatives ........................................... 8.2
B. Privacy, Confidentiality, Loss of Benefits and Other Harms ............................ 8.2
C. Genetic Counselling ....................................................................................... 8.4
D. Gene Alteration ............................................................................................. 8.5
E. Eugenic Concerns ......................................................................................... 8.6
F. Banking of Genetic Material ......................................................................... 8.7
G. Commercial Use of Genetic Data ................................................................... 8.8

SECTION 9 – RESEARCH INVOLVING HUMAN GANETES, EMBRYOS OR FOETUSES .... 9.1
A. Research Involving Human Gametes ............................................................ 9.2
B. Research Involving Human Embryos ........................................................... 9.2
C. Research Involving Foetuses ........................................................................ 9.3
D. Research Involving Foetal Tissue ................................................................... 9.4

SECTION 10 – HUMAN TISSUE .................................................................................. 10.1
A. Privacy and Confidentiality ........................................................................... 10.1
B. Free and Informed Consent ........................................................................... 10.2
C. Previously Collected Tissue ........................................................................... 10.4

APPENDICES
Appendix 1: Scope of Research Requiring Ethics Review ................................. A.1
Appendix 2: Articles Included in Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans ... A.2

SUMMARY OF AMENDMENTS
October 2005 .................................................................................................. M.1
September 2002 .............................................................................................. M.1
May 2000 ......................................................................................................... M.1
INTRODUCTION

This *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) describes the policies of the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC). The document replaces SSHRC’s *Ethics Guidelines for Research with Human Subjects*, as well as the guidelines produced by the former Medical Research Council of Canada's *Guidelines on Research Involving Humans* and *Guidelines for Research on Somatic Cell Gene Therapy in Humans*.

These Agencies will consider funding (or continued funding) only individuals and institutions that certify that they comply with this Policy regarding research involving human subjects.

This joint Policy expresses the three Agencies’ continuing commitment to the people of Canada to promote the ethical conduct of research involving human subjects. This commitment was first expressed in the publication of guidelines in the late 1970s. Work on the joint Policy began with the formation of the Tri-Council Working Group in 1994. The Agencies published three documents prepared by the Working Group: an issues paper in November 1994, a discussion draft in May 1996, and its Final Report (*Code of Ethical Conduct for Research Involving Humans*) in July 1997. Each of these documents stimulated extensive discussion in the academic community. The present Policy Statement was prepared by the Agencies by revision of the Working Group’s Final Report in the light of consultations held between mid-1997 and May 1998.

The Agencies believe that this Policy Statement will benefit research by addressing the paramount need for the highest ethical standards. The key is sensitive and thoughtful implementation of the spirit and requirements of the document. Nonetheless, the Agencies recognize that considerations around the ethical conduct of research involving human subjects are complex and continually evolving. We therefore welcome comment and discussion, and commit to regular updates of this document.

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**Endnotes**

1. In 2000, the Government of Canada created the Canadian Institutes of Health Research and dissolved the Medical Research Council of Canada.

[i.1]
GOALS OF THE POLICY

This *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) describes standards and procedures for governing research involving human subjects.

A. Mandate of the Agencies

The people of Canada, through Acts of Parliament, have created and funded CIHR, NSERC and SSHRC to promote, assist and undertake research in the domains indicated by their names. In discharging our mandates, the Agencies wish to promote research that is conducted according to the highest ethical standards. The Agencies have therefore adopted this Policy as our standard of ethical conduct for research involving human subjects. As a condition of funding, we require, as a minimum, that researchers and their institutions apply the ethical principles and the articles of this Policy.

B. Goals and Rationale of the Policy

The interests of the Agencies in promoting ethical research, combined with the evolving needs of the research community, have led us to define a common policy of ethical conduct for research involving human subjects. This Policy seeks to respond to, and address, several needs:

1. The Policy addresses the interdependent duties to research subjects, which are shared by researchers, institutions and Research Ethics Boards (REBs).

2. By addressing common issues and needs, the Policy seeks to articulate ethical norms that transcend disciplinary boundaries. The fundamental ethical issues and principles in research involving human subjects are common across the social sciences and humanities, the natural sciences and engineering, and the health sciences. They reflect shared fundamental values that are expressed in the duties, rights and norms of those involved in research. Research subjects reasonably expect that their rights shall be equally recognized and respected, regardless of the researcher’s discipline. Similarly, Canadian society legitimately expects that the benefits and harms of research shall be fairly distributed.

3. The Policy seeks to harmonize the ethics review process. The Agencies expect that REBs will benefit from common procedures within a shared ethical framework. This will also benefit those projects involving researchers from different disciplines or institutions. The Agencies hope that the Policy will serve as an educational resource.

4. The effective working of ethics review—across the range of disciplines conducting research involving human subjects—requires reasonable flexibility in the implementation of common principles. The Policy therefore seeks to avoid imposing one disciplinary perspective on others, while expressing the shared principles and wisdom of researchers in diverse fields. It is designed to help both researchers and REBs, as a matter of sound ethical reasoning, to scrutinize the contexts and accommodate the needs of specialized research disciplines.

[ i.2 ]
5. The Policy updates some norms, while seeking to encourage continued reflection and thoughtful consensus around more contentious ethical issues. The Policy does not offer definitive answers to such ethical questions. Rather, it seeks (a) to outline guiding principles and basic standards and (b) to identify major issues, and points of debate and consensus, which are essential to the development and implementation of coherent policies for research ethics.

Endnotes

1 See Canadian Institutes of Health Research Act, Statutes of Canada, 2000, Chapter 6; Natural Science and Engineering Research Council Act, Revised Statutes of Canada, 1985, Chapter N-21; Social Sciences and Humanities Research Council Act, Revised Statutes of Canada, 1985, Chapter S-12.

2 During preparation of this Policy Statement, there was extensive discussion of the optimal term to describe those on, or about whom, the research is carried out. This discussion focused on the terms “participant” and “subject.” Though research subjects may participate actively in research, so also do many others, including the researchers and their staff, administrators in the institutions, and funding sponsors and members of research ethics boards. Research subjects are unique among the many participants because it is they who bear the risks of the research. The Agencies have therefore chosen to retain the word “subject” because of its relative unambiguity in this context, and because the prime focus of the Policy Statement is on those who bear the risks of research.
CONTEXT OF AN ETHICS FRAMEWORK

Norms for the ethics of research involving human subjects are developed and refined within an ever-evolving societal context, elements of which include the need for research and the research community, moral imperatives and ethical principles, and the law.

A. The Need for Research

Research involving human subjects is premised on a fundamental moral commitment to advancing human welfare, knowledge and understanding, and to examining cultural dynamics. Researchers, universities, governments and private institutions undertake or fund research involving human subjects for many reasons; for example, to alleviate human suffering, to validate social or scientific theories, to dispel ignorance, to analyze policy, and to understand human behaviour and the evolving human condition. Research involving human subjects imparts at least three general categories of benefits:

- The basic desire for new knowledge and understanding is the driving force for research.
- The quest to advance knowledge sometimes benefits research subjects. Subjects may benefit from improved treatments for illnesses; the discovery of information concerning one's welfare; the identification of historical, written, oral or cultural traditions; or the satisfaction of contributing to society through research.
- As well, research benefits particular groups and society as a whole. Thus, insights into political behaviour may produce better policy; information about the incidence of disease may improve public health; sociological data about lifestyles may yield social reform; and disciplines based on, for example, texts, dance, theatre or oral history, continue to illuminate past and present realities.

B. A Moral Imperative: Respect for Human Dignity

An ethic of research involving human subjects should include two essential components: (1) the selection and achievement of morally acceptable ends and (2) the morally acceptable means to those ends.

The first component is directed at defining acceptable ends in terms of the benefits of research for subjects, for associated groups, and for the advancement of knowledge. The second component is directed at ethically appropriate means of conducting research. For example, even in the most promising of research initiatives, the Agencies object to a person being tricked into participating through a promise of false benefits. Part of the core moral objection would concern the use of another human solely as a means toward even legitimate ends.
The objection provides moral insight that proves pertinent to human research in several ways: First, it translates into the familiar moral imperative of respect for human dignity. It is unacceptable to treat persons solely as means (mere objects or things), because doing so fails to respect their intrinsic human dignity and thus impoverishes all of humanity. Second, it translates into the requirement that the welfare and integrity of the individual remain paramount in human research. Thus, the moral imperative of respect for human dignity translates into a number of important correlative ethical principles in research ethics. These are elaborated in Section C, below.

C. Guiding Ethical Principles

The approach taken in this framework is to guide and evoke thoughtful actions based on principles. The principles that follow are based on the guidelines of the Agencies over the last decades, on more recent statements by other Canadian agencies, and on statements from the international community. The principles have been widely adopted by diverse research disciplines. As such, they express common standards, values and aspirations of the research community.

Respect for Human Dignity: The cardinal principle of modern research ethics, as discussed above, is respect for human dignity. This principle aspires to protect the multiple and interdependent interests of the person—from bodily to psychological to cultural integrity. This principle forms the basis of the ethical obligations in research that are listed below.

In certain situations, conflicts may arise from application of these principles in isolation from one other. Researchers and REBs must carefully weigh all the principles and circumstances involved to reach a reasoned and defensible conclusion.

Respect for Free and Informed Consent: Individuals are generally presumed to have the capacity and right to make free and informed decisions. Respect for persons thus means respecting the exercise of individual consent. In practical terms within the ethics review process, the principle of respect for persons translates into the dialogue, process, rights, duties and requirements for free and informed consent by the research subject.

Respect for Vulnerable Persons: Respect for human dignity entails high ethical obligations toward vulnerable persons—to those whose diminished competence and/or decision making capacity make them vulnerable. Children, institutionalized persons or others who are vulnerable are entitled, on grounds of human dignity, caring, solidarity and fairness, to special protection against abuse, exploitation or discrimination. Ethical obligations to vulnerable individuals in the research enterprise will often translate into special procedures to protect their interests.

Respect for Privacy and Confidentiality: Respect for human dignity also implies the principles of respect for privacy and confidentiality. In many cultures, privacy and confidentiality are considered fundamental to human dignity. Thus, standards of privacy and confidentiality protect the access, control and dissemination of personal information. In doing so, such standards help to protect mental or psychological integrity. They are thus consonant with values underlying respect for privacy, confidentiality and anonymity.
Respect for Justice and Inclusiveness: Justice connotes fairness and equity. Procedural justice requires that the ethics review process have fair methods, standards and procedures for reviewing research protocols, and that the process be effectively independent. Justice also concerns the distribution of benefits and burdens of research. On the one hand, distributive justice means that no segment of the population should be unfairly burdened with the harms of research. It thus imposes particular obligations toward individuals who are vulnerable and unable to protect their own interests, to ensure that they are not exploited for the advancement of knowledge. History has many chapters of such exploitation. On the other hand, distributive justice also imposes duties to neither neglect nor discriminate against individuals and groups who may benefit from advances in research.

Balancing Harms and Benefits: The analysis, balance and distribution of harms and benefits are critical to the ethics of human research. Modern research ethics, for instance, require a favourable harms-benefits balance—that is, that the foreseeable harms should not outweigh anticipated benefits. Harms-benefits analysis thus affects the welfare and rights of research subjects, the informed assumption of harms and benefits, and the ethical justifications for competing research paths. Because research involves advancing the frontiers of knowledge, its undertaking often involves uncertainty about the precise magnitude and kind of benefits or harms that attend proposed research. These realities as well as the principle of respect for human dignity, impose ethical obligations on the prerequisites, scientific validity, design and conduct of research. These concerns are particularly evident in biomedical and health research; in research they need to be tempered in areas such as political science, economics or modern history (including biographies), areas in which research may ethically result in the harming of the reputations of organizations or individuals in public life.

Minimizing Harm: A principle directly related to harms-benefits analysis is non-maleficence, or the duty to avoid, prevent or minimize harms to others. Research subjects must not be subjected to unnecessary risks of harm, and their participation in research must be essential to achieving scientifically and societally important aims that cannot be realized without the participation of human subjects. In addition, it should be kept in mind that the principle of minimizing harm requires that the research involve the smallest number of human subjects and the smallest number of tests on these subjects that will ensure scientifically valid data.

Maximizing Benefit: Another principle related to the harms and benefits of research is beneficence. The principle of beneficence imposes a duty to benefit others and, in research ethics, a duty to maximize net benefits. The principle has particular relevance for researchers in professions such as social work, education, health care and applied psychology. As noted earlier, human research is intended to produce benefits for subjects themselves, for other individuals or society as a whole, or for the advancement of knowledge. In most research, the primary benefits produced are for society and for the advancement of knowledge.
D. A Subject-Centred Perspective

Research subjects contribute enormously to the progress and promise of research in advancing the human condition. In many areas of research, subjects are participants in the development of a research project, and collaboration between them and the researcher in such circumstances is vital and requires nurturing. Such collaboration entails an active involvement by research subjects, and ensures both that their interests are central to the project or study, and that they will not be treated simply as objects. Especially in certain areas of the humanities and social sciences this collaborative approach is essential, and the research could not be conducted in any other way. For example, a study on how a theatrical company developed its approach to a particular play would be difficult without the participation of the theatre company in question. Nevertheless, some research will require a more formal separation between subject and researcher because of the nature of the research design.

A subject-centred approach should, however, also recognize that researchers and research subjects may not always see the harms and benefits of a research project in the same way. Indeed, individual subjects within the same study may respond very differently to the information provided in the process of free and informed consent. Hence, researchers and REBs must strive to understand the views of the potential or actual research subjects.

In this context, researchers should take into account that potential subjects who are asked to participate in research by, for example, their caregiver, teacher or supervisor may be overly influenced by such factors as trust in the researcher or the hope for other goals—more than by assessment of the pros and cons of participation in the research. A patient may hope for a cure from an experimental drug, an employee for better working conditions, and a student for better marks. This places extra demands on the researcher for accuracy, candour, objectivity and sensitivity in informing potential subjects about proposed research.

However, researchers and REBs should also be aware that some research may be deliberately and legitimately opposed to the interests of the research subjects. This is particularly true of research in the social sciences and the humanities that may be critical of public personalities or organizations. Such research should, of course, be carried out according to professional standards, but it should not be blocked through the use of harms-benefits analysis or because it may not involve collaboration with the research subjects.
E. Academic Freedoms and Responsibilities

Researchers enjoy, and should continue to enjoy, important freedoms and privileges. To secure the maximum benefits from research, society needs to ensure that researchers have certain freedoms. It is for this reason that researchers and their academic institutions uphold the principles of academic freedom⁶ and the independence of the higher education research community. These freedoms include freedom of inquiry and the right to disseminate the results thereof, freedom to challenge conventional thought, freedom from institutional censorship, and the privilege of conducting research on human subjects with public monies, trust and support. However, researchers and institutions also recognize that with freedom comes responsibility, including the responsibility to ensure that research involving human subjects meets high scientific and ethical standards. The researcher’s commitment to the advancement of knowledge also implies duties of honest and thoughtful inquiry, rigorous analysis, and accountability for the use of professional standards. Thus, peer review of research proposals, the findings and their interpretation contribute to accountability, both to colleagues and to society.

Review of the ethics of research helps ensure a more general accountability to society. Accountability, moreover, requires that the whole process should always be open to critical assessment and debate.⁷

F. Ethics and Law

The law affects and regulates the standards and conduct of research involving human subjects in a variety of ways, such as privacy, confidentiality, intellectual property, competence, and in many other areas. Human rights legislation prohibits discrimination on a variety of grounds. In addition, most documents on research ethics prohibit discrimination and recognize equal treatment as fundamental. REBs should also respect the spirit of the Canadian Charter of Rights and Freedoms, particularly the sections dealing with life, liberty and the security of the person as well as those involving equality and discrimination.

This legal context for research involving human subjects is constantly evolving, and varies from jurisdiction to jurisdiction. For this reason, researchers, institutions and REBs should have recourse to expertise to identify legal issues in the ethics review process.

However, legal and ethical approaches to issues may lead to different conclusions. The law tends to compel obedience to behavioural norms. Ethics aim to promote high standards of behaviour through an awareness of values, which may develop with practice and which may have to accommodate choice and liability to err. Furthermore, though ethical approaches cannot preempt the application of the law, they may well affect its future development or deal with situations beyond the scope of the law.
G. Putting Principles into Practice

For meaningful and effective application, the foregoing ethical principles must operate neither in the abstract, nor in isolation from one another. Ethical principles are sometimes criticized as being applied in formulaic ways. To avoid this, they should be applied in the context of the nature of the research and of the ethical norms and practices of the relevant research discipline. Good ethical reasoning requires thought, insight and sensitivity to context, which in turn help to refine the roles and application of norms that govern relationships. Thus, because principles are designed to guide ethical reflection and conduct, they admit flexibility and exceptions. To preserve the values, purpose and protection that they attempt to advance, the onus for demonstrating a reasonable exception to a principle should fall on those claiming the exception.

National norms in research ethics should not be developed in a vacuum. REBs should be aware that there are a variety of philosophical approaches to ethical problems, and that debate between various schools of thought both informs ethical decisions and ensures an evolving context for ethical approaches. Some approaches are traditional, but others, such as feminist analysis, are centred on context, relationships of power and allocations of privilege that perpetuate disadvantage and inequality. Hence, the approach may help to correct the systemic exclusion of some groups from research.

Often, more than one principle will apply to a specific case. This is due in part to the diversity of research and in part to the range of fundamental values upon which the research ethics enterprise is founded. If the application of principles yields conflicts, then such conflicts properly demand probing ethical reflection and difficult value choices. Such choices and conflicts are inherent in the ethics review process. In their best uses, principles serve as short-hand reminders of more complex and context-specific moral reflection.

REBs should recognize that certain types of research—particularly biographies, artistic criticism or public policy research—may legitimately have a negative effect on organizations or on public figures in, for example, politics, the arts or business. Such research does not require the consent of the subject, and the research should not be blocked merely on the grounds of harms-benefits analysis because of the potentially negative nature of the findings.

Beyond a keen appreciation for context, effective guiding principles also depend on procedures and policies for their implementation. Indeed, modern research ethics are premised on a dynamic relation between ethical principles and procedures. This relationship is implemented through a mechanism that has emerged in many countries over the last decades and which consists of the articulation of national norms that are applied through prospective ethics review of research projects. Typically, the review is undertaken in local research institutions by independent, multidisciplinary ethics committees that apply substantive and procedural norms. This Policy is consistent with this model.
Endnotes


5 During preparation of this Policy Statement, there was extensive discussion of the optimal way to refer to the decision made by the potential research subject on whether to participate in the research. The frequently used phrase “obtain informed consent” was rejected early in the discussion because “obtain” implies that getting the consent is the goal, whereas ethically the goal must be to enable the potential subject to choose freely, and with full information, on whether to agree to participate in the research. Though earlier drafts used both “choice” and “consent,” it was often difficult to be certain which was the most appropriate in the various contexts. Hence, a brief means of expressing this concept was sought. “Free and informed consent” was decided upon for a number of reasons: it states the requirement for voluntariness and information; it was felt to include the idea that consent is the act of deciding, perhaps as a result of balancing a number of choices; it retains the traditional word “consent”; and the phrase has unambiguous meaning in the law.

6 For a definition of academic freedom, see UNESCO, Recommendation concerning the Status of Higher-Education Teaching Personnel, Paris, 1997, Chapter VI. For responsibilities, see Section VII—“Duties and Responsibilities of Higher Education Teaching Personnel” and Section V—“Institutional Rights, Duties and Responsibilities.” Canada spoke in favour of, and voted for, this statement when it was adopted by the General Conference of UNESCO in 1997. For further definitions of academic freedom, see Canadian Association of University Teachers (CAUT), Policy Statement on Academic Freedom, Ottawa, 1977; Association of Universities and Colleges of Canada (AUCC), Statement on Academic Freedom and Institutional Autonomy, Ottawa, 1988.

Based on the Evidence:
Logan Promotes Research and Collaboration at ACC-RAC 2007

On May 29, 2006, nearly one million BusinessWeek readers got a dose of today’s health care realities courtesy of its cover story “Medical Guesswork.” There is little doubt the article’s report that “roughly 20-25 percent of medicine today has been proven effective” presented a difficult pill for readers to swallow.

This surprisingly low percentage, combined with the health care marketplace’s increasing demand for efficacy, have left many physicians calling for a health care revolution with evidence-based medicine as their rallying cry. Thus, the question remains: what does this mean for chiropractic?

The answer:

“Research is a critical component of all contemporary issues in chiropractic,” says Rodger Tepe, PhD, Logan’s dean of research and development. “Policy makers in academic, scientific, political and economic areas must use evidence-based decision models to advance our position in the health care community. If you connect these dots, they spell research.”

At the ACC-RAC 2007 Conference held this past March in Phoenix, the forum’s participants, who included Logan senior administrators, faculty representatives and presenters, discussed the importance of following evidence-based protocols in providing care. Under the banner of the conference theme “Professionalism and Ethics,” attendees advanced the profession’s movement to a patient-centered model, says Clayton Skaggs, DC, CCRD, Logan associate professor and ACC-RAC presenter.

“Providing a patient-centered practice requires chiropractic physicians to work from an evidence-based model,” says Dr. Skaggs. “This type of care focuses on what the patient needs, what has been proven to deliver better patient outcomes and what supports the role of chiropractic in today’s integrated health care system.”

Applying Evidence to Clinical Practice

Coined in the early 1980s, the term “evidence-based” has gained recent momentum as physicians across all disciplines are held to more rigorous standards to demonstrate safe, effective outcomes. Getting patients better faster with longer-lasting results is no longer ideal but demanded by current standards. The chiropractic profession’s ability to embrace this paradigm will prove critical for future multidisciplinary, collaborative initiatives.

When it comes to integrating evidence-based care into the clinical setting, it’s more than just a textbook application. As defined by researcher Ronnie Evans with Northwestern University:

Evidence-based care is a combination of what the literature validates plus the practitioner’s clinical knowledge paired with the patient’s health care goals.

Logan College of Chiropractic takes a progressive approach to bring research in close alignment with its curriculum offerings, dedicated research department and laboratory, publications and national/international conference involvement.

“Logan College recognizes the importance of evidence-based health care, the expansion of clinical research and its role in clinical practice,” says Dr. Skaggs. “Our evolving curriculum demonstrates this commitment to professionalism and scientific and clinical exploration.”

Today in the Logan classroom, for example, instructors emphasize the importance of assessment as the evidence now suggests that success on the first treatment has a
significant correlation to long-term outcomes. Logan's curriculum also incorporates the latest research for resolving a patient's low back pain. For instance, new clinical research minimizes the importance of flexibility in low back pain treatment and recovery. Rather, the latest findings support building strength in the deep muscles of the low back as more effective rehabilitation for low back pain.

Logan College's educational objective is not only to school students on the most current literature, but more broadly, Logan's curriculum is designed to propel the profession forward in its acceptance and application of research-driven, patient-focused practices.

**Academic Agents for Research**

Whether at home on the Logan campus and or on the international scene through presentations and publications, Logan students and faculty contribute new areas of clinical research to the body of chiropractic science.

According to Dr. Tepe, who also presented at the ACC-RAC conference, the consistent exchange of scholarly information presented in a collaborative setting is what will drive greater acceptance of evidence-based practices throughout the chiropractic community.

"Chiropractic does not yet have the critical mass of scientific resources and infrastructure necessary to have significant impact in the larger health care community," says Dr. Tepe. "We need well-targeted strategies to address the most pressing educational, economic and political issues while we continue to develop. As representatives from an academic institution, we must serve as proactive agents for research. Conferences like the ACC-RAC provide us with a venue to promote research as a priority and share our findings for the benefit of our profession."

**Burden of Proof**

Aside from expanding chiropractic into new areas of integrative medicine and supporting patient-centered practices, evidence-based protocols are also shifting how policymakers and insurers review and reimburse chiropractic care now and in the future.

"The burden of proof is upon us," says Dr. Tepe. "If you think evidence-based practice, such as you see in the practice of medicine, does not apply to chiropractic, you're wrong. It is incumbent on us to provide the quality and quantity of evidence sufficient to demonstrate the safety and efficacy of chiropractic care."

The American Chiropractic Association (ACA) agrees. In March, the ACA's House of Delegates announced its commitment of $150,000 for allocation over the next six months, to ensure chiropractic representation in the policy discussions on quality initiatives that "are sweeping the health care marketplace." Such initiatives fall under the health care community's umbrella of evidence-based medicine.

According to ACA president Richard Brassard, DC, "The movement toward reimbursement for quality measures will have a significant impact on the chiropractic profession in terms of both practice and reimbursement."

"Take a look at your denied insurance claims," says Dr. Tepe. "When an insurance provider challenges you to supply evidence regarding a specific treatment method, the burden of proof is on you. The demand for evidence-based care is a constant reminder of the need for research and collaboration within our profession. Logan College and the entire chiropractic industry exist for one shared purpose—the patient."

"If you examine the most successful chiropractic practitioners today based on patient outcomes, the leaders in our profession are those who follow the patient-centered, evidence-based model," says Dr. Skaggs. "The secret to their success lies in their ability to consistently meet patients' needs and remain well-versed in the latest literature, both of which constantly evolve. As practitioners, we must break through the practice bubble and constantly seek out information if we are to maintain and advance our clinical and academic position."
April 24, 2007

Mark Stafford
General Counsel
Kansas State Board of Healing Arts
235 S. Topeka Boulevard
Topeka, KS 66603-3068

Re: Experimental or Investigational Treatments

In response to a request from a member of the Kansas State Board of Healing Arts, the following recommendation is respectfully submitted.

To more closely regulate the activities associated with chiropractic treatment of patients and to help protect the public, it is recommended that the KSBHA permit only those experimental or investigational treatment methods that have been approved by an Institutional Review Board registered through the Office for Human Research Protections of the U.S. Department of Health and Human Services. CCE accredited chiropractic colleges, or regionally accredited institutions of higher education, conduct investigations only after approval of OHRP registered IRBs. Any project that is not affiliated with an institution of higher learning should be approved through an IRB that is federally registered through OHRP.

Additionally, all patients receiving investigational treatment should be given appropriate informed consent, approved by an OHPR registered IRB and investigators/providers should document that they have completed “Protecting Human Subjects Training” (as documented in the Health and Human Services Regulations 45-CFR-46 Protection of Human Subjects, revised June 1991) or the equivalent. More information related to protection of human subjects can be found at http://www.hrsa.gov/humansubjects/.

Please contact me with any questions regarding this communication at 816-501-0179.

Respectfully,

[Signature]

Carl S. Cleveland III, D.C.
President - Cleveland Chiropractic College
ABOUT US

Policies

Preface: Master Plan Definitions

The ACA Master Plan, ratified by the House of Delegates in June 1984 (Amended June 1979, June 1989, July 1994 and September 2000), and will govern future policies of ACA as quoted:

"With regard to the core chiropractic principle, which holds that the relationship between structure and function in the human body is a significant health factor and that such relationships between the spinal column and the nervous system are highly significant because the normal transmission and expression of nerve energy are essential to the restoration and maintenance of health.

"Chiropractic shall be described in accordance with the foregoing principle as follows:

"Chiropractic is a branch of the healing arts which is concerned with human health and disease processes. Doctors of Chiropractic are physicians who consider man as an integrated being and give special attention to the physiological and biochemical aspects including structural, spinal, musculoskeletal, neurological, vascular, psychological, nutritional, visceral, emotional and environmental relationships and are trained in diagnosis so they may treat patients effectively and make timely referral to appropriate health care providers.

"The practice and procedures which may be employed by Doctors of Chiropractic (chiropractic physicians) are based on the academic and clinical training received in and through accredited chiropractic colleges and include, but are not limited to, the use of current diagnostic and therapeutic procedures. Such procedures specifically include the adjustment and manipulation of the articulations and adjacent tissues of the human body, particularly of the spinal column. Included is the treatment of intersegmental aberrations for alleviation of related functional disorders.

"Chiropractic is a drug-free, non-surgical science and, as such, does not include pharmaceuticals or incisive surgery. Due regard shall be given to the fact that state laws, as well as the nation's antitrust laws, [may] allow Doctors of Chiropractic (Chiropractic Physicians) to utilize ancillary health care procedures commonly referred to as being in the common domain.

"Without prejudice to our commitment to this vital core concept and, in conformity with the nation's antitrust laws, Doctors of Chiropractic (Chiropractic Physicians) may elect in their practice to use common domain procedures, otherwise allowed by applicable law, and assuming they are properly qualified by background, education and training to do so.

ACA POLICIES ON PUBLIC HEALTH AND RELATED MATTERS ACUPUNCTURE

The board of governors of the ACA encourages the judicious development of curricula, research, and clinical procedures of this ancient healing method, and that it be integrated, when appropriate, as an adjunctive and supportive procedure which may complement the chiropractic adjustment. This modality should be utilized only by the doctor of chiropractic who is qualified by education and clinical experience, and who has been examined and certified by an appropriate accredited body. (Ratified by the House of Delegates, June 1975).

AIRLINE SEATS AND EXERCISE

Health aboard airlines is a growing issue due to seat design and placement and the failure of passengers to exercise during flights greater than 3 hours. The concern for these health care issues is of great concern to travelers worldwide. As the foremost and largest professional chiropractic association in the country, the American Chiropractic Association (ACA) takes a strong position for the development of ergonomically designed and adjustable seats in an attempt to reduce back pain, vascular stress and spinal discomfort suffered by travelers. The ACA also supports the demonstration of on-board exercises to reduce thrombosis, thrombophlebitis and spinal pain. There are many exercises that can be done directly in the seats without the use of additional space aboard aircraft.

In addition to providing seats that are ergonomically designed, it is further recommended that airlines continue to increase the distance between seats (from front to back and side to side).
CHIROPRACTIC PRACTICE AND PROCEDURES

"The practice and procedures which may be employed by Doctors of Chiropractic (chiropractic physicians) are based on the academic and clinical training received in and through accredited chiropractic colleges and include, but are not limited to, the use of current diagnostic and therapeutic procedures. Such procedures specifically include the adjustment and manipulation of the articulations and adjacent tissues of the human body, particularly of the spinal column. Included is the treatment of intersegmental aberrations for alleviation of related functional disorders.

"Chiropractic is a branch of the healing arts which is concerned with human health and disease processes. Doctors of Chiropractic are physicians who consider man as an integrated being and give special attention to the physiological and biochemical aspects including structural, spinal, musculoskeletal, neurological, vascular, psychological, nutritional, visceral, emotional and environmental relationships and are trained in diagnosis so they may treat patients effectively and make timely referral to appropriate health care providers. (ACA Master Plan, ratified by the House of Delegates, June 1964, amended, June 1977, June 1979, June 1989, July 1994 and September 2000)

CLINICAL RESEARCH TRIALS REGISTRY
Resolved, the American Chiropractic Association support the establishment of a mandatory national health care clinical trials registry, as modeled in the Food and Drug Administration Modernization Act of 1997, Public Law 105-115. Such a registry should be available to the public, federal and state legislators and to members of the health care professions. It should allow open access to the results of all clinical trials, regardless of results. This type of registry is a critical component of the scientific clinical research paradigm as it strengthens the reliability of clinical research, by making all available trials open to critical scrutiny. Such open access and discussion will certainly further human health care and the clinical management of the sick and infirm. Moreover, open access to all clinical trials, and not just select findings published in scientific journals, will greatly enhance trust in the clinical research system. (Ratified by the House of Delegates, September 2004).

DIAGNOSIS
When a doctor of chiropractic clinically observes a condition in a patient, he seeks to find why, just as is done in physics, chemistry, and medicine. After such clinical observations are made, an attempt is made to explain the condition by a hypothesis. Such hypotheses are found in chiropractic literature under the heading of "Chiropractic Principles or Philosophy", but they are chiropractic hypotheses.

The probability or non-probability of the hypothesis does not alter the chiropractic clinical facts, for the hypothesis is simply an interim attempt to explain the etiology of the clinical fact. Chiropractic treats the ailment disclosed by the clinical facts, not by hypothesis. The patient's needs are met by the clinical efficacy of chiropractic, not by conflicting arguments on hypothesis.

Every chiropractic college teaches physical examination and diagnostic procedures and examines
(or tests) in physical, clinical, laboratory, and differential analysis, in addition to chiropractic analysis.
Before receiving a license to practice chiropractic, candidates are examined in diagnosis either by official state boards or by the National Board of Chiropractic Examiners, or both. The chiropractic curriculum is oriented toward patient management, that is, to the recognition of the measures best suited to the restoration and maintenance of the patient's good health (whether such measures are applied by a doctor of chiropractic or by another health professional on referral). Present day chiropractic does not hold that the subluxation is the only cause of disease. Whatever may have been said in chiropractic literature years ago, today's chiropractic education and practice recognizes multiple causes of, and multiple methods of treatment for, disease. The doctor of chiropractic must first evaluate the needs of the patient before administering any type of care. If he should determine that the case is within his scope, he proceeds to provide appropriate care. But if he determines that the patient requires another type of care, he refers the patient to that method which he believes is most advantageous. (Chiropractic White paper, May 1969, Board approved, July 1975).

**DIAGNOSIS - ACC STATEMENT**
Resolved, that the House of Delegates endorse the ACC statement on Diagnosis:
"A diagnosis is an expert opinion identifying the nature and cause of a patient's concern or complaint, and/or abnormal finding(s). It is essential to the ongoing process of reasoning used by the doctor of chiropractic in cooperation with the patient to direct, manage, and optimize the patient's health and well being.
The process of arriving at a diagnosis by a doctor of chiropractic includes: obtaining pertinent patient history; conducting physical, neurological, orthopedic, and other appropriate examination procedures; ordering and interpreting specialized diagnostic imaging and/or laboratory tests as indicated by symptoms and/or clinical findings; and performing postural and functional biomechanical analysis to determine the presence of articular dysfunction and/or subluxation."
The Association of Chiropractic Colleges continues to foster a unique, distinct chiropractic profession that serves as a health care discipline for all. The ACC advocates a profession that generates, develops, and utilizes the highest level of evidence possible in the provision of effective, prudent, and cost-conscious patient evaluation and care. (Ratified by the House of Delegates, September 2003) [Note: This does not replace the current definitions of diagnosis as found in the ACA Master Plan and other policy statements of the ACA.]

**ETHICAL CONDUCT**
Resolved, that the ACA vigorously condemns suggestions which infer the application of chiropractic treatment primarily for personal monetary gain rather than for the patients' health, safety and welfare.
Resolved, further, that the ACA emphasizes the highest ethical conduct in both research and patient care. (Ratified by the House of Delegates, June 1982).

**EVIDENCE BASED MEDICINE AND BEST PRACTICES**
The American Chiropractic Association (ACA) supports Evidence Based Medicine and Best Practices that are predicated by an objective review of the most current and valid evidence available in literature and other sources. Information yielded from a thoughtful review of the
literature is intended for use in designing the most beneficial course of care for an individual patient. The ACA respects provider clinical expertise and recognizes the importance of individual provider competence in combination with the most current evidence based practices to fit the needs of a patient. The unique nature of each patient and a provider's right to choose a quality course of treatment for each individual is also supported.

The ACA supports the definition of evidence based medicine as:

"Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgment that individual clinicians acquire through clinical experience and clinical practice. Increased expertise is reflected in many ways, but especially in more effective and efficient diagnosis and in the more thoughtful identification and compassionate use of individual patients' predicaments, rights, and preferences in making clinical decisions about their care. By best available external clinical evidence we mean clinically relevant research, often from the basic sciences of medicine, but especially from patient centered clinical research into the accuracy and precision of diagnostic tests (including the clinical examination), the power of prognostic markers, and the efficacy and safety of therapeutic, rehabilitative, and preventive regimens. External clinical evidence both invalidates previously accepted diagnostic tests and treatments and replaces them with new ones that are more powerful, more accurate, more efficacious, and safer."


In response to medical literature of poor standards and extreme bias, the creation of practice guidelines is shifting to rely solely upon randomized clinical trials (RCTs), which have strong clinical evidence. This is problematic because the patient base often included in RCTs is taken from very restrictive groups of individuals. When guidelines are based on evidence that is representative of a narrow group of patients and those guidelines are applied unequivocally, a disconnect occurs, and patients do not receive the best treatment. Another unfortunate consequence of relying strictly on RCTs is that there is a lapse in time between valuable advances in therapies and completed RCTs. Providers should have the most proven up to date methods at hand to treat their patients, either by science or by clinical experience or a combination thereof. Best Practices, in contrast to restrictive clinical guidelines, allow for the integration of research and clinical expertise while respecting the unique nature of individual patients and are preferred due to their patient centered focus as opposed to guidelines that are meant to impose restrictions or limits on providers.

While RCTs are, without doubt, highly valuable clinical evidence, they have limitations and weaknesses when applied across the board. Because of this, it is important to take into review a variety of other clinical evidence information including case studies, cohort studies, literature reviews and historical performance for applicability and value when developing guidelines and patient care plans. Third party payers and providers have an obligation to the public to remain
aware of new evidence that is released which may affect patient care.

The ACA is aware of over-utilization and questionable utilization of care that occurs in the health care delivery system. The ACA does not support those who engage in these actions nor does the ACA support guidelines developed by third party payers that draw upon out of date literature and impede the doctor-patient relationship through excessive management of providers. The ACA supports patient-centered healthcare that draws upon a provider's expertise and the available research while effectively and cost-consciously treating the patient. (Ratified by the House of Delegates, September 2004).

**FRAUDULENT CURES**
Resolved, that the American Chiropractic Association support enforcement efforts against quack medicines, medical devices and other fraudulent cures that endanger the public health or substantially mislead consumers. (Ratified by the House of Delegates, June 1991).

**INFORMED CONSENT REGARDING EXPERIMENTAL TREATMENT**
Any procedure not taught in a chiropractic college maintaining a standard of reputation and training with the U.S. Department of Education should be considered experimental and the patient should be so informed. (Board approved, June 1983).

**MEDICAL NECESSITY**
Third-party contracts usually call for a direct relationship between covered services and medical necessity. There is also much concern in this area by federal and state legislators, particularly as it pertains to quality assurance and professional standards review organizations. The ACA agrees that there should be a responsible position relative to this by our profession and has researched the subject as it is understood by numerous of the third-party payers.
The ACA position refers to those appropriate examinations, therapeutic substances, and treatment procedures that are used by licensed practitioners to diagnose and treat patients with a specific condition.
Implied is the fact that the condition be a recognized one and that the examinations, tests, therapeutic substances, and treatment procedures used are based on scientific principles and studies, are generally accepted by the profession as being needed, essential, and appropriate to properly diagnose and treat patients with the particular condition. Quality and quantity of examination and therapeutic procedures must be within the norms and/or criteria established by the profession as a whole for such a condition.
Implied also is the fact that there must be documentation in the medical records and/or reports to substantiate the need for the services rendered. (Approved, July 1975).
Resolved, that medical necessity should be based on a standard that is tied to principles of professional practice as accepted by the particular field of professional practice. Health plans should be prohibited from interfering with medically necessary care as determined by the treating health care provider acting within the scope of his or her practice. The patients of all health care providers should have the right to receive medically necessary care as determined by their practitioners. This position should also be included in the list of patient protections in any managed care legislation that is passed by Congress. (Ratified by the House of Delegates, August 1999).
RESEARCH - PATIENT SOLICITATION
The American Chiropractic Association is committed to the highest standards of the professional practice of chiropractic and to the highest standards of chiropractic research. However, there exists within the profession individuals and groups, which attempt to utilize what appears to be or may in fact be research efforts as a means to solicit patients. Such research/patient solicitation efforts erode the credibility of legitimate chiropractic research and threaten to endanger the professional relationship between patient and chiropractor.
Therefore, be it resolved that the American Chiropractic Association encourage research by individual doctors of chiropractic, e.g. case studies, as part of a continuing learning process that will ultimately result in better practitioners. This research will also contribute to the ever-growing body of knowledge and to a better understanding of the benefits of chiropractic care. Chiropractors are encouraged to participate in and support chiropractic research as part of their commitment to the chiropractic profession.
Be it further resolved that the American Chiropractic Association recognizes that a normal part of the everyday chiropractic practice involves communication in some form that will allow members of the public to better understand the benefits of chiropractic care and to recognize the services available from a specific doctor of chiropractic. This communication can take many forms of advertising and marketing. Ultimately, this communication is governed by applicable federal and state laws as well as specific chiropractic codes of ethical conduct.
Be it further resolved that the American Chiropractic Association caution its members that it regards the practice of utilizing research programs for the designed purpose of patient solicitation to be an unacceptable and possibly illegal method of patient inducement that will ultimately damage the credibility of chiropractic as a whole and in particular damage the credibility of chiropractic research.
Chiropractic examining boards and other authorized governmental regulatory agencies are encouraged to investigate and to take proper action in regard to these improper patient solicitation/research programs. (Ratified by the House of Delegates, June 1991).
Axiom Worldwide, Inc.
% TÜV Rheinland of North America, Inc.
Mr. Tamas Borsai
Program Manager
12 Commerce Road
Newtown, Connecticut 06470

Re: K060735
Trade/Device Name: DRX9000 True Non-Surgical Spinal Decompression System
Regulation Number: 21 CFR 890.5900
Regulation Name: Power traction equipment
Regulatory Class: Class II
Product Code: ITH
Dated: May 9, 2006
Received: May 11, 2006

Dear Mr. Borsai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA’s issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act’s requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known):
Device Name:
Indications For Use:

Prescription Use AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

________________________________________________________________________

Concurrence of CDRH, Office of Device Evaluation (ODE)
Indications for Use

510(k) Number (if known): K060735

Device Name: DRX9000 True Non-Surgical Spinal Decompression System

INDICATIONS FOR USE

The DRX9000 True Non-Surgical Spinal Decompression System provides a primary treatment modality for the management of pain and disability for patients suffering with incapacitating low back pain and sciatica. It is designed to apply spinal decompressive forces to compressive and degenerative injuries of the spine. It has been found to provide relief of pain and symptoms associated with herniated discs, bulging or protruding intervertebral discs, degenerative disc disease, posterior facet syndrome and sciatica.

Prescription Use ___ X ___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

[Signature]
(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K060735

Page 1 of ___
SECTION VIII
510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. **Sponsor Identification**
   Axiom Worldwide, Inc.
   9423 Corporate Lake Dr
   Tampa, FL 33634
   Telephone: (813) 249-6444
   Facsimile: (813) 249-6445

2. **Sponsor Establishment Registration Number**
   Establishment Registration Number: 3004378341
   Owner / Operator Number: 9044586

3. **Official Contact Person**
   Jim Gibson
   Telephone: (813) 249-6444
   Facsimile: (813) 249-6445

4. **Device Information**
   Device Trade Name: DRX9000 True Non-Surgical
   Spinal Decompression System
   Common Name: Traction Equipment
   Classification Name: Power Traction Equipment
   Class and Reference: Class II (21 CFR Section 890.5900)
   Product Code: 89 ITH
   Panel Code: 87 ORS

5. **Predicate Devices**
   K022602 DRX3000 – Axiom Worldwide
   K053503 VAX-D Genesis System – VAX-D Medical Technologies

6. **Device Description**
The DRX9000 True Non-Surgical Spinal Decompression System provides
accurately controlled tensions designed to relax and confuse paraspinal muscles and
allow distractive forces to decompress intervertebral spinal disc space. The user
interface provided by the treatment computer constantly updates a servo-amplifier
controlling a servo-motor to immediately and safely apply forces as determined by
qualified healthcare personnel. Load-cell feedback is utilized to further verify and
adjust tensile forces, allowing for variations in patient posture and outside forces
such that continuous and smooth tension is experienced by the patient. The patient
safety switch is held by the patient who at anytime and for any reason may quickly
pause any tensile forces. This patient safety switch is monitored and executed by two redundant systems. Integral to effective spinal decompression and included in the device are continuous load-cell tensile feedback into the treatment computer, dedicated and matched servo-amplifier and servo-motor, smoothly modulated cyclic tension application (high and low tension plateaus transitioned into via non-linear tension change), two segment (upper and lower) textile patient harness, patient safety switch, and free-floating lower body mattress. The free-floating lower body mattress allows the interdiscal segments of the lumbar spine to decompress at their own rate. As tension is cycled, the lower body can extend independent of the upper body which is held in place via an upper body textile patient harness. The treatment bed and textile harness allow the patient to relax completely and require no conscious exertion on the part of the patient. Total patient relaxation encourages paraspinal muscle relaxation from both a physical and psychological standpoint and is a key to spinal decompression.

7. **Intended Use**
The DRX9000 True Decompression System is designed to relieve pressure on structures that may be causing low back pain and sciatica. It relieves the pain associated with herniated discs, degenerative disc disease, posterior facet syndrome and radicular pain. Intervertebral disc decompression is achieved non-surgically through the application of logarithmic distraction tensions applied to the patient according to the Axiom protocol.

8. **Indications for Use**
The DRX9000 True Non-Surgical Spinal Decompression System provides a primary treatment modality for the management of pain and disability for patients suffering with incapacitating low back pain and sciatica. It is designed to apply spinal decompressive forces to compressive and degenerative injuries of the spine. It has been found to provide relief of pain and symptoms associated with herniated discs, bulging or protruding intervertebral discs, degenerative disc disease, posterior facet syndrome and sciatica.

9. **Technological Characteristics**
The Axiom Worldwide DRX9000 True Non-Surgical Spinal Decompression System is essentially the same product as the predicate device (DRX3000). Axiom Worldwide has made some modifications to the appearance and components used in the Axiom Worldwide DRX3000 to provide more accurate application of tension. Each of these changes were evaluated by Axiom Worldwide and found not to impact the safety and effectiveness of this device.

10. **Summary of Safety and Effectiveness**
The DRX9000 True Non-Surgical Spinal Decompression System provides accurately controlled tensions designed to relax and confuse paraspinal muscles and allow distractive forces to decompress intervertebral spinal disc space. Integral to
effective spinal decompression and included in the device are continuous load-cell tensile feedback into the treatment computer, dedicated and matched servo-amplifier and servo-motor, smoothly modulated cyclic tension application (high and low tension plateaus transitioned into via non-linear tension change), two segment (upper and lower) textile patient harness, patient safety switch, and free-floating lower body mattress. An important safety feature is that patients hold a patient safety switch to allow at anytime the pausing of any tensile forces. Axiom Worldwide therapy has been in clinical use since 2002 and has been the subject of clinical studies examining its effectiveness. Axiom Worldwide maintains contact with the clinics administering the therapy, and over the past twelve years, not a single MDR report of injury has been filed, which reflects the inherent safety of the device.
TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER A--GENERAL

PART 56 -- INSTITUTIONAL REVIEW BOARDS

Subpart B--Organization and Personnel

Sec. 56.107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review the specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards or professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with those subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.
(c) Each IRB shall include at least one member whose primary concerns are in the scientific area and at least one member whose primary concerns are in nonscience areas.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB’s initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.