# CLINICAL RESEARCH DATA COLLECTION STUDY

***Cervical Spine Patients Treated with Cox® Technic***

Headed by **Dr. Jerrilyn Cambron** at the National University of Health Sciences Research Department, co-investigator and author of papers regarding the randomized controlled clinical trials comparing flexion-distraction to medical conservative care for low back pain and for neck pain, this study is reliant upon chiropractic physicians proficient in flexion distraction for the cervical spine.



## DESCRIPTION OF STUDY FROM NUHS RESEARCH WEBSITE:

### DOSAGE OF TREATMENT FOR CERVICAL PAIN BY FIELD DOCTORS USING CERVICAL FLEXION DISTRACTION

Principal Investigator: Jerrilyn A. Cambron, D.C., M.P.H., Ph.D.

This project will look at the number of chiropractic visits needed to reach maximum medical improvement in patients with cervical spine pain. The treatments will be given by field clinicians who volunteered to participate in this study; these chiropractors specialize in cervical flexion distraction care. Each field study clinician will recruit up to 10 patients to participate in this study by informing consecutive new neck pain patients about the study. The clinician will examine and treat each patient based on his/her usual and customary treatment protocol. At every visit, the patient and clinician will complete surveys indicating symptoms, diagnosis, and treatment parameters. The patient will complete the study protocol when s/he reaches maximum medical improvement (MMI) equating with complete reduction of pain, return to pre-injury state, or three months of care (whichever comes first). At no time during the patient's treatment period will s/he receive experimental treatments or a modified treatment schedule because of participation in this study. The data will be descriptively analyzed to assess the number of treatments necessary to MMI and any associated factors leading to a reduction in the time to MMI such as patient demographics or clinical symptoms, radicular/non-radicular symptoms, or treatment parameters. The number of treatments that each neck pain patient receives in a chiropractic office is thought to be dependent on many factors. However, no study has measured the number of cervical flexion distraction treatments to MMI in patients with neck pain nor defined the factors that might influence the number of treatments.

Funding: Internal

*(Continued from page 1)*

## FROM DR. CAMBRON:

***Thank you for your involvement. Dr. Cox and I are excited for this opportunity to work with you.***

***This project is very important to the profession in that we will look at the number of chiropractic visits needed to reach maximum medical improvement (MMI) in patients with cervical spine pain. The number of treatments that each neck pain patient receives in a chiropractic office is thought to be dependent on many factors. However, no study has measured the number of cervical distraction treatments to MMI of neck pain nor defined the factors that might influence the number of treatments.***

***We realize that it is some paperwork; however, the results of this study will greatly outweigh the difficulties in getting this study started.***

***This study will be very important to the profession, and it is exciting to have you all involved! If you have any questions at all , please feel free to contact me at any time.***

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## REQUIREMENTS OF PARTICIPANT CHIROPRACTORS:

National University of Health Sciences and the IRB have approved this study (3/27/07).

### *1— Protection of Research Subjects Training*

The IRB has asked that all of you are trained in protection of research subjects. This training is (1) online, (2) provided by the government, (3) at no cost, (4) takes about an hour to complete, and (5) explains the international and national regulations regarding the use of research subjects. It is mandatory that all clinicians who want to be involved in this study to go through Human Subjects' Protection training.

**NEEDED:** To complete this training, please go to http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp and register as a new user. Again it does not cost anything. Registration is so you can receive a certificate with your name on it when you have completed the course. After you register, go through each section and take the quiz at the end of the section. If you get any wrong, it will explain to you the correct answer and will still allow you to continue with the process (no 'grades' are given out at the end!). Once you complete all sections and receive the certification, please send a copy of this certificate to me. You can either print it out and mail it, print it and fax it, scan it and email it, print screen and email a Word document of it, or cut/past it into Word and email it. Anyway you can get it to Dr. Cambron is fine.

### *2 —Informed Consent of Participating Doctors*

This consent form explains the study and informs you of your rights as a study participant (clinician). This is *not the same informed consent form that the patients will sign*. The patient's informed consent forms will be mailed to you.

**NEEDED:** Your signature on the page that follows. (pages 4-5)

### *3– Physician's Agreement Form*

This form defines your role as a clinician within this study as well as the role of the University.

**NEEDED:** Your signature on the page that follows. (pages 6-7)

### *4—Proof of Malpractice Insurance*

Proof of insurance is usually a one page form defining the insurance coverage for the defined physician.

**NEEDED:** For the University, a copy of this information can be **mailed or faxed directly to Dr. Cambron**.

*Once we receive these two signed forms and a copy of your malpractice insurance, we will mail you the directions and forms necessary to get started with data collection.*

*Version Date: 03/25/2007*

**National University of Health Sciences**
**Individual Clinician Agreement**

**Research Project Covered by this Agreement:**
__Dosage of treatment for neck pain_____

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Participation in the National University of Health Sciences (NUHS) research study is voluntary, although practitioners with particular practice characteristics may be invited to participate in order to meet the goals of specific projects. Participation does not signify any official relationship or formal business partnership between NUHS and the practitioners involved.

***All participating practitioners are required to sign this agreement specifying the conditions of their participation before they take part in any program activities.***

**Practitioners** who sign this form agree that they will:

1. Be currently licensed under the law(s) or the jurisdiction in which s/he practices;
2. Provide written evidence, to the satisfaction of the University, of current malpractice insurance coverage in the amount of at least $200,000-$600,000;
3. Have no record of license or disciplinary sanctions during the last three (3) years or any conviction or plea of nolo contendere to any offense, whether felony or misdemeanor, which is substantially related to the practice of chiropractic;
4. Complete an annual training session on human subjects protection and submit the associated certificates;
5. Comply with: (1) the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects Research (or other international equivalent), (2) the US Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46, and (3) the relevant NUHS policies and procedures for the protection of human subjects;
6. Comply with all federal, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement;
7. Follow all data collection and return protocols as accurately and completely as possible;
8. Maintain patient confidentiality, return signed informed consents and all other forms with no patient identifiers except research identification numbers to the NUHS Department of Research;
9. Immediately report any unanticipated problems involving risks to subjects within this study;
10. Acknowledge that you (the practitioner) are primarily responsible for safeguarding the rights and welfare of each research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of the research;

11. Hold NUHS harmless from any loss, claim, damage, or liability;
12. Communicate with NUHS if significant changes in a practice occur during your study participation (such as moving or discontinuing practice);
13. Obtain written approval from the Principal Investigator for release of information to the public relating to the research study prior to such release, except for the use of approved press releases provided by the NUHS;
Not use the project to recruit patients, as such use is strictly prohibited by the NUHS Department of Research.

The **NUHS Department of Research** agrees to fulfill these obligations to participating practitioners:

1. Protect patient confidentiality, using only research identification numbers on all forms except for informed consent forms;
2. Protect practitioners' confidentiality, both in routine data collection and reporting;
3. Provide necessary training in human subjects' protection through NUHS or other approved methods;
4. Communicate with practitioners regularly and if significant changes in the research study occurs;
5. Provide a summary report at the end of each project;

Acknowledge practitioners participation as a group in all resultant publications and provide practitioners with a copy of the publication.

| | |
|---|---|
| _____ | _____ |
| Practitioner's Signature | Principal Investigator's Signature |
| _____ | _____ |
| Practitioner's Name (please print) | Principal Investigator's Name (please print) |
| _____ | _____ |
| Date | Date |

| OFFICE USE ONLY |
| --- |
| **Clinician ID:** |

# CONSENT TO PARTICIPATE IN STUDY ON PRACTICE CHARACTERISTICS FOR NEW NECK PAIN PATIENTS

We invite you to participate in a study being conducted through the National University of Health Sciences (NUHS). Your decision whether or not to take part in this study will not affect your relationship with NUHS in any way.

**Purpose of the Study**

The purpose of this study is to gather information about chiropractic treatment for patients with cervical pain, and to assess how diagnosis relates to the number and type of treatments provided by the physician. We will stratify (divide) the data based on many factors, including treating clinician. Therefore, your information will be assessed separately from other clinicians to determine variability in treatment styles. However, your name will not be associated with any of the data you provide. You are being asked to participate because you are a chiropractic physician certified in the Cox cervical distraction technique.

## What will we ask you to do?

If you agree to participate as a treating clinician in this study, we will ask you to complete a training certificate on human subjects' protection prior to discussing this study with any patients. If you agree to participate, you will be asked to recruit ten of your new neck pain patients to participate in this study. The care rendered to this patient will be your usual and customary care, and we will not ask you to provide any experimental treatments. Only patients who are interested in and eligible to participate should participate. We will also instruct you on all study tasks including: administering an informed consent to eligible patients, collecting survey information on eligible and interested patients during each treatment visit for up to three months of patient participation, providing specific diagnostic and treatment information, and entering all data into an online data collection site after each visit. The type and timing of the treatments you provide to your patients should not be modified just because you are participating in this study. We are interested in your usual and customary treatment protocol, and do not want this study to influence your treatment decisions.

**Potential Risks and Benefits of this study**

There are no health risks to you or your patients directly related to participation in this study. All health risks are based on your usual and customary treatments and do not directly involve this study.

There are no immediate or direct benefits to you for your participation. However, the chiropractic profession may benefit from learning best practices for cervical spine pain. No study has measured the number of cervical flexion distraction treatments to maximum medical improvement or defined the factors that may influence the number of treatments. The results of this study may lead to larger, more developed studies and eventually to a standardized treatment for patients with uncomplicated cervical spine pain.

It will take you about 20 minutes to administer the informed consent and collect a demographic survey from each patient (one time only) and the follow-up questions for you to complete after each visit will take about 3 minutes per visit. All data entered into the online database should not take longer then 5 minutes of your time per patient visit.

## Assurance of Confidentiality

Your information, as well as, you patients' information, will be considered completely confidential and will be used for research purposes only. You and your patients will each be assigned a research number that will be used on every survey form. Only designated personnel associated with the research study will have access to your data, but information may be disclosed as required by the law. All research data

will be maintained in a special room where only research personnel have access to the data. You will never be individually identified in the published results.

**Right to Refuse or Withdrawal**

Your participation in this research study is entirely voluntary. You are free to refuse to take part in this study and free to withdraw your consent and discontinue participation at any time without any effect on your relationship with NUHS.

**Questions?**

If you have any questions about this study, you may speak with the Principal Investigator of this study, Dr. Jerrilyn Cambron, at (630) 889-6853. If you have any questions about your rights as a research participant you may also speak with the chair of the NUHS Institutional Review Board, Dr. Ezra Cohen, at (630) 889-6846, who oversees protection of all people involved in research.

## Statement of Consent

Your signature indicates that you have read and understand the above information, had all questions answered to your satisfaction, and you decided to participate in this research study.

Signature of Clinician:_____

Printed name: _____ Date: _____