Subject Name: _____ Date: _____

Title of Study: Benefit of lumbar bracing for chronic low back pain due to degenerative disc disease; #15-088

Principal Investigator: Dr. Thiru Annaswamy

Key Member(s): Karen Schwarm, DPT

Coordinator: Mitchell Kroll, MS

Before agreeing to take part in this research study, it is important that you read and understand the proposed research explained below. It describes the procedures, benefits, risks and discomforts of the study. It also describes other treatments that are open to you and your right to withdraw from the study at any time. It is important for you to understand that no promises can be made about the results of the study.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

1. WHAT IS THIS RESEARCH STUDY ABOUT?

The purpose of this research is to evaluate the benefits of back braces in managing the symptoms of patients with chronic low back pain (CLBP) due to degenerative lumbar disc disease. You have been invited to participate in this research study because it has been determined that you have uncomplicated CLBP.

The expected duration of your participation is 6 months.

The approximate number of research subjects involved in this study is 120.

Aspen Medical Products, the manufacturer of study back brace, is providing support and funding for this study.

2. WHAT WILL HAPPEN DURING THE STUDY?

During the baseline visit, patients will complete the following questionnaires and assessments:

1) Pain diary for 7 days prior to visit

SUBJECTS IDENTIFICATION (last name, first, middle and full SSN)

2) The Pain Disability Questionnaire (PDQ)

3) PROMIS instruments that will include: pain interference, pain behavior, pain intensity, physical function, emotional distress- depression, fatigue, sleep disturbance, satisfaction with social roles and activity, social isolation, global health scale and PROMIS-29 profile.
4) European Quality of Life (EQ-5D) questionnaire, which is composed of 5 questions on quality of life.
After the baseline assessment, you will be randomized either to the treatment group or to the control group.

Control group: Control group patients will participate in a 2-week back school program which provides basic education at improving their ability to self-control and self-manage their chronic low back pain symptoms.

Treatment group: Patients in the treatment group will be provided a back brace.. The prescribed brace will be the same standardized orthotic for all study patients, throughout the study period. After the fitting of the brace, treatment group patients will participate in the same 2-week back school program as the control group.

You will be instructed to wear the brace during work (if applicable) or during their typically symptomatic periods. Wear the brace at least once a day-for 30-minutes, up to 6 hrs/day (maximum). The back brace will be replaced within the study period for any unusual wear/tear as necessary.

You will be provided with a diary in which you will document the number of hours you wore the brace on each day and document adverse events, if any. All control group patients will be asked to document in a diary their pain and exercise routine.

Study patients will be assessed at the following time points:

Baseline – completing the questionnaires and assessments as explained above.

3 Weeks – All study patients will receive a brief phone call to assess any reports of adverse events. At this time, the treatment group will be able to discuss concerns of your brace wear, as well.

6 Weeks - All study patients will be re-assessed on all questionnaires and assessments from the baseline visit.

12 Weeks and 6 Months – All study patients will be re-assessed on all questionnaires and assessments. Patients will also disclose if any other interventions or treatments were done to alleviate their pain. Patients will be requested not to undergo any additional treatments and interventions during the 6-week period after the baseline appointment. We will coordinate with your spine & pain clinic providers as well as with your primary care clinics to ensure compliance with the study protocol during this period.

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3. WHAT ARE MY RISKS?

You might experience minor pain and discomfort while participating in this study. Some patients may feel like they are labeled as a person with a disability or a disabling condition while wearing the back brace. The overall classification for the research is considered minimal.

Unforeseen risks: A previously unknown problem could result from your taking part in this research. It is not possible to estimate the chances of such problems or how serious the problems could be. Any new findings will be given to you that may affect your willingness to take part in this study. If new findings are discovered, you will be asked to sign a new (updated) informed consent form to document that new information provided in the updated Consent Form has been explained to you.

4. WILL THE RESEARCH BENEFIT ME OR OTHERS?

This study may not make your health better. However, the potential benefit(s) may be pain relief, increased mobility, improved quality of life, or the decreased need for pain medication, doctor visits and further treatments.

5. WHAT ARE MY ALTERNATIVES TO BEING A RESEARCH SUBJECT?

You do not have to be in this study to receive treatment for your condition. Your other choices may include bed rest, pain management with oral medications, changing your activity, physical therapy, invasive spine surgery, or injection of pain medication. You should talk to the researcher and your regular physician about each of your choices before you decide if you will take part in this study.

6. WILL I GET PAID?

If you finish the study, you will be paid $50. If you start but stop before finishing the study, you will receive only a portion of this money. We will pay you $25 for completing baseline

questionnaires and $25 at the study completion. We will send you a payment after completion of each of the above time points.

Your Name, mailing address and Social Security Number must be disclosed to DVARC employees in order to process any payments to you.

7. WILL I HAVE TO PAY?

Subjects do not pay for treatment associated with participation in a VA research program.

8. DOES BEING PREGNANT OR THE POSSIBILITY OF BEING PREGNANT PREVENT ME FROM TAKING PART?

Every effort will be made to have females enter this study on an equal basis with male subjects. Medically accepted birth control is needed to enter this study. This includes, but is not limited to: abstinence, birth control pills, IUD's, condoms, diaphragms, implants, being surgically sterile, or being in a post-menopausal state. However, no birth control method completely prevents pregnancy. If you become pregnant there may be a high risk of miscarriage, birth defects or other problem for the fetus. If you are female and of child bearing age, you must have a negative pregnancy test before starting the study.

9. WHAT IF I GET INJURED?

The VA has the obligation to provide medical treatment to participants injured by participation in a VA study. If you are injured as a result of being in this study, the VA will provide the necessary medical treatment in accordance with federal law.

10. ARE MY RESEARCH RECORDS SAFE FROM THE PUBLIC?

The study doctors keep your research records private in the same way as your other medical records. No one has access to your records except as required by law. You are, however, authorizing Aspen Medical Products, The Foundation of Physical Medicine and Rehabilitation, the Dallas VA Institutional Review Board (IRB), the Dallas VA Research and Development Committee and the members of the Dallas VA Research Office to inspect your medical and research records.

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These committees, people, and offices at the Dallas VAMC are responsible for overseeing human research studies.

If you choose to take part in the study, certain government agencies (such as the FDA or VA) may look at your research records. Your name as a subject in this study is private, and will not be included in any report prepared as a result of this study.

11. DO I HAVE TO TAKE PART IN THIS STUDY, OR CAN I WITHDRAW FROM THE STUDY?

Taking part in this study is voluntary and you may refuse to take part without penalty or loss of benefits to which you are otherwise entitled. You are free to withdraw your consent and stop taking part at any time. Not taking part in the study will in no way affect the quality of care you receive now or in the future from the VA. This will also not affect your right to take part in other studies. The study doctors will answer any questions you may have about the study.

Your doctor may also take you out of the study without your consent for medical or administrative reasons. Any significant new findings that develop during the course of the research study that the study doctor thinks may affect your willingness to continue to take part will be given to you as soon as possible.

12. WHOM SHOULD I CONTACT FOR QUESTIONS OR PROBLEMS?

If you have any questions about this study or have any bad effects of your treatment, you should call the study doctor at 214-857-0273 or a member of the research team at 214-857-1544. You should also contact the study doctor or a member of the research team to discuss problems, concerns you may presently have, or offer input about the research.

If you have any questions about whether this is a VA North Texas Healthcare System-approved research study, you may contact the Research Compliance Officer at 214-857-0341.

If you have any questions about your rights as a patient, complaints about your treatment or general concerns about the conduct of the research study, of if you have questions, complains, concerns you may contact the Dallas VAMC Patient Representatives at 214-857-0482. The Patient Representative will guide you in resolving your question or complaint.

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If you have a medical emergency you should immediately call 911 for assistance.

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RESEARCH SUBJECT'S RIGHTS:

I have read or have had read to me all of the above. The study has been explained to me and all of my questions have been answered. If I have questions later, it has been explained to me that I can contact Dr. Annaswamy. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment open to me.

It has been explained to me that I do not have to take part in this study and my refusal to take part will involve no penalty or loss of rights to which I am entitled. I may withdraw at any time without penalty or loss of VA or other benefits to which I am entitled. The study doctor can take me out of the study at any time if it appears to be medically harmful to me, if I fail to follow directions for taking part in this study, if it is discovered that I do not meet the study requirements, or if the study is canceled.

In case there are medical problems or questions, I have been told I can call Dr. Annaswamy at 214-857-0273 during the day or at 800-725-4436 after hours.

I was informed of my rights as a research subject, and I voluntarily consent to take part in this study. I authorize the use of my identifiable patient health information as described in this form. I will receive a signed copy of this consent form.

_____ _____

Participant's Signature Date

_____ _____ _____

Name of person obtaining consent Signature of person obtaining consent Date

Research Subject's Bill of Rights

1. Be informed of the nature and purpose of the research.

2. Be clearly told of the procedures to be followed in the medical research, and any drug or device to be used.

3. Be clearly told of any discomforts and risks that might be expected from the research.

4. Be clearly told of any benefits that the patient might expect from the research.

5. Be clearly told of any other appropriate procedures, drugs, or devices that might be helpful to the patient, and their risks and benefits.

6. Be clearly told how to get medical treatment, if needed, after the research is finished if problems should arise.

7. Be given the chance to ask any questions about the research or the procedures involved.

8. Be clearly told that consent to take part in the medical research and/or release of identifiable patient health information may be taken back at any time. The patient may stop taking part in the medical research without any penalty or loss of VA or other benefits.

9. Be given a copy of the signed and dated written consent form.

10. Be given the chance to decide to consent or not to consent to a medical research study without any force, fraud, deceit, duress, coercion, or undue influence on the patient's decision.