Kevin P. McCarthy, M.D., Baton Rouge, Louisiana, United States
ER-001
20120255

RESEARCH SUBJECT INFORMATION AND CONSENT FORM	
TITLE:	ER-001: Prospective analysis of pain and functional outcomes after lumbar rhizotomy assisted by direct endoscopic visualization, a novel approach to nerve ablation in the zygapophysial joint.

This consent form contains important information to help you decide whether to participate in a research study.

The study staff will explain this study to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family or friends.

- **Being in a study is voluntary – <u>your choice</u>.**
- **If you join this study, you can still <u>stop at any time</u>.**
- **<u>No</u> one can <u>promise</u> that a study will help you.**
- **Do not join this study unless all of your <u>questions</u> are <u>answered</u>.**

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the study;
- Any possible benefits to you;
- The possible risks to you;
- Other options you could choose instead of being in this study;
- How your personal health information will be treated during the study and after the study is over;
- Whether being in this study could involve any cost to you; and
- What to do if you have problems or questions about this study.

<u>Please read this consent form carefully.</u>

APPROVED
AS MODIFIED
Aug 21, 2013
WIRB®

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: ER-001: Prospective analysis of pain and functional outcomes after lumbar rhizotomy assisted by direct endoscopic visualization, a novel approach to nerve ablation in the zygapophysial joint.

PROTOCOL NO.: ER-001
WIRB® Protocol #20120255

SPONSOR: Kevin P. McCarthy, M.D.

INVESTIGATOR: Kevin P. McCarthy, M.D.
7301 Hennessy Blvd.
Baton Rouge, Louisiana 70808
United States

SITE(S): Bone and Joint Clinic of Baton Rouge
Suite 200
7301 Hennessy Blvd.
Baton Rouge, Louisiana 70808
United States

STUDY-RELATED PHONE NUMBER(S): Kevin P. McCarthy, M.D.
225-776-0050 (24 hours)

Adaire O'Brien
225-766-0050 ext. 5096

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

SUMMARY

You are being asked to be in a research study. The purpose of this consent form is to help you decide if you want to be in the research study. Please read this form carefully. To be in a research study you must give your informed consent. "Informed consent" includes:

- Reading this consent form,
- Having the study doctor or staff explain the research study to you,
- Asking questions about anything that is not clear, and
- Taking home an unsigned copy of this consent form. This gives you time to think about it and to talk to family or friends before you make your decision.

You should not join this research study until all of your questions are answered.

Things to know before deciding to take part in a research study:

- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.
- Parts of this study may involve standard medical care. Standard care is the treatment normally given for a certain condition or illness.
- After reading the consent form and having a discussion with the research staff, you should know which parts of the study are experimental and which are standard medical care.
- Your medical records may become part of the research record.
- Your medical insurance may be billed for any standard medical care you receive during the research study.

If you take part in this research study, you will be given a copy of this signed and dated consent form.

PURPOSE OF THE STUDY

The purpose of this study is to examine subject outcomes following Endoscopic Rhizotomy through subject questionnaires administered at normal post-operative visits.

You are being invited to participate in this study because your low back pain has not resolved with conservative treatment and you are eligible for a diagnostic medial branch nerve block. Good pain relief after a diagnostic nerve block may help determine if you are a good candidate for Endoscopic Rhizotomy.

Rhizotomy is a minimally invasive, outpatient spine procedure in which the portion of the nerve root that is pinched and causing your pain is removed with a radiofrequency probe.
Dr. McCarthy routinely performs this procedure with the help of direct visualization with an endoscope in his practice**.** None of the study procedures are experimental.

PROCEDURES
If you participate in this research study, you will be asked to take part in some or all of the activities listed in order of occurrence below.

- **Screening Office Visit**
  - Physical Examination
  - Sign Informed Consent
  - Schedule diagnostic nerve block
- **Diagnostic Facet Nerve Block**
  - You will receive an injection of pain medication (local anesthetic) in your back performed under IV conscious sedation (standard procedure)
  - 1 hour after the injection, in a designated recovery area, you will be asked to rate your pain improvement on a four-step scale.
  - Depending on your relief from this injection, you may be offered the rhizotomy procedure. If so, you will return to clinic to complete baseline questionnaires and sign your surgery consent forms.
- **Pre-operative Clinic Visit with Dr. McCarthy**
  - In addition to standard pre-surgical planning, you will complete pain and disability questionnaires (Visual Analog Scale and Oswestry Disability Index)
- **Operative Visit**
  - Dr. McCarthy will perform endoscopic rhizotomy at the appropriate spinal levels. This is an outpatient procedure performed under IV conscious sedation with fluoroscopic (x-ray) and endoscopic guidance. (standard procedure)
- **Week 2 Post-Operative Visit**
  - In addition to standard post-operative examination, you will complete pain and disability questionnaires.
- **Week 6 Post-Operative Visit**
  - In addition to standard post-operative examination, you will complete pain and disability questionnaires.
- **Month 3 Post-Operative Visit**
  - In addition to standard post-operative examination, you will complete pain and disability questionnaires.

RISKS AND DISCOMFORTS
The risks of participating in this study should be no greater than receiving the standard diagnostic injection and the rhizotomy procedure outside of the study. You will sign separate standard consent forms for these procedures. The only discomfort may be the additional time required to answer the subject questionnaires at operative and post-operative visits. This will require about 10 minutes at each office visit and 5 minutes after the injection.

Women who are pregnant or nursing a child may not take part in this study. If you think that you have gotten pregnant during the study, you must tell your study doctor immediately. Pregnant women will be taken out of the study.

NEW INFORMATION
You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

BENEFITS
It cannot be promised that you will receive any medical benefits from being in this study, but your participation may help future patients.

COSTS
You or your insurance company will be billed for:

- All injections, procedures and office visits listed in this study, because all of these treatments are standard procedures.
- Any additional standard medical care given during this research study.

If your insurance company does not pay, you may be billed for these charges.

ALTERNATIVE TREATMENT
If you decide not to enter this study, there is other care available to you. You may receive the diagnostic injection and the rhizotomy procedure outside of this study. The study doctor will discuss your options with you. You do not have to be in this study to be treated for your back pain.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits.

Who may use and give out information about you?
The study doctor and the study staff.

Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Western Institutional Review Board® (WIRB®)

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to see if the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?

- Yes, but this permission will not stop automatically.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Your participation in this study may be stopped at any time by the study doctor without your consent for any of the following reasons:

- if it is in your best interest;
- you do not consent to continue in the study after being told of changes in the research that may affect you;
- or for any other reason.

QUESTIONS
Contact Dr. McCarthy or Adaire O'Brien at (225) 766-0050 ext. 5096 for any of the following reasons:

- if you have any questions about this study or your part in it, or
- if you have questions, concerns or complaints about the research

Contact Dr. McCarthy at (225) 766-0050 (24 hours) for the following reason:

- if you feel you have had a research-related injury.

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
Olympia, Washington 98502
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com.

WIRB is a group of people who independently review research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

CONSENT
I have read this consent form. All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above

By signing this consent form, I have not given up any of my legal rights.

_____
Subject Name (printed)

CONSENT SIGNATURE:

_____ _____
Signature of Subject (18 years and older) Date

Attestation Statement

I confirm that the research study was thoroughly explained to the subject. I reviewed the consent form with the subject and answered the subject's questions. The subject appeared to have understood the information and was able to answer the following questions correctly:

1. What is the purpose of this study?
2. If you decide to be in the study, what will you be asked to do?
3. What is the possible benefit of participating in this study?
4. What are the possible risks of participating in this study?
5. If you decide not to participate in this study, what options do you have?
6. Will participating in this study cost you anything? If so, what will you have to pay for?
7. Do you have to be in this study?
8. If you decide to be in the study, can you leave the study when you want to?

_____	_____
Printed Name of Person Conducting the Informed Consent Discussion	Position
_____	_____
Signature of Person Conducting the Informed Consent Discussion	Date