INFORMED CONSENT FORM TO PARTICIPATE AND AUTHORIZATION FOR RESEARCH

TITLE OF RESEARCH:

A Randomized, Double-Blind, Placebo-Controlled Study of Neuromuscular Electrical Stimulation (NMES) use for Recovery After Elective Total Hip Replacement Surgery

A. PURPOSE OF THE STUDY:

You are being asked to volunteer in a research project. This consent/authorization form includes information about this study. The purpose of this study is to determine how safe and effective a device delivering neuromuscular electrical stimulation (NMES) after hip surgery will be to improve recovery.

You are being asked to participate in this study because you recently underwent hip surgery.

B. SUBJECT PARTICIPATION:

We estimate that the following number of subjects will enroll in this study:
At this site: 40 Total at all sites: 40

SUBJECT PARTICIPATION:
X Inpatient
X Outpatient

Your participation will take place over your inpatient stay here at Rusk until your 6 week post-op follow up visit (4 weeks after discharge).

The device will be used daily for two 20 minute sessions, beginning in Tisch hospital after your epidural is removed, and self-administered through the end of the study. Research staff will teach you how to use the device.
C. DESCRIPTION OF THE RESEARCH:

If you have undergone recent hip surgery, then you will be asked to participate in this study. If you agree to participate, you will be randomly selected (somewhat like the flip of a coin) to either be placed on the NMES device during your inpatient stay following your surgery or to receive the trainer of the device. Both devices will look the same, the sticker electrodes will be placed on the affected hip which will then receive stimulation from the unit. If you are placed in the group not receiving the device, you will have the trainer of the device placed on you; the trainer will be unable to deliver the level of electrical stimulation that we are testing. The NMES (neuromuscular electrical stimulation) device is FDA approved for pain management, and you may or may not feel delivery of electrical stimulation.

We will place the device on your hip. We will be conducting routine physical therapy that you would have received with or without the device. The physical therapist working with you will note any observations regarding pain, as well as you will be asked about the pain you are feeling. At any point, if you feel any discomfort or pain, you can ask the healthcare practitioner with you to remove the device. If you choose to withdraw from the study, you can contact the principal investigator. You can withdraw at any point and it will not affect the ongoing care you receive.

D. COSTS/REIMBURSEMENTS:

The DJO, LLC is providing the neuromuscular electrical stimulation (NMES) free of charge to participating research subjects.

You will be receiving medical care as a part of this research study. You or your insurance company will be charged or held responsible for the costs of that care. Some of these tests would have been done as part of regular care. You or your insurance carrier will be charged or held responsible for the costs of that care. Your individual insurance or government health insurance program may not cover certain services, items or procedures. You may want to discuss this with your insurance carrier in advance. You will be responsible for any co-payments and/or deductibles for services rendered.

All study-related costs associated with your being in this study will be paid by the DJO, LLC.

You or your insurance company will not be charged or held responsible for the costs outside of your routine care.

The sponsor of this study DJO, LLC, is paying New York University to perform this research.

2 of 9  Subject’s Initials: _____________  Date: _____________

(IRB Official Use Only)
This Consent Document is approved for use by the New York University’s Institutional Review Board (IRB).
Only the IRB-stamped approved form may be used.

Approved: From: 04/05/2010 To: 05/28/2010
The study expiration date applies for this form
Template rev. date: 11-09
Revised Consent NMES 09_002.doc

NYUSOM
IRB APPROVED
E. POTENTIAL RISKS AND DISCOMFORTS:

The following are risks and discomforts that you may experience during your participation in this research study. The NMES device has minimal risks: no physical injury, psychological, social or economic harm, discomfort or inconvenience, or breach of confidentiality is foreseen.

If any physical or psychological discomfort is experienced, or you no longer want to participate in the study, you can withdraw at any point and it will not affect the ongoing care you receive.

F. POTENTIAL BENEFITS:

This research study is designed to select by chance which treatment you will receive. It is not known if the treatment you will receive will be of benefit to you. There may be no direct benefit from agreeing to participate in this study.

G. ALTERNATIVES TO PARTICIPATING IN THE STUDY

You do not have to participate in this study to receive ongoing care for your condition. You can continue with the standard of care provided at Rusk Institute.

H. CONFIDENTIALITY:

Private information about you that identifies you may be used or shared for the purposes of this research project. This section of the consent/authorization form describes how your information will be used and shared in this research, and the ways in which NYU School of Medicine will safeguard your privacy and confidentiality.

If you agree to be in this research program, Dr. Alex Moroz and his study team will ask you to consent to placing a NMES device on you during your inpatient stay at Rusk. Some of these tests would have been done as part of your regular care. He will use is device to both treat you and to complete this research. The results of these tests will be kept in your medical chart and will be reported to DJO, LLC. Results of tests and studies done just for this research study and not as part of your regular care will also be included in your medical record.

Other persons and organizations, including co-investigators, federal and state regulatory agencies, and the IRB(s) overseeing the research may receive your information during the
Institutional Review Board  
NYU School of Medicine  

This Consent Document is approved for use by the New York University’s Institutional Review Board (IRB).  
Only the IRB-stamped approved form may be used.  

Approved: From: 04/05/2010 To: 05/28/2010  
The study expiration date applies for this form  
Template rev. date: 11-09  
Revised Consent NMES 09_002.doc  

Confidentiality of Your Medical Records  
Your medical records will be kept in accordance with state and federal laws concerning the privacy and confidentiality of medical information. If your participation in this research is for treatment or diagnostic purposes, the facility in which you are treated may ask you to sign a separate informed consent document for specific procedures or treatment, and that informed consent form may be included in the medical record of that facility. The confidentiality of your medical record is also protected by federal privacy regulations, as described below.  

Confidentiality of Your Study Information  
Your study records include information that identifies you and that is kept in research files. We will try to keep this information confidential, but we cannot guarantee it. If data from this study are to be published or presented, we will first take out the information that identifies you.  

Retention of Your Study Information  
The study results will be kept in your research record for at least six years or until after the study is completed, whichever is longer. At that time either the research information not already in your medical record will be destroyed or information identifying you will be removed from such study results at NYU. Any research information in your medical record will be kept indefinitely.  

Your HIPAA Authorization  
A new federal regulation, the federal medical Privacy Rule, has taken effect as required by the Health Insurance Portability and Accountability Act (HIPAA). Under the Privacy Rule, in most cases we must seek your written permission to use or disclose identifiable health information about you that we use or create [your “protected health information”] in connection with research involving your treatment or medical records. This permission is called an Authorization.  

If you sign this form you are giving your Authorization for the uses and sharing of your protected health information described below. You have a right to refuse to sign this form. If you do not sign the form you may not be in the research program, but refusing to sign will not affect your health care (or payment for your health care) outside the study.  

This Authorization will not expire unless you withdraw it in writing. You have the right to withdraw your authorization at any time, except to the extent that NYU has already relied upon
Institutional Review Board
NYU School of Medicine

it or must continue to use your information to complete data analysis or to report data for this study. The procedure for revoking your authorization is described below in Section K.

By signing this form you authorize the use and disclosure of the following information for this research:

- Your medical records
- Your research record
- Results of laboratory tests
- Clinical and research observations made during your participation in the research

By signing this form you authorize the following persons and organizations to receive your protected health information for purposes related to this research:

- Every health care provider who provides services to you in connection with this study
- Any laboratories and other individuals and organizations that analyze your health information in connection with this study in accordance with the study’s protocol
- The members and staff of the hospital’s affiliated Institutional Review Board
- The members and staff of the hospital’s affiliated Privacy Board
- Principal Investigator: Alex Moroz, MD
- Study Coordinator
- Members of the Research Team
- The Patient Advocate or Research Ombudsman (CTSI)
- Members of the NYU/NYUMC Clinical Trials Office/Office of Research and Sponsored Programs
- Contract Research Organization (Name: DJO, LLC)
- Data Safety Monitoring Board/Clinical Events Committee

If any of the companies or institutions listed above merges or is sold during the course of this research, your Authorization will cover uses and disclosures of your protected health information to the new company or institution that assumes responsibility for the research.

Please be aware that once your protected health information is disclosed to a person or organization that is not covered by the federal medical Privacy Rule, the information is no longer protected by the Privacy Rule and may be subject to redisclosure by the recipient.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is prohibited from redisclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (212) 480-2493 or the New York City Commission of Human Rights at (212) 306-7450. These agencies are responsible for protecting your rights.
I. COMPENSATION/TREATMENT IN THE EVENT OF INJURY:

All forms of medical (or mental health) diagnosis and treatment – whether routine or experimental – involve some risk of injury. In addition, there may be risks associated with this study that we do not know about. In spite of all precautions, you might develop medical complications from being in this study.

If you sustain any injury during the course of the research or experience any side effect to a study drug or procedure, please contact the Principal Investigator Dr. Alex Moroz at the following telephone number 212-263-6037. If such complications arise, the study doctor will assist you in obtaining appropriate medical treatment but this study does not provide financial assistance for medical or other injury-related costs. You do not give up any rights to seek payment for personal injury by signing this form.

J. VOLUNTARY PARTICIPATION AND AUTHORIZATION:

Your decision as to whether or not to take part in this study is completely voluntary (of your free will). If you decide not to take part in this study it will not affect the care you receive and will not result in any loss of benefits to which you are otherwise entitled.

You will be told of any significant new findings developed during the course of the research that may influence your willingness to continue to participate in the research.

Your decision as to whether to give your Authorization for the use and disclosure of your protected health information for this study is also completely voluntary; however, if you decline to give your Authorization or if you withdraw your Authorization you may not participate in the study.

K. WITHDRAWAL FROM THE STUDY AND/OR WITHDRAWAL OF AUTHORIZATION:

...
If you decide to take part in the study, you may withdraw from participation at any time without penalty or loss of benefits to which you would otherwise be entitled. You may also withdraw your Authorization for us to use or disclose your protected health information for the study. If you do decide to withdraw your consent, we ask that you contact Dr. Alex Moroz and let him know that you are withdrawing from the study. His mailing address is 400 E. 42nd Street, 6th Floor Department of Rehabilitation, New York, New York, 10016. If you wish to withdraw your Authorization as well you must contact Dr. Alex Moroz in writing.

Remember that withdrawing your Authorization only affects uses and sharing of information after your written request has been received, and you may not withdraw your Authorization for uses or disclosures that we have previously made or must continue to make to complete analyses or report data from the research.

The Principal Investigator or another member of the study team will discuss with you any considerations involved in discontinuing your participation in the study. You will be told how to withdraw from the study and may be asked to return for a final check-up.

The study doctor may also decide to withdraw you from the study for certain reasons. Some possible reasons for withdrawing a subject from the study would be worsening health or other conditions that might make it harmful for you.

(a) failure to keep appointments, follow directions or take medications as instructed
(b) a serious adverse reaction to drug therapy
(c) the need for treatment that is not allowed in the study
(d) termination or cancellation of the study by study sponsor.

L. PERMISSION TO CONTACT YOU ABOUT FUTURE RESEARCH:

I authorize the principal investigator and his or her co-investigators to contact me about future research on the NMES device within the Department of Rehabilitation provided that this future research is approved by the original IRB of record and that the principal investigator and co-investigator are affiliated with the research protocol.

If I agree, then someone from Dr. Alex Moroz’s research staff might contact me in the future and he or she will tell me about a research study. At that time, I can decide whether or not I am interested in participating in a particular study. I will then have the opportunity to contact the researcher to schedule an appointment to be fully informed about the research project.

☐ I agree to be contacted by the Principal Investigator or Co-Investigators of the research

7 of 9  Subject’s Initials: ______________  Date: ______________

(IRB Official Use Only)
This Consent Document is approved for use by the New York University’s Institutional Review Board (IRB). Only the IRB-stamped approved form may be used.

Approved: From: 04/05/2010 To: 05/28/2010
The study expiration date applies for this form
Template rev. date: 11-09
Revised Consent NMES 09_002.doc
study titled: A Randomized, Double-Blind, Placebo-Controlled Study of Neuromuscular Electrical Stimulation (NMES) use for Recovery After Elective Total Hip Replacement Surgery

☐ I do not want to be contacted by the Principal Investigator or Co-Investigator of the research study titled: A Randomized, Double-Blind, Placebo-Controlled Study of Neuromuscular Electrical Stimulation (NMES) use for Recovery After Elective Total Hip Replacement Surgery

Signature of participant or legal representative __________________________ Date ______________

Your permission to allow us to contact you about future research would be greatly appreciated, but it is completely voluntary. If you choose not to allow us to contact you, it will not affect your care at any of the NYUSM facilities. Please understand that giving your permission to do this is only for the purpose of helping us identify subjects who may qualify for one of our future research studies. It does not mean that you must join in any study.

M. CONTACT PERSON(S):

For further information about your rights as a research subject, or if you are not satisfied with the manner in which this study is being conducted and would like to discuss your participation with an institutional representative who is not part of this study, please contact the Administrator, Institutional Review Board, Telephone No. 212-263-4110.

If you have any questions or sustain any injury during the course of the research or experience any adverse reaction to a study drug or procedure, please contact the Principal Investigator Dr. Alex Moroz at the following telephone number 212-263-6037.

AGREEMENT TO PARTICIPATE AND AUTHORIZATION FOR THE USE OR DISCLOSURE OF PROTECTED HEALTH INFORMATION:

Part of the consent process includes your Authorization to use Protected Health Information for the purposes of this study, as described above. If you do not want to authorize the use of this PHI, you should not agree to be in this study.

☐ I have read this consent form
☐ it was read to me by: __________________________.

Any questions I had were answered by: __________________________.

8 of 9 Subject’s Initials: ______________ Date: ______________

(RIR Official Use Only)
This Consent Document is approved for use by the New York University’s Institutional Review Board (IRB).
Only the IRB-stamped approved form may be used.

Approved: From: 04/05/2010 To: 05/28/2010
The study expiration date applies for this form
Template rev. date: 11-09
Revised Consent NMES 09_002.doc

NYUSOM IRB APPROVED
R#: 09-0020                                    Consent Version Date: 03/24/10

Institutional Review Board
NYU School of Medicine

I □ am   □ am not    participating in another research project at this time.  
(If yes, you should discuss this with your study doctor.)

I voluntarily agree to participate in this research program at:
•   □ The NYU Hospitals Center (Tisch Hospital; the Rusk Institute of Rehabilitation Medicine);

I understand that I am entitled to and will be given a copy of this signed Consent/Authorization 
Form.

By signing this Consent/Authorization form, I give my Authorization for the uses and disclosures 
of my protected health information as described above.

WHEN THE SUBJECT IS AN ADULT:

* For subjects who may not be capable of providing informed consent, the signature of a legal 
representative is required.  For a valid HIPAA authorization, the “personal representative” must 
have authority under state law to make health care decisions for the subject.

Print Name of Participant or Legal Representative*                     Signature of Participant or Legal Representative*     Date

Print Name of Person Obtaining Consent                              Signature of Person Obtaining Consent                  Date

** When the elements of informed consent are presented orally to the subject or representative, 
a witness to the oral presentation is required.   [NOTE:  it is unclear whether HIPAA 
authorization may be presented orally – this might require an IRB waiver to permit alteration of 
the form of authorization]

Print Name of Witness**                                           Signature of Witness**                         Date

9 of 9                                                                 Subject’s Initials:               Date:             

(IRB Official Use Only)
This Consent Document is approved for use by the New York University's Institutional Review Board (IRB). 
Only the IRB-stamped approved form may be used.

Approved: From: 04/05/2010 To: 05/28/2010
The study expiration date applies for this form
Template rev. date: 11-09
Revised Consent NMES 09_002.doc

NYUSOM IRB APPROVED