Institutional Review Board
NYU School of Medicine

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Laith Jazrawi, MD

INFORMED CONSENT FORM TO PARTICIPATE AND AUTHORIZATION FOR RESEARCH

TITLE OF RESEARCH:

Outcomes after Shoulder Surgery

A. PURPOSE OF THE STUDY:

You are being asked to volunteer in a research study. This consent/authorization form includes information about this study. The purpose of this study is to develop a database of comprehensive, prospective data to further the base of knowledge on the general surgical outcomes in multiple patient populations. You are being asked to participate in this study because you are going to undergo shoulder surgery.

B. SUBJECT PARTICIPATION:

We estimate that the following number of subjects will enroll in this study:
At this site: 500 Total at all sites: 500

SUBJECT PARTICIPATION:
☐ Inpatient
☐ Outpatient
☐ other [healthy subjects, etc.] Please specify:

[The IRB expects that research will be available, as appropriate, to all persons regardless of race, gender, age, or economic circumstances]

Your medical record information contained within the NYU HJD Department of Orthopaedic Surgery research registry will be used and disclosed for research purposes for an indefinite period of time.

 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: 10-24-2006 *To:* 10-23-2007
The study expiration date applies for this form
Template rev. date: 2006-03-16
shoulder database consent.doc

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C. DESCRIPTION OF THE RESEARCH:

Outcomes research has long been a popular topic explored in the literature. It is through this dat that medical science can closely examine interventions that are employed in patient care and can assess the actual benefit and functinoal results patients are experiencing at different time periods after the intervention. Patients going through shoulder surgery at the Hospital for Joint Diseases will be asked to participate. By the collection of comprehensive, prospective data, we expect to be able to further the base of knowledge on the general surgical outcomes in multiple patient populations undergoing various shoulder surgeries, particularly, rotator cuff repair, instability repair, surgeries fo GH arthritis and those falling into an "other" category as yet to be defined. A collection of such a database as aforementioned will provided us with the opportunity to ask yet undefined questions int the future with the novel approach of having prospectively collected data to analyze on the outcomes of shoulder surgery.

D. COSTS/REIMBURSEMENTS:

The Department of Orthopaedics is providing the questionaires free of charge to participating research subjects.
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.

E. POTENTIAL RISKS AND DISCOMFORTS:

There are no risks and discomforts associated with this study. The evaluations are commensurate with normal physical exams, both pre-operative and post-operative.

F. POTENTIAL BENEFITS:

There is no direct benefit to you expected from your participation in this study. It is hoped the knowledge gained will be of benefit to others in the future.

G. ALTERNATIVES TO PARTICIPATING IN THE STUDY

This is not a study related to diagnosis or treatment of a disease or condition in eligible subjects.
You are free to choose not to participate in the study.
You do not have to participate in this study to receive ongoing care for your condition

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. Laith Jazrawi and his study team will ask you to fill out various questionnaires and go through a normal, functionality assessment. Some of these tests would have been done as part of your regular care. He will use these test results both to treat you and to complete this research. The results of these tests will be kept in your medical chart and will be reported to the Musculoskeletal Research Center. 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 course of this study. Except when required by law, study information shared with persons and organizations outside of New York University School of Medicine (NYUSM) will not identify you by name, social security number, address, telephone number, or any other direct personal identifier.
When your study information will be disclosed outside of NYUSM as part of the research, the information that can identify you as listed above will be removed and your records will be assigned a unique code number. NYUSM will not disclose the code key, except as required by law.
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 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 research site for this study, including this hospital, and including each sites' research staff and medical staff
- 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 United States research regulatory agencies and other foreign regulatory agencies
- 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: Laith M Jazrawi, MD
- Study Coordinator
- Members of the Research Team
- The Patient Advocate or Research Ombudsman (GCRC)
- Members of the NYU/NYUMC Clinical Trials Office/Office of Research and Sponsored Programs
- 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. Laith M Jazrawi at the following telephone number 212-598-6784. 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. Laith M Jazrawi and let him know that you are withdrawing from the study. His mailing address is 301 E. 17th St, New York, NY 10003. If you wish to withdraw your Authorization as well you must contact Dr. Laith M Jazrawi 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 or follow directions
(b) the need for treatment that is not allowed in the study
(d) termination or cancellation of the study.

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 shoulder surgeries within the Department of Orthopaedics 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. Jazrawi'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 *[am interested in having my child participate]* 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 study titled: (insert title of study)

☐ I **do not** want to be contacted by the Principal Investigator or Co-Investigator of the research study titled:

_____

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 *[or your child's 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 *[your child]* 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 Board of Research Associates, 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. Laith M Jazrawi at the following telephone number 212-598-6784.

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
or
☐ it was read to me by: _____.

Any questions I had were answered by: _____.

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:

- ☐ NYUSM [Skirball Institute; Nelson Institute of Environmental Medicine; Post Graduate Medical School]
- ☐ The NYU Hospitals Center (Tisch Hospital; the Rusk Institute of Rehabilitation Medicine);
- ☐ Bellevue Hospital Center: this form and your study information will be available to Bellevue Hospital administration and their auditors.
- ☐ Hospital for Joint Diseases Orthopedic Institute;
- ☐ NYU College of Dentistry;
- ☐ The New York Campus of the Veteran's Affairs New York Harbor Healthcare System.

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:

 Subject's Initials: _____ Date: _____

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* 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