UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

NAME OF STUDY AND RESEARCHERS

Title of Project: Shoulder Pain Registry

Principal Investigator: Bruce S. Miller, MD

Co-Investigators: James E. Carpenter, MD; Richard Hughes, PhD; Asheesh Bedi, MD; Brian K. Downie, PA-C; Joel Gagnier, MD; Theresa Kijek.

GENERAL INFORMATION

We are conducting research about shoulder disorders to find out how these problems affect daily life and medical care.

To participate in this research, we are asking that you complete surveys, allow us to collect information from your medical record, and allow us to contact you by mail regarding future research opportunities. The surveys should take about 20 minutes to complete. However, these questionnaires can be completed while you are waiting to be seen by your doctor or from your home if you have internet access. They ask about how your shoulder disorder affects your daily life. Some people may find the surveys uncomfortable or embarrassing. If you participate, you may skip any question you do not wish to answer, or you may stop taking the surveys at any time.

You will be asked to take the surveys approximately 9 times during your participation. We also ask permission to collect information about your shoulder disorder from your medical record, and to maintain your directly identifiable data within a database for future research purposes. We will use the surveys and the information from your medical record to learn more about shoulder pain.

There is one risk by participating in this study, breach of confidentiality. Significant precautions have been taken to minimize this risk. All electronic data collected will be stored in a password protected, secure database. Any other paper-based research information will be stored in a locked cabinet. Only those who have been designated to have access to this information will be allowed privileges. In light of these risk minimization procedures, the likelihood of a breach of confidentiality is low.

Based on the information we collect, we may also wish to contact you in the future to invite you to participate in other research opportunities. You would be contacted by phone, mail or e-mail. You would only ever be contacted by members of this study team – the study team would not provide your contact information to anyone else. You may request not to be contacted further at any time, and the study team will also remind you of this option each time we contact you.

This research is voluntary. You do not have to take part in this study. Choosing not to be in this research study will not affect your care in any way.

If you participate, we will continue to monitor your medical records unless you withdraw your permission. This will allow us to learn more about the long-term effects of shoulder pain.

There is no charge to you or your health insurance for being in this study.

Like the information in your medical record, the records of this study will remain confidential and protected.

There are no direct benefits to you for taking part in this study. In the future, we hope other people with shoulder pain may benefit by the information we learn.

You are free to leave the registry at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the registry record. The preexisting data relating to your condition will remain in the database, but follow-up information will not be added. If you decide to leave the study before it is finished, please notify Dr. Miller at the number below.

AUTHORIZATION TO RELEASE PROTECTED HEALTH INFORMATION

By signing this form you authorize the University of Michigan Health System its agents and employees to release protected health information about you to the researchers of this study.

You can revoke this authorization in writing by contacting the principal investigator and asking for this authorization to be revoked. After a revocation UMHS will make no further disclosures to the above persons without a new authorization. UMHS can rely on this authorization until revoked.

Once information has been disclosed it can no longer be protected from redisclosure by UMHS. No treatment, payment, enrollment or benefit eligibility is conditioned on this document.

Information about you may include information about your health and your medical care before, during, and after the study, even if that information wasn't collected as part of this research study. For example:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Billing information

There are many reasons why information about you may be used or seen by the researchers or others during this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results.
- University and government officials may need the information to make sure that the study is done properly.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

This authorization does not expire unless you revoke it.

Your signature in the next section means that you have received copies of all of the following documents:

- ❑ This "Consent to be Part of a Research Study" document. (Not: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)

CONTACT INFORMATION

To find out more about the study, ask a question or express a concern about the study contact one of the following:

Principal Investigator: Bruce Miller, MD Mailing Address: 24 Frank Lloyd Wright Drive, Box 0391 Ann Arbor, MI 48106-0391 Telephone: (734) 930-7400 Email: bsmiller@med.umich.edu	Study Coordinator: Theresa Kijek Mailing Address: 24 Frank Lloyd Wright Drive, Box 0391 Ann Arbor, MI 48106-0391 Telephone: (734) 930-7388 Email: iguckian@med.umich.edu
University of Michigan Compliance Help Line at 1-888-296-2481 or if you are concerned about a possible violation of your privacy, contact the University of Michigan Health System Privacy Officer at 1-888-296-2481	University of Michigan Medical School Institutional Review Board (IRBMED) 2800 Plymouth, Room 2850 Ann Arbor, MI 48109-2800 734-763-4768 E-mail: irbmed@umich.edu

SIGNATURES

Research Subject:

I understand the information printed on this form. My questions so far have been answered.

Signature of Subject: _____ Date: _____

Name (Print legal name): _____

Patient ID:_____ Date of Birth: _____

Legal Representative (if applicable):

Signature of Person Legally
Authorized to Give Consent_____ Date: _____

Name (Print legal name): _____ Phone: _____

Address: _____

Check Relationship to Subject:

☐Parent ☐Spouse ☐Child ☐Sibling ☐Legal Guardian ☐Other: _____

If this consent is for a child who is a ward of the state (for example a foster child), please tell the study team immediately. The researchers may need to contact the IRBMED.

Reason subject is unable to sign for self:_____

_____

Principal Investigator (or Designee):

I have given this research subject (or his/her legally authorized representative, if applicable) information about this study that I believe is accurate and complete. The subject has indicated that he or she understands the nature of the study and the risks and benefits of participating.

Name: _____ Title: _____

Signature: _____ Date of Signature: _____