UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and
AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

Please read this form which describes the study in some detail. A member of the research team will describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study?

Predicting Response to Intra-Articular Corticosteroid Injection in Patients with Osteoarthritis of the Glenohumeral Joint

3. Who do you call if you have questions about this research study?

Principal Investigator: Bradley Schoch, M.D. at 352-273-7375

Other research staff: Michelle Bruner, Study Coordinator at 352-273-7337

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3. Who do you call if you have questions about this research study?

Principal Investigator: Bradley Schoch, M.D. at 352-273-7375

Other research staff: Michelle Bruner, Study Coordinator at 352-273-7337

4. Who is paying for this research study?

The sponsor of this study is The University of Florida.

5. Why is this research study being done?

The purpose of this research study is to determine how effective a single corticosteroid injection is in patients with shoulder arthritis. We are also interested in identifying clinical and radiographic (such as x-rays) indicators that could be used to help physicians predict how successful a corticosteroid (or cortisone) injection will be for patients with shoulder arthritis.

You are being asked to be in this research study because you are a patient in the Department of Orthopaedics and Rehabilitation at University of Florida, age 18-100 years, with painful shoulder arthritis, and have elected to receive a cortisone injection in your shoulder.

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.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this research study)?

Your shoulder physician may order one or more x-rays of your shoulder, even if you recently had other x-rays taken, to make sure they get the best views to properly assess the level of arthritis in your shoulder. Your physician has also determined that a cortisone injection in one or both of your shoulders may be beneficial to you. This procedure, and its benefits and risks, will be described in detail by your physician. These x-rays and course of treatment have been recommended regardless of your participation in this study.

7. What will be done only because you are in this research study?

You will be asked to complete a series of surveys or questionnaires about how your shoulder is feeling and functioning, and to let us know of any changes in your medical care such as medication changes at six (6) different time points throughout your care: to the day of your injection, and 2 weeks, 1 month, 2 months, 3 months, and 6 months after your injection. These surveys or questionnaires will take approximately 10-15 minutes to complete. The follow-up surveys may be completed online through a link

sent to you by email or by a telephone call made to you by a member of the study staff.

Information will also be copied from your medical record such as your shoulder pain history, previous shoulder injections, range of motion, and information from your shoulder x-rays or other radiographic studies (MRI or CT scan).

If you have any questions now or at any time during the study, please contact one of the research team members listed in question 3 of this form.

8. How long will you be in this research study?

You will participate in this research study for 6 months following your cortisone injection.

9. How many people are expected to take part in this research study?

500 subjects will be recruited to participate in this study.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

10. What are the possible discomforts and risks from taking part in this research study?

You will be receiving a cortisone injection regardless of your participation in this study. There are certain discomforts or risks associated with any injection. If you have any questions about these risks, please discuss these with your shoulder physician prior to receiving the injection.

Although a minimal risk, completing the study questionnaires may cause stress to some participants who may believe that they are not providing correct answers to the research team. To reduce this stress, the investigators will reassure you that all survey answers are based on what you feel, and there is no “correct” answer.

Researchers will take appropriate steps to protect any information they collect about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you, or possibly affect your insurability or employability. Questions 17-21 in this form discuss what information about you will be collected, used, protected, and shared.

This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform one of the research team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

Throughout the study, the researchers will notify you of new information that may become available and might affect your decision to remain in the study.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the research team members or listed in question 3 of this form.

11a. What are the potential benefits to you for taking part in this research study?

There is no direct benefit to you by participating in this study.

11b. How could others possibly benefit from this study?

This study may benefit future patients by helping physicians identify clinical and radiographic (such as x-rays) indicators that could predict how successful a cortisone injection will be for patients with shoulder arthritis.

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator listed in question 3 may benefit if the results of this study are presented at scientific meetings or in scientific journals.

12. What other choices do you have if you do not want to be in this study?

You may choose to not participate in this study. You may still receive the cortisone injection in your shoulder as previously determined by your physician; however, you would not complete the questionnaires before or after the injection.

If you do not want to take part in this study, tell the member of the research staff that is speaking to you about the study and do not sign this Informed Consent Form.

The investigators associated with this project may or may not be involved with your medical care before, during, and after this research study. Your participation in this study is voluntary, and any decision to take part or not participate will in no way affect any medical care you receive from members of the research team.

If you believe that your participation in this study or your decision to withdraw from or to not participate in this study has improperly affected your medical care, you should discuss this with the IRB office.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

University of Florida Students:

You have been invited to participate in this research project because you are a student with painful shoulder arthritis and have elected to receive a cortisone injection in your shoulder. The investigators associated with this project may or may not teach in your college or be associated with courses for which you are enrolled or might be expected to register in the future. Your participation in this study is voluntary and any decision to take part or not to participate will in no way affect your grade or class standing.

If you believe that your participation in this study or your decision to withdraw from or to not participate in this study has improperly affected your grade(s), you should discuss this with the dean of your college or you may contact the IRB office.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

If you withdraw your consent to participate, information used and/or collected from the date of consent up to the date of withdrawal may still be used by the investigators; however, no further information will be collected and used in the study.

13c. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

- You choose not to have the standard of care shoulder injection;
- The investigators decide that continuing in the study would be harmful to you;
- At a later time, you no longer consent to any future changes that may be made to this study plan;
- Failure to complete follow-up surveys; or
- For any other reason.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?

No. There will be no extra cost to you for participating in this Research Study.

15. Will you be paid for taking part in this study?

You will not receive any payment for taking part in this study.

16. What if you are injured because of the study?

Please contact the Principal Investigator listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this study.

17. How will your health information be collected, used and shared?

If you agree to participate in this study, the Principal Investigator will create, collect, and use private information about you and your health. This information is called protected health information or PHI. In order to do this, the Principal Investigator needs your authorization. The following section describes what PHI will be collected, used and shared, how it will be collected, used, and shared, who will collect, use or share it, who will have access to it, how it will be secured, and what your rights are to revoke this authorization.

Your protected health information may be collected, used, and shared with others to determine if you can participate in the study, and then as part of your participation in the study. This information can be gathered from you or your past, current or future health records, from procedures such as physical examinations, x-rays, blood or urine tests or from other procedures or tests. This information will be created by receiving study treatments or participating in study procedures, or from your study visits and telephone calls. More specifically, the following information may be collected, used, and shared with others:

- Demographic information including name, date of birth, sex
- Phone number, e-mail and mailing address for the purpose of follow-up surveys
- Records about phone calls made as part of this research
- Past and present medical records
- Records about your study visits
- Information obtained during this research study about
    - Physical exams and prior operative exams
    - X-ray, and other test results
    - Responses to questionnaires and surveys

This information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices.

Some of the information collected could be included in a "limited data set" to be used for other research purposes. If so, the limited data set will only include information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, photographs, or other codes that link you to the information in the limited data set. If limited data sets are created and used, agreements between the parties creating and receiving the limited data set are required in order to protect your identity and confidentiality and privacy.

18. For what study-related purposes will your protected health information be collected, used, and shared with others?

Your PHI may be collected, used, and shared with others to make sure you can participate in the research, through your participation in the research, and to evaluate the results of the research study. More specifically, your PHI may be collected, used, and shared with others for the following study-related purpose(s):

- To assess the effectiveness of a single cortisone injection in patients with shoulder arthritis.
- To assess factors that can help clinicians predict the success of cortisone injections in patients with shoulder arthritis.

Once this information is collected, it becomes part of the research record for this study.

19. Who will be allowed to collect, use, and share your protected health information?

Only certain people have the legal right to collect, use and share your research records, and they will protect the privacy and security of these records to the extent the law allows. These people include:

- The study Principal Investigator (listed in question 3 of this form) and research staff associated with this project.
- Other professionals at the University of Florida or Shands Hospital that provide study-related treatment or procedures.
- The University of Florida Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research).

20. Once collected or used, who may your protected health information be shared with?

Your PHI may be shared with:

- The study sponsor (listed in Question 4 of this form).
- United States governmental agencies that are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections.
- Government agencies who are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.

Otherwise, your research records will not be released without your permission unless required by law or a court order. It is possible that once this information is shared with authorized persons, it could be shared by the persons or agencies who receive it and it would no longer be protected by the federal medical privacy law.

21. If you agree to take part in this research study, how long will your protected health information be used and shared with others?

Your PHI will be used and shared with others until the end of the study.

You are not required to sign this consent and authorization or allow researchers to collect, use and share your PHI. Your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you allow the collection, use and sharing of your protected health information by signing this consent and authorization.

You have the right to review and copy your protected health information. However, we can make this available only after the study is finished.

You can revoke your authorization at any time before, during, or after your participation in this study. If you revoke it, no new information will be collected about you. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

Signature of Person Obtaining Consent and Authorization	Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described in sections 17-21 above. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting and Authorizing	Date

4. Who is paying for this research study?

The sponsor of this study is The University of Florida.

5. Why is this research study being done?

The purpose of this research study is to determine how effective a single corticosteroid injection is in patients with shoulder arthritis. We are also interested in identifying clinical and radiographic (such as x-rays) indicators that could be used to help physicians predict how successful a corticosteroid (or cortisone) injection will be for patients with shoulder arthritis.

You are being asked to be in this research study because you are a patient in the Department of Orthopaedics and Rehabilitation at University of Florida, age 18-100 years, with painful shoulder arthritis, and have elected to receive a cortisone injection in your shoulder.

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.

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sent to you by email or by a telephone call made to you by a member of the study staff.

Information will also be copied from your medical record such as your shoulder pain history, previous shoulder injections, range of motion, and information from your shoulder x-rays or other radiographic studies (MRI or CT scan).

If you have any questions now or at any time during the study, please contact one of the research team members listed in question 3 of this form.

8. How long will you be in this research study?

You will participate in this research study for 6 months following your cortisone injection.

9. How many people are expected to take part in this research study?

500 subjects will be recruited to participate in this study.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

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You will be receiving a cortisone injection regardless of your participation in this study. There are certain discomforts or risks associated with any injection. If you have any questions about these risks, please discuss these with your shoulder physician prior to receiving the injection.

Although a minimal risk, completing the study questionnaires may cause stress to some participants who may believe that they are not providing correct answers to the research team. To reduce this stress, the investigators will reassure you that all survey answers are based on what you feel, and there is no “correct” answer.

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12. What other choices do you have if you do not want to be in this study?

You may choose to not participate in this study. You may still receive the cortisone injection in your shoulder as previously determined by your physician; however, you would not complete the questionnaires before or after the injection.

If you do not want to take part in this study, tell the member of the research staff that is speaking to you about the study and do not sign this Informed Consent Form.

The investigators associated with this project may or may not be involved with your medical care before, during, and after this research study. Your participation in this study is voluntary, and any decision to take part or not participate will in no way affect any medical care you receive from members of the research team.

If you believe that your participation in this study or your decision to withdraw from or to not participate in this study has improperly affected your medical care, you should discuss this with the IRB office.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

University of Florida Students:

You have been invited to participate in this research project because you are a student with painful shoulder arthritis and have elected to receive a cortisone injection in your shoulder. The investigators associated with this project may or may not teach in your college or be associated with courses for which you are enrolled or might be expected to register in the future. Your participation in this study is voluntary and any decision to take part or not to participate will in no way affect your grade or class standing.

If you believe that your participation in this study or your decision to withdraw from or to not participate in this study has improperly affected your grade(s), you should discuss this with the dean of your college or you may contact the IRB office.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

If you withdraw your consent to participate, information used and/or collected from the date of consent up to the date of withdrawal may still be used by the investigators; however, no further information will be collected and used in the study.

13c. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

- You choose not to have the standard of care shoulder injection;
- The investigators decide that continuing in the study would be harmful to you;
- At a later time, you no longer consent to any future changes that may be made to this study plan;
- Failure to complete follow-up surveys; or
- For any other reason.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?

No. There will be no extra cost to you for participating in this Research Study.

15. Will you be paid for taking part in this study?

You will not receive any payment for taking part in this study.

16. What if you are injured because of the study?

Please contact the Principal Investigator listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this study.

17. How will your health information be collected, used and shared?

If you agree to participate in this study, the Principal Investigator will create, collect, and use private information about you and your health. This information is called protected health information or PHI. In order to do this, the Principal Investigator needs your authorization. The following section describes what PHI will be collected, used and shared, how it will be collected, used, and shared, who will collect, use or share it, who will have access to it, how it will be secured, and what your rights are to revoke this authorization.

Your protected health information may be collected, used, and shared with others to determine if you can participate in the study, and then as part of your participation in the study. This information can be gathered from you or your past, current or future health records, from procedures such as physical examinations, x-rays, blood or urine tests or from other procedures or tests. This information will be created by receiving study treatments or participating in study procedures, or from your study visits and telephone calls. More specifically, the following information may be collected, used, and shared with others:

- Demographic information including name, date of birth, sex
- Phone number, e-mail and mailing address for the purpose of follow-up surveys
- Records about phone calls made as part of this research
- Past and present medical records
- Records about your study visits
- Information obtained during this research study about
    - Physical exams and prior operative exams
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This information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices.

Some of the information collected could be included in a "limited data set" to be used for other research purposes. If so, the limited data set will only include information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, photographs, or other codes that link you to the information in the limited data set. If limited data sets are created and used, agreements between the parties creating and receiving the limited data set are required in order to protect your identity and confidentiality and privacy.

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Your PHI may be collected, used, and shared with others to make sure you can participate in the research, through your participation in the research, and to evaluate the results of the research study. More specifically, your PHI may be collected, used, and shared with others for the following study-related purpose(s):

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- Other professionals at the University of Florida or Shands Hospital that provide study-related treatment or procedures.
- The University of Florida Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research).

20. Once collected or used, who may your protected health information be shared with?

Your PHI may be shared with:

- The study sponsor (listed in Question 4 of this form).
- United States governmental agencies that are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections.
- Government agencies who are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.

Otherwise, your research records will not be released without your permission unless required by law or a court order. It is possible that once this information is shared with authorized persons, it could be shared by the persons or agencies who receive it and it would no longer be protected by the federal medical privacy law.

21. If you agree to take part in this research study, how long will your protected health information be used and shared with others?

Your PHI will be used and shared with others until the end of the study.

You are not required to sign this consent and authorization or allow researchers to collect, use and share your PHI. Your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you allow the collection, use and sharing of your protected health information by signing this consent and authorization.

You have the right to review and copy your protected health information. However, we can make this available only after the study is finished.

You can revoke your authorization at any time before, during, or after your participation in this study. If you revoke it, no new information will be collected about you. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

Signature of Person Obtaining Consent and Authorization	Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described in sections 17-21 above. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting and Authorizing	Date