UNIVERSITY OF CALIFORNIA, SAN DIEGO
CONSENT TO PARTICIPATE IN RESEARCH

IRB #805530

Biopsy Collection for Study of Musculoskeletal Pathologies

Samuel Ward, PT., Ph.D. and his colleagues are developing a biorepository to learn more about orthopaedic disorders, cancer, diabetes, and many other health-related problem
s. A biorepository is a collection of samples and/or health information (data) that can be used for research now and in the future. Researchers may apply to the biorepository to ask for data or samples for studies they wish to do. If a study is approved, the biorepository will give the researcher samples and/or information to learn more about health and many different diseases. Through these studies, researchers hope to find new ways to detect, treat, and maybe prevent or cure health problems. Some of these studies may be about how genes affect health and disease, or how genes affect response to treatment. Some of them may lead to new products, such as drugs or tests for diseases. We anticipate obtaining biopsies from about 1000 participants each year in this long-term project.

You have been asked to contribute to the biorepository because you are an adult willing to undergo a tissue biopsy. A biopsy is a sample of tissue taken from the body in order to examine it more closely.

The biopsy will be obtained from: _____.

Specifically, a doctor will clean and numb the biopsy site to collect the following tissue for research:

Tissue: _____

If you agree to participate in this study, you will be asked to do the following:

1) Sign this document. You may be asked to do this in person or electronically. In the latter case, you will be asked to provide your email address so that the document could be securely sent to you for digital signature. Your email address will not be used for any other purpose and will not be stored or shared with any one.
2) Provide information to the study team to verify your eligibility. Specifically, you will be asked about your age, history of infections, use of blood thinners (such as warfarin) and pregnancy (only in case of women).
3) Provide information about history of metabolic diseases, hematologic (blood) diseases, endocrinal (hormonal) diseases, autoimmune diseases, musculoskeletal diseases, and any other health concerns.
4) Provide information about current medications and allergies.
5) Register as a patient at UCSD. A study team member will provide you with information to help you obtain a medical record number.
6) Have a coagulation panel test done within 7 days before the tentative date of your biopsy. A coagulation panel test is a test of your blood's clotting capability, and this test must be normal for a biopsy procedure to be performed. Order for this test will be placed in your medical record and you can go to any of the UCSD labs (including some

urgent care centers) to get the test done. A lab phlebotomist will draw about 5cc (1 teaspoon) of your blood using venipuncture (needle). The test results will be available in your medical record typically within 48 hours. If the test is normal, a study team member will follow up with you and confirm your biopsy appointment. If the test is abnormal, you will be provided with guidance on next steps and no biopsy will be performed.

7) Arrive for your biopsy procedure (described below).
8) Complete a questionnaire on your physical health. This questionnaire typically takes no more than five minutes to complete.

The biopsy procedure will be performed by a trained clinician at UCSD. The procedure will be performed at our health facilities in La Jolla. The doctor will initially interview you to reestablish your eligibility for a biopsy. You will be asked to position yourself on an exam table to be as comfortable as possible for the upcoming biopsy procedure. The target site will be marked with a surgical marker. If needed, the target site may be shaved. Ultrasound may be used to plan the trajectory for the biopsy. In this case, ultrasound gel may be applied on your skin and the ultrasound probe will be moved along your skin surface to plan the angle of biopsy. The target site will then be numbed using a local anesthetic such as lidocaine and sterilized using antiseptics. The procedure will be performed under sterile conditions.

Biopsy procedures involve using a needle to obtain samples of the target tissue. The biopsy needle typically consists of an outer cannula (a thin tube) with a small opening (a window) at the side of the tip and an inner trocar (a surgical instrument with a three-sided cutting point) with a cutting blade at the distal end. An incision, about 1 cm, will be made and the needle is advanced into the skeletal tissue. Next, suction is applied to the inner trocar, the outer trocar is pulled back, skeletal muscle tissue is drawn into the window of the outer cannula by the suction, and the inner trocar is rapidly closed, thus cutting or clipping the skeletal tissue sample. The needle is rotated 90^{o} and another cut is made. This process may be repeated 2-3 times more. In some cases, the doctor may forgo the needle and obtain a biopsy directly by incising the tissue or scraping it off. Up to 200 mg (approximately the size of a pencil eraser) of the tissue may be obtained.

Once the biopsy has been collected, direct pressure will be applied to the biopsy site with a sterile gauze. The incision site will be cleaned and the wound closed using any of the closing methods including surgical adhesive, tape, or sutures. Non-sterile gauze pads will then be placed on the incision site and secured with adhesive wrap or tape. The doctor will discharge you when they consider you fit to be discharged.

You will be instructed to avoid soaking in water (e.g. in bath tub, swimming pool, sea etc.) for at least a week, and avoid strenuous activities for at least 4-5 days.

Approximately 48 hours after your biopsy procedure, a member of the study team will reach out to you by phone to enquire about any adverse events from the biopsy.

About 2 hours of you time will be required for the screening visit including coagulation test, and another 2 hours will be required for the biopsy procedure. The follow up phone call is expected to require about 5 minutes of your time. Thus, for the whole study, a little over 4 hours of your time may be required.

As part of this study we may:

- Store your de-identified samples (biospecimens and/or genetic samples) and associated clinical information in a Data/Biobank, along with information and/or samples from all the other people who take part. De-identification is the process of removing any information (like your name) from your personal health information or samples that could identify you and replacing it with a code. There is no limit on the length of time we will keep this information and/or your samples. Any information that may be publicly available will be completely deidentified. No identifying information will ever be publicly available.
- Allow other researchers to use the materials stored in the Data/Biobank for approved studies. Researchers from UCSD, other universities, the government, and drug- or health-related companies can apply to use the materials. A science committee at the Data/Biobank will review each request. There may also be an ethics review, such as a review by an Institutional Review Board (IRB). An IRB is a panel of qualified members who review and monitor biomedical research involving human subjects in accordance with FDA regulations. We will not give researchers your name or any other information that could directly identify you.
- Associate health information, such as your name, medical record number, date of birth, date of surgery, gender, race, ethnicity, health history, and medications at the time of surgery with your tissue samples. These data will, however, be kept separately from the tissue samples and not be a part of the label on the tissue.
- Collect research data from any studies done using your sample and clinical information

By consenting to be a part of this study, your tissue will be biopsied, and the biopsied tissue will be stored to be studied in the future. This research could involve studying your biology and the likelihood that a particular biological feature (including genes) may increase the chance of developing a disease. Genes are pieces of DNA, or deoxyribonucleic acid that give instructions for building the proteins that make our bodies work. These instructions are stored in the form of a code. You inherit this code from your parents. We will not use your specimens for whole genome testing. This means making a list of the entire order, or sequence, of your DNA.

It may also include any potential future research that cannot be foreseen or anticipated at this time.

Benefits to you: There will be no direct benefit to you from this study since you will not be provided with any results or information resulting from study of your tissue. The research team; however, may learn more about various health-related issues and potentially identify treatments or cures.

Confidentiality: Your confidentiality is very important to us and we will make every effort to protect it. Here are just a few of the steps we will take:

- We will remove your name and other identifiers from your sample and personal health information and replace them with a code number. We will keep the list that links the code number to your name separate from your sample and personal health information. Only a few of the Biobank staff will have access to the list and they are required to keep your identity a secret.
- Researchers who study your sample and information will not know who you are. They must also sign an agreement that they will not try to find out who you are.
- We will not give information that identify you to anyone, except if required by law. Information that is shared outside UCSD may no longer be protected by the federal privacy law called 'HIPAA'. But it will be protected as described in this form and may be covered by other privacy laws.

Potential Risks

Participation in this study may involve risks or discomforts.

The blood draw required for the coagulation panel may result in minor discomfort at the site of venipuncture. It may also cause redness, swelling, bruising or bleeding at the site of needle puncture. You may also feel lightheaded or faint when the blood is drawn. In rare cases, blood clots or an infection may occur.

Local anesthetics such as lidocaine may cause nausea or vomiting, dizziness, drop in blood pressure, flushing or redness of skin, or blurred vision. In rare cases, it may also cause swelling, fast heartbeat, difficulty breathing, or hives (urticaria).

The biopsy may cause bleeding, infection, temporary stiffness, swelling, and pain in the surrounding tissue. There may be damage to surrounding nerves or tendons. You may also experience an allergic reaction from the lidocaine, ultrasound gel, antiseptics, adhesive tape or sutures.

Risks of Loss of Confidential Information: There is also a risk that information about you could be released to an unauthorized party. To minimize this risk, we will use a code on any specimens and/or information we collect and we will keep a link between the code and your identity in a different location. Only designated and trained research personnel will have access to study information and will only access them on the secure research drive.

Risks of Genetic Testing: Federal and State laws generally protect your genetic information in the following ways: a) Health insurance companies and group health plans may not request your genetic information from this research. b) Health insurance companies and group health

plans may not use your genetic information when making decisions regarding your eligibility or premiums. c) Employers with 5 or more employees may not use your genetic information from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment. Be aware that these laws **do not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.
We will minimize the possibility of results from this research being linked to you, but there is always the remote possibility that information from the research may be disclosed. If your genetic risk for certain diseases is accidently divulged to the wrong source, you might be discriminated against in obtaining life or health insurance, or employment.

There may be unknown risks that cannot be anticipated at this time.

Costs Associated with Participating in this Study: You will not incur any additional costs as a participant in this study. The study will pay for all procedures described above including your test for coagulation panel and biopsy.

Compensation Associated with Participating in this Study: You will be compensated with a $100 gift card at the end of your biopsy procedure.

Research Related Injury: If you are injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if you are injured. You may call the UCSD Human Research Protections Program office at (858) 246-4777 for more information about this, or to inquire about your rights as a research subject, or to report research-related problems.

Alternatives to Participating in this Study: The alternatives to participation in this study are not participating in the study at all.

New information: Any new information that may affect your health, welfare or willingness to participate will be made available to you.

Withdrawal from the Study: You may be withdrawn from the study for the following reasons:
(1) the principal investigator has decided to discontinue the study;
(2) the doctor/PI believes that it is in your best medical interest to not obtain a biopsy.

If you decide later that you do not want the specimens collected from you to be used for research, please inform the study team, who will use their best efforts to stop the use of your specimens for research. However, in some cases, such as if your cells are grown up and are found to be generally useful, it may be impossible to locate and stop such future research once the materials have been widely shared with other researchers.

Research-related questions: You can reach the PI (lead researcher), Dr. Samuel Ward, at 858-534-4918 or the doctor who performed your biopsy by calling the Orthopaedic Clinic at 858-657-8200. You can also call the UC San Diego Office of IRB Administration at 858-246-4777 with any questions or concerns about this study.

Consent to use biospecimens and data: Biospecimens (such as muscle, bone, tendon etc.) collected from you for this study and/or information obtained from your biospecimens and medical records may be used in this research or other research, and shared with other organizations. It is possible that researchers may give your deidentified biospecimen and health information to companies that may profit from this research. This will only happen if their request is reviewed and approved by the Biobank Governing Board. You will not share in any commercial value or profit derived from the use of your biospecimens and /or information obtained from them. Biospecimens will be maintained under Dr. Ward through his Biorepository protocol (IRB#181569: *Collecting biological tissues from all Orthopaedic Surgery Patients: Orthopaedic Biorepository Protocol*).

Rights when providing electronic consent:

California law provides specific rights when you are asked to provide electronic consent:

- You have the right to obtain a copy of the consent document in a non-electronic format.
- You have the right to provide consent in a non-electronic format.
- If you change your mind about electronic consent, you have the right to request your electronic consent to be withdrawn and you can then provide consent in a non-electronic format; however, a copy of your electronic consent will be maintained for regulatory purposes. If you wish to withdraw your electronic consent please tell the study team.

This agreement for electronic consent applies only to your consent to participate in this research study.

YOUR SIGNATURE ON THIS FORM MEANS:

1. You have read and understood the information given in this form.
2. You understand that participation in data/biobank is **voluntary**. Not participating will have no impact on the procedure and care you are entitled to receive at UCSD.
3. You have been explained (i) the purpose of obtaining biopsy and data for data/biobanking; (ii) associated risks, benefits, and alternatives; and (iii) other written information in this form.
4. You understand that participation in this study does not mean that you have had genetic testing. Genetic testing means having a test performed and the results provided to you and your doctor. If you are interested in having genetic testing performed you should consult your doctor, as some commercial tests are available. Your doctor can provide you with the necessary information to determine if such a test would be appropriate for you.
5. You understand that there will be no direct benefit to you from this study as you will not be provided with any results or information obtained through analysis of your biospecimens.

6. You understand that these specimens (such as muscle, bone etc.), DNA, and their derivatives collected from you for this study and/or information obtained from your biospecimens may be used in research and shared with other organizations. Future investigators may have a financial interest in the outcome of future studies. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them.
7. You agree to have your tissue biopsied and data collected and banked for research purposes.

Signature Block for Adults Able to Provide Consent

Participant
I have received a copy of this consent document and a copy of the "Experimental Participant's Bill of Rights" to keep. I agree to participate in the research described in this form. Printed Name of Participant Signature of Participant Date
Person Obtaining Consent
I document that: • *I (or another member of the research team) have fully explained this research to the participant.* • *I have personally evaluated the participant's understanding of the research and obtained their voluntary agreement.* Printed Name of Person Obtaining Consent Signature of Person Obtaining Consent Date
Witness (if applicable)
I document that the information in this form (and any other written information) was accurately explained to the participant. The participant appears to have understood and freely given consent to join the research. Printed Name of Witness Signature of Witness Date

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Experimental Participant's Bill of Rights

Every individual asked to participate in a research study has the right to be:

1. Informed about the nature and purpose of the study.

2. Provided an explanation of the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.

3. Given a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.

4. Informed about any benefits that would reasonably be expected from the participation in the study, if applicable.

5. Informed about of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.

6. Told of the types of medical treatment, if any, available if complications should arise.

7. Provided an opportunity to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.

8. Informed that individuals can refuse to participate in the research study. Participation is voluntary. Research participants may refuse to answer any question or discontinue their involvement at any time without penalty or loss of benefits to which they might otherwise be entitled. Their decision will not affect their right to receive the care they would receive if they were not in the experiment.

9. Provided a copy of the signed and dated written consent form and a copy of this form.

10. Given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study contact the researchers listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research participant, please contact:

- UC San Diego Office of IRB Administration at irb@ucsd.edu or 858-246-4777