UNIVERSITY OF CALIFORNIA, SAN DIEGO
CONSENT TO PARTICIPATE IN RESEARCH

1. Study Title and Number

Title: Collecting biological tissues from all Orthopaedic Surgery patients: Orthopaedic Biorepository Protocol
Study # 181569

2. Principal Investigator

Samuel Ward, PT, PhD
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3. Principal Investigator Phone Number, Research Team Number, and Emergency Contact Number

Dr. Samuel Ward:
- 858-534-4918

Orthopaedic Clinic:
- 858-657-8200

Research Team:
- Dominic Baun:
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5. Study Overview

This research study is being conducted to develop a biorepository to learn more about orthopaedic disorders and many other health-related problems. A biorepository is a collection of samples and/or health information (data) that can be used for research now and in the future. Researchers, both a part of and outside of UC San Diego, 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 research 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 tissue samples from about 1000 participants each year in this long-term project.

We are inviting you to participate in a research study because you are scheduled to undergo a procedure in Orthopaedic Surgery. The purpose of this document is to obtain your consent to collect tissue samples from you that would otherwise go to waste. There is no additional surgical intervention and you will receive the same treatment whether you choose to enroll in this study or not.

This form explains the research so that you may make an informed decision about participating.

- Research is voluntary - whether or not you participate is your decision. You can discuss your decision with others (such as family, friends or another physician).
- You can say yes, but change your mind later.
- If you say no, we will not hold your decision against you.
- You can say no even if the person inviting you is part of your healthcare team.
- Your decision will not affect your health care or other benefits you may be entitled to.

- Please ask the study doctor or study team questions about anything that is not clear, and feel free to ask questions and mention concerns before, during, and after the research.
- You may consult with friends, family, a personal doctor, or anyone else before deciding whether or not to be in the study.
- You will be given a copy of this consent form and the Participant's Bill of Rights.

The purpose of this research study is to collect waste tissue from orthopaedic procedures along with health information to contribute to a biorepository for long-term storage. Waste tissue is any tissue that is determined to be medical waste during a surgery or procedure. This means that this tissue is not needed or will be used for any required testing and it is considered extra tissue that would otherwise be thrown away. These tissue samples and information may be made available to qualified researchers to further understanding of biology and disease.

There is no additional surgical interventions or treatment as a part of this study. The only additional component of this study is the completion of a questionnaire which typically takes less than 10 minutes. Instances where the administration of questionnaires is not necessary or may hinder clinical care, clinical investigators may choose not to administer the questionnaire.

There is no added risk with regard to clinical treatment for this study as the collection of waste tissue is considered as standard of care practice. Essentially, every patient who is consented for an orthopaedic procedure will also be consented for collection of waste tissue for research purposes by their orthopaedic care provider in clinic.

Although rare, the only potential risk is for loss of confidentiality. This risk is very small since information in the database will be encrypted and protected by a firewall server. Only designated research personnel will have access to the database.

There are no benefits to you from participating in this research. However, the knowledge gained from this study will potentially have a major benefit to society by improving future research and medical management of patients. This future benefit could potentially apply to some of the patients enrolled in this study.

The alternative to being in this study is not to participate.

More detailed information about this research study is provided below.

6. Whom can I talk to if I have questions?

If during your participation in the study you have questions or concerns, or if you think the research has hurt you, contact the research team at the numbers listed in Section 3 on the first page of this form. You should not agree to participate in this study until the research team has answered any questions you have about the study, including information contained in this form.

If before or during your participation in the study you have questions about your rights as a research participant, or you want to talk to someone outside the research team, please contact:

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

7. How many people will take part?

We plan to study 500,000 people here.

8. What happens if I take part in the research?

Here is what will happen to you if you agree to be in this study:

As you read this form, ask questions if something is not clear.

If you choose to be in this study, waste tissue from your surgery will be collected and associated with some health data including name, medical record number, date of birth, and date of surgery. There is no additional surgical or other medical intervention as a part of this study. We will de-identify your samples/data while it is stored and when it is used in research. This code allows your data to be used without anyone knowing that it is your sample just by looking at the label. You will also complete questionnaires related to your physical health which is expected to take no more than 10 minutes of your time.

As apart of this study we may:

- Store your de-identified samples (biospecimens and/or genetic samples) and associated clinical information that may include medical/surgical history and imaging in a data/biobank, along with information and/or samples from all the other people who take part. There is no limit on the length of time we will keep this information and/or your samples.
- Allow other researchers to use the materials stored in the Data/Biobank for approved studies. Your de-identified samples may be securely sent to researchers wishing to study them. Researchers from UCSD, other universities, the government, and drug- or health-related companies can apply to use the materials. A governing board will review each request to ensure all regulatory, logistical and ethical requirements are met prior to granting approval. 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

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.

9. What are the risks and possible discomforts?

Participation in this study may involve risks or discomforts.

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.

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.

10. How will information about me be protected?

While we cannot guarantee complete confidentiality, we will limit access to information about you. Only people who have a need to review your information, documents, or specimens will have access. These people might include:

- Members of the research team and other staff or representatives of UCSD whose work is related to the research or to protecting your rights and safety.
- Representatives of Federal and other regulatory agencies who make sure the study is done properly and that your rights and safety are protected.

Study information will be labeled with a code instead of your name or other information that can easily identify you. The record linking your identifying information (name, address, etc.) and the code will be kept separate from the rest of the study information.

The results of this study may be published once the study is completed. However, we will keep your name and other identifying information confidential. We expect this study will be completed in 10 years. This is only an estimate and the actual time to complete the study may be longer or shorter depending on a number of factors.

You will be asked to sign separate UC Health Insurance Portability and Accountability Act (HIPAA) Research Authorization form to use and disclose (share) your health information that identifies you for the purposes of this research study. Your permission as described in this informed consent and authorization form does not have an automatic expiration date.

11. Will I need to pay to participate in the research?

There will be no cost to you for participating in this study. You and/or your health plan/insurance company will need to pay for all costs of treating your condition while in this study.

12. What if I agree to participate, but change my mind later?

You can stop participating at any time for any reason, and it will not be held against you. Your choice will not affect any treatment relationship you have with healthcare providers at UC San Diego Health or any services you receive from them. No matter what you decide, there will be no penalty to you. You will not lose medical care or any legal rights.

If you stop participating, we may not be able to remove the information we have already collected about you or specimens we have already collected from you.

If you decide later that you do not want the specimens collected from you to be used for future research, you may tell this to Dr. Ward or the research team, who will use their best efforts to stop any additional studies.

However, in some cases, such as if your specimens have already been tested, the data from these tests are no longer linked to your identity and cannot be removed from the research database.

13. What will happen to information and/or biospecimens collected from me?

The data and specimens we collect with your identifiable information (for example, your name, medical record number, or date of birth) as a part of this study may be used to answer other research questions or may be shared with other investigators for other research. If we do so, we will remove all identifiable information before use or sharing. Once identifiers have been removed, we will not ask for your consent for the use or sharing of your data and/or specimens in other research. In addition, data that have been de-identified will be uploaded to the orthopaedic biorepository for other researchers to access and use.

Biospecimens (such as blood, tissue, or saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research, and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them.

14. Will I be compensated for participating in the research?

We will not pay you to take part in this study or pay for any out of pocket expenses related to your participation.

15. What else is important for me to know?

You will not be provided any clinically relevant information that may pertain to your health. You will not be provided a summary of the research findings.

This study receives funding through the Wu Tsai Human Performance Alliance.

16. What are my 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.

17. Additional Choices to Consider

The study team would like your permission to contact you about participating in future studies. You may still join this study even if you do not permit future contact. You may also change your mind about this choice. Please initial your choice below:

_____YES, you may contact me

_____NO, you may NOT contact me

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

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