The Ohio State University Consent to Participate in Research

Study Title: Fragility Fracture Program

Principal Investigator: Laura Phieffer, MD

Sponsor: None

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.

- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.

- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. **Why is this study being done?**

   This study is being done to collect observational information on people who have had a “fragility fracture.” A fragility fracture occurs when a person falls from a standing height or less and breaks a bone because of poor bone health due to osteoporosis (a disease of the bone that causes thinning of the bone making them weaker) or osteopenia (beginning stage of osteoporosis). Doctors and hospitals have established guidelines on how best to treat patients with fragility fractures, and the data we collect at here at OSUMC will help to evaluate how those guidelines are being followed. It will also create a source of information that will help medical providers to identify, evaluate, diagnose and treat patients with poor bone health.

2. **How many people will take part in this study?**
Everyone aged 50 and older who comes to the Medical Center with a fragility fracture will be eligible to participate in this study. We expect to enroll up to 100 patients per year for the first 5 years of the study, for a total of 500 subjects.

3. **What will happen if I take part in this study?**

If you agree to take part in the study, we will collect:

- general information about you (like your age, date of injury, gender, race/ethnicity, height & weight);
- information about your fracture and any history of other broken bones;
- your risk factors for having a fracture;
- your medication and nutritional supplement use;
- any recent lifestyle changes, use of aids for walking (cane, walker), location of your current residence;
- any bone density scans previously completed we will reviewed

At your regularly scheduled follow-ups (2 weeks, 6 weeks, 6 months and 1 year) we will also collect some follow-up information about the results of these tests, lifestyle changes, and any medications that you may have had or used since the fracture. This will add about 35 minutes to your regularly scheduled follow-up appointment.

The information that we collect will not include any information that directly identifies you (like your name or social security number). The data will be stored and analyzed through the life of the project, which will be at least 5 years but possibly more.

4. **How long will I be in the study?**

If you agree to participate, you will be enrolled in the study through your 12-month follow-up with your doctor. Your study data will be analyzed throughout the Fragility Fracture Program study.

Throughout the life of the database, We will use the information we have collected to answer questions about fragility fractures. We do not yet know the specific research questions we will ask. By agreeing to participate in this study, you are giving us your permission to use your data for this type of “retrospective” study.

We may also wish to invite you to participate in future, “prospective” studies that will involve re-examination of the existing data we have collected. If you do not want your data to be used in any further studies, you may “opt-out” by indicating your decision below.

___ I give my permission for the data that is collected about me to be used in other orthopaedic research studies that is related to the data that has been collected for this study.
5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University or your relationship with your physician.

You may withdraw from the study at any time by notifying your study doctor. If you wish, you may also request that your data be removed (deleted) from the database. While the study is ongoing, we can withdraw all your information from the database. However, once the study has ended and/or OSUMC is no longer participating in the study, the key that links your name with your data will be destroyed. Since we will no longer be able to identify which data is yours, you will not be able to withdraw the data.

6. What risks, side effects or discomforts can I expect from being in the study?

Because this is a minimal risk study involving the collection of observational data from surveys and from your medical record, there is no anticipated risk of physical harm or discomfort.

Although the information that we record about you for the study will not directly identify you, this information is linked to your name with a unique identifying number. This number is considered part of your protected health information (PHI). As with any study involving PHI, there is a risk of breach of confidentiality. Every effort will be made to prevent this from happening. The research team is committed to maintaining confidentiality and protecting your privacy.

7. What benefits can I expect from being in the study?

You will receive no direct benefit from your participation in this study. However, your participation will help to provide orthopaedic clinicians with a large source of information about fragility fractures. This information will help them to identify and treat patients with poor bone health, which will mean better care for patients.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled. Your medical and surgical treatment will be the same regardless of whether or not you take part in the study.
9. **Will my study-related information be kept confidential?**

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):
- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician’s office records. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

You will also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form because the study involves the use of your protected health information.

Your study data will be analyzed by the American Orthopaedic Association (AOA) along with patient data from other health care facilities that are participating in the study. No information that directly identifies you will ever be shared with researchers outside of the OSU study.

Results of this research study may be cited by the AOA, published in a medical journal, or used to teach others. However, your name or other identifying information will not be used. The investigators are only interested in the results of groups of patients; the results of individual study subjects are not useful for this type of study.

10. **What are the costs of taking part in this study?**

There is no cost to participate in this study.

11. **Will I be paid for taking part in this study?**

You will not be paid for participating.
12. What happens if I am injured because I took part in this study?

As this is an observational data collection study only, we do not anticipate that you will be physically harmed or injured in any way.

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

13. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact the study coordinator, Beth Sheridan Wagg, MPH, at 293-9013.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Dr. Laura Phieffer at 293-2633, or Beth Sheridan Wagg at 293-9013.
Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

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Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

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