

**Tulane University Human Research Protection Office**  
**Biomedical IRB Consent Form for Participation in a Research Study**  
***[Louisiana Osteoporosis Study]***

**Principal Investigator:** Lan-Juan Zhao, Ph.D.

**Study Title:** Louisiana Osteoporosis Study

**Performance Sites:** Tulane University School of Public Health and Tropical Medicine

**Sponsor:** Tulane University

**Introduction**

You are invited to participate in a research study to identify risk factors (including genetic and environmental) important for osteoporosis and related health problems. You are being asked to participate because you are a potential eligible subject for this study.

This consent form will give you the information you will need to understand why this study is being done and why you are being invited to participate. It will also describe what you will need to do to participate and any known risks, inconveniences or discomforts that you may have while participating. We encourage you to take some time to think this over and to discuss it with your family, friends and doctor. We also encourage you to ask questions now and at any time. If you decide to participate, you will be asked to sign this form and it will be a record of your agreement to participate. You will be given a copy of this form.

**Disclosure of Potential Conflict of Interest**

The investigator(s) in this study are interested in the knowledge to be gained from this study and in your well-being. Investigators may obtain salary or other financial support for conducting the research. You are under no obligation to participate in any research study offered to you.

If you are a Tulane student/employee, your participation in this research is voluntary. Your decision to participate, decline, or withdraw from participation will have no effect on your grades at, status at, or future relations with Tulane University.

**Why is this study being done?**

The goal of this research study is to identify risk factors (including genetic and environmental) important for osteoporosis and related health problems. To reach this goal, we will recruit 20,000 human subjects in New Orleans and surrounding areas.

Osteoporosis is a condition of low bone mass which results in high risk of fractures. It is a major public health problem. Osteoporosis is also associated with many other conditions, such as obesity, heart disease, and high blood pressure. The risk of osteoporosis has gender difference. While women have a relatively higher risk for developing osteoporosis comparing with men, men have a significantly higher mortality

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upon osteoporotic fractures. The most powerful, measurable determinant of fracture risk is bone mineral density (BMD). Osteoporosis is affected by both environmental factors (e.g., dietary calcium intake, alcohol consumption, smoking, weight-bearing exercise, etc.) and genetic factors.

Genetic factors involve genes. Genes are the factors people are born with, which determine traits such as hair and eye color. Genes can influence susceptibility to certain diseases. Genes are made up of DNA segments. DNA is reproducible in humans and can be transferred from parents to offspring. Proteins are the major products of genes. Different protein expression profiles between individuals may be caused by their genetic difference.

A gene is a segment of DNA that carries out a specific function including bone metabolism. A gene functions by being made into its products, such as protein, by a process called expression. Researchers study genes and their functional products, such as proteins, in order to understand why some people have certain health problems, such as an inherently low BMD and thus a high risk of osteoporosis, and why some people have high BMD and thus a low risk of osteoporosis. Understanding protein expression may also be able to explain why some people respond to a treatment, while others do not, or why some people experience a side effect from a medication and others do not.

This study is the first step in the process of osteoporosis research. Eventual gene therapy could be developed to prevent or reduce the risk of developing osteoporosis and fractures. This could significantly reduce pain, morbidity, and mortality in millions of patients. It could also save the United States, and other countries, billions in health care dollars.

**What are the study procedures? What will I be asked to do?**

If you are eligible and agree to take part in this study, you will be invited to our clinical enrollment site for study consent and enrollment into the study. Our clinical enrollment site is located at Tulane University School of Public Health and Tropical Medicine

The embryo/fetus dose in bone density measurements is lower than the average daily natural background in the United States. However, in order to eliminate any adverse effects (X-ray exposure) (even though very remote) of the bone density scan on fetus, women who are, or could be pregnant, will be excluded from any further clinical procedures and not included in this study. Please read the statement below carefully and check the option you prefer.

Only women that are confirmed to be “not pregnant” may participate in this research study. If you are younger than age 55 and you do not allow a pregnancy test to be

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conducted at our clinical site, you will not be enrolled into this research study and no research procedures will be performed. Do you consent to have a pregnancy test done? If you are a male, please skip this question.

\_\_\_\_\_ YES    \_\_\_\_\_ NO    \_\_\_\_\_ Subject's Initials

During the one-time, 2-hour visit,

- 1) You will be asked about your age, gender, ethnic background, medical history, family history, reproduction and menstrual history (women only), physical activity, alcohol use, diet habits, and smoking history, which will be assessed by a medical history questionnaire.
  
- 2) Your anthropometric measures such as weight, height, hip circumference, waist circumference will be measured by our research staff. Your blood pressure will be measured after you have been at rest for ten minutes. Your grip strength will also be measured. One sample of blood (about 2 tablespoons) will be collected from your vein. Collection of 2 milliliters of human saliva will be requested when 2 attempts at drawing blood is unsuccessful or we can't draw blood from you. DNA will be extracted and stored from the saliva specimen for the purpose of genetic/genomic studies of osteoporosis.
  
- 3) You will have your BMD, body composition and other related traits measured using our standard bone densitometry machine.

The DNA will be extracted from your blood specimen and will be stored in Tulane Center for Bioinformatics and Genomics (CBG) at Tulane University School of Public Health and Tropical Medicine for an indefinite period. Your blood cells will not be made to grow indefinitely in the laboratory (immortalized). Your DNA sample and all other information will be stored there with a code but not your name, in a way that will keep your identity a secret. The only people who can link the code to your name are the investigators at Tulane University. For stored DNA samples, future research which will be performed on these specimens will first be reviewed by an Institutional Review Board, such as the one which has reviewed this research and consent form. After you donate your blood, you still have the option to withdraw your sample and other information at a later date by contacting Dr. Zhao at Tulane University School of Public Health and Tropical Medicine in writing.

This research will not have any immediate effect on your health care; therefore, neither you nor your doctor will receive the results of this DNA testing. No medical report will be added to your medical records. Findings of the project will be published in the research

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literature in aggregate only, so that your name is never associated with the research findings, except as may be required by law.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.
- All employers with 15 or more employees must follow this law as of Nov. 21, 2009. Be aware that this new federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

You should read each of the statements below carefully and check the options that you prefer.

1. Do you wish your blood/saliva to be used in other research projects for studies of osteoporosis and associated diseases/conditions, including obesity, cardiovascular diseases, and female health related problems?

\_\_\_\_\_ YES

\_\_\_\_\_ NO

2. Is it acceptable to share your DNA samples with other institutes in de-identified format when it is necessary for the research of osteoporosis and related health problem?

\_\_\_\_\_ YES

\_\_\_\_\_ NO

3. Is it acceptable to share the genetic information derived from this study with other institutes in de-identified format for the general biomedical and genetic research relevant to the etiology, prevention, and treatment of osteoporosis and related health problems?

\_\_\_\_\_ YES

\_\_\_\_\_ NO

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4. Should further research opportunity arise and should you be identified potentially eligible, may study investigators contact you again to discuss your taking part in more research? The research would be related to human diseases and health issues, which cannot be specified and defined at this stage.

\_\_\_\_\_ YES

\_\_\_\_\_ NO

If yes, please write your address and/or telephone number by which we can contact you below:

Address: \_\_\_\_\_

Phone: \_\_\_\_\_

Email address: \_\_\_\_\_

**What are the risks or inconveniences of the study?**

Obtaining blood via phlebotomy can cause pain, bleeding, bruising, or swelling at the site of the needle stick. These are all immediate risks and there is no latent risk associated with phlebotomy. To reduce the above risks, we will follow the standard procedure for phlebotomy (disinfection of the local site using antiseptic before the procedure and stoppage of bleeding using medical cotton and a band-aid after the procedure). Before and after the phlebotomy, we will monitor the subject's blood pressure and pulse. The subject will be allowed to leave only after being monitored for 15 minutes, when we find his blood pressure and pulse is stable and there is no bleeding in the site of phlebotomy. In addition, our phlebotomists are all experienced in this procedure.

BMD measurements will be performed using a Dual Energy X-ray Absorptiometry (DXA) machine. This will consist of lying on a padded open scanning table for approximately half hour while a scanning arm passes over you (this arm will not touch you). There is no discomfort involved. BMD measurements involve exposure to a very small amount of radiation, approximately equal to that encountered during a brief exposure to sunlight. Therefore, the risk involved in DXA examination is minimal. In addition, DXA examination will be performed by trained professional research staff with competent technical skills.

Another risk of this study is the possible loss of privacy or breach of confidentiality. This risk can be classified as both immediate and latent. We will take all possible measures to reduce this risk, such as assigning a coded study number to your data. In addition, all information collected from you will be kept confidential and will not be released to any

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third parties (e.g., your Health Insurance Company, employer, family members, etc.). Thus, risks of potential discrimination, social stigmatization, and intra-family conflict will be minimized.

The time required to finish the visit (including medical history interview, basic clinical measurement, DXA measurement and phlebotomy) may be ~2 hours. Abstention from food and sitting or standing for a long time is not required.

You will be given any new information gained during the course of the study, which might affect your willingness to participate.

**What are the benefits of the study?**

Information gleaned from your bone density and body composition reports could greatly benefit your future bone and related health. Important objective measurements will be obtained, which are useful in assessing current health status. These include body mass index (BMI), fat mass, percentage fat mass, waist and hip circumference, and blood pressure. These clinical measurements will be performed at no cost to you. Any clinical abnormalities discovered will be brought to your attention. Should any abnormalities be found, you will be encouraged to visit your primary care physician.

Your participation in this study may add to the medical knowledge about osteoporosis.

**Will I receive payment for participation?**

To thank you for your contribution to our study and to compensate you for your time and transportation expenses for this visit, you will receive a \$25.00 gift card after the bone density test is completed.

If you were determined to be ineligible for the study based on our follow-up screening result, you will still receive a \$10.00 gift card as compensation.

**Are there costs to participate?**

There are no costs to you to participate in this study.

**How will my personal information be protected?**

The following procedures will be used to protect the confidentiality of your data. The researchers will keep all study records (including any codes to your data) locked in a secure location. Research records will be labeled with a unique code. A master key that links names and codes will be maintained in a separate and secure location. All electronic files (e.g., database, spreadsheet, etc.) containing identifiable information will be password protected. Any computer hosting such files will also have password protection to prevent access by unauthorized users. Only the members of the research staff will have access to

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the passwords. Data that will be shared with others will be coded as described above to help protect your identity. At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations. Any master key and other data described in this paragraph will be maintained in accordance with the security provisions of this paragraph until destroyed by the researchers.

The research data obtained from you may be stored for future use. However, the use of the data will not reveal or implicate your true identification as the data will be associated with a code (the same code mentioned above that is assigned to you at the beginning of this recruitment). In this way, the data will be de-identified and your identification will not be known by looking at the data. In addition, only the authorized personnel from the research team will have access to the data and data will not be transferred to any third party.

You should also know that the Tulane University Human Research Protection Office and the Biomedical Institutional Review Board (IRB) may inspect study records as part of its auditing program, but these reviews will only focus on the researchers and not on your responses or involvement. The IRB is a group of people who review research studies to protect the rights and welfare of research participants.

**What happens if I am injured or sick because I took part in the study?**

In the event you become sick or injured during the course of the research study, immediately notify the principal investigator or a member of the research team. The Tulane University Health Sciences Center and the investigators in this protocol will provide necessary medical treatment for any injury or illness which may arise from your participation in this research, but either you or your insurer must pay for it.

If your insurer refuses to pay for aftercare related to a study-related illness or injury, you will be responsible for paying costs for aftercare related to a study-related illness or injury, including but not limited to applicable co-payments and deductibles.

The Tulane University Health Sciences Center does not offer any form of compensation for injury or illness arising from participation in this research.

If you have any questions about your rights as a research subject, please call the Tulane University Human Research Protection Office at (504) 988-2665 or email [irbmain@tulane.edu](mailto:irbmain@tulane.edu).

**Can I stop being in the study and what are my rights?**

You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time. There are no penalties or consequences of any kind if you decide that you do not want to participate. You do not have to answer any question that you do not want to answer.

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**Who do I contact if I have questions about the study?**

Take as much time as you like before you make a decision to participate in this study. We will be happy to answer any question you have about this study. If you have further questions about this study, want to voice concerns or complaints about the research or if you have a research-related problem, you may contact the principal investigator, Dr. Lan-Juan Zhao at (504)988-0252 or email lzhao2@tulane.edu, or the study coordinators at (504)988-1016 or email [bonestudyneworleans@tulane.edu](mailto:bonestudyneworleans@tulane.edu) for New Orleans site. If you would like to discuss your rights as a research participant, discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who is unaffiliated with the specific research, you may contact the Tulane University Human Research Protection Office at 504-988-2665 or email at [irbmain@tulane.edu](mailto:irbmain@tulane.edu).

**Documentation of Consent:**

I have read this form and decided that I will participate in the research project described above. Its general purposes, the particulars of involvement and possible risks and inconveniences have been explained to my satisfaction. I understand that I can withdraw at any time. My signature also indicates that I have received a copy of this consent form.

Do you understand in full all the content in this consent form? Yes ( ) No ( )

\_\_\_\_\_  
 Subject Date

\_\_\_\_\_  
 Parent/Legally Authorized Representative (if applicable) Date

\_\_\_\_\_  
 Person Obtaining Consent Date

I am unable to read but this consent document has been read and explained to me by \_\_\_\_\_ (name of reader). I volunteer to participate in this research.

\_\_\_\_\_  
 Subject Date

\_\_\_\_\_  
 Witness Date

\_\_\_\_\_  
 Person Obtaining Consent Date

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