

Document Coversheet

Study Title: Novel Precision Medicine Approach to Treatment of Osteoporosis Based on Bone Turnover

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Consent and Authorization to Participate in a Research Study

IRB Approval
8/19/2025
IRB # 70781
IRB2

KEY INFORMATION FOR NOVEL PRECISION MEDICINE APPROACH TO TREATMENT OF OSTEOPOROSIS BASED ON BONE TURNOVER:

We are asking you to choose whether or not to volunteer for a research study to find out what is the best approach to treat your osteoporosis. We are asking you because you are a woman, 45 years old or over, who has been diagnosed with osteoporosis. You will have an X-ray to diagnose how dense the bones are and a bone biopsy which is considered necessary to find the reason for your bone disease. You can lose bone due to low formation of new bone (usually associated with aging) or increased destruction of old bone (usually associated with menopause). This page is to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

At this time, treatment for osteoporosis is usually done with one type of drug only. This drug is effective only in a limited number of patients. This study will document the need to choose the drug initially selected for treatment tailored to the individual need of the patient. Your participation in this research will last up to 18 months (12 months for the treatment and 2 to 6 months for required measurements).

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

- You will help others by contributing to clinical research and improving the treatment for osteoporosis.
- You will learn about the different bone diseases and you will receive additional care and attention from the clinical staff.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

- You may be moving away from Kentucky and won't be able to stay in the study for 1 year.
- You don't think you will have time for the study.
- You will not select your study group, you are assigned to the group 1 (low turnover receiving **Forteo®**) or group 2 (low turnover receiving **Alendronate**) by chance.
- You may not want to have a bone biopsy. For a complete description of risks, refer to the Detailed Consent that follows.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer or if you decide to stop at any time during the study. If you decide not to take part in this study, your decision will have no effect on the other medical care you receive.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

Before you decide whether to accept this invitation to take part in the study, please ask, the Principal Investigator (PI), **Madhumathi Rao, MD (859-323-2637) or the study coordinator at 859-323-2672 or 859-619-5304**, any questions that might come to mind now. Later, if you have questions, suggestions, concerns or complaints regarding this study or you want to withdraw from the study contact the PI, **Dr. Madhumathi Rao at 859-323-2637 or the Study Coordinator at 859-323-2672 or 859-619-5304**.

If you have any concerns or questions about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

DETAILED CONSENT:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

The reasons for you to be excluded from volunteering for this study are:

- Pregnant or trying to become pregnant or are breastfeeding
- Participation in a study of an investigational drug during the past 30 days
- Treatment with anabolic or antiresorptive bone drugs.
- Use of systemic anticoagulation (blood thinner)
- Planned or anticipated oral surgery within the next 12 months
- Allergy to the antibiotics demeclocycline or tetracycline
- Planning to move out of the area within 18 months of the study
- Inability to stand or sit upright for at least 30 minutes
- Chronic alcoholism and/or drug addiction
- Prior radiation therapy (external beam or implant radiation) involving the skeleton (only if randomized to the bone forming drug (anabolic Forte®))
- Systemic illnesses or organ diseases that may affect bone (except type 1 or type 2 diabetes mellitus)
- Clinical condition that may limit study participation (e.g., heart diseases (unstable angina), lung diseases (severe COPD), other infections)
- Abnormalities of the esophagus (tube connecting the mouth to the stomach) which delay esophageal emptying such as stricture (narrowing) or achalasia (a condition that prevents normal swallowing)
- Have other bone diseases that are not linked to age or menopause
- Have a history of malignancy (cancer), not including non-melanoma skin cancer.
- Vitamin D (Calcidiol) level below the normal range (below 20ng/mL)
- **After Randomization:** If randomized to Group 1 Teriparatide **AND** DXA measurement of the forearm are lower than -3.5 T-scores **AND** you decline to sign a consent to continue to participate.

WHERE WILL THE STUDY TAKE PLACE AND WHAT IS THE TOTAL AMOUNT OF TIME INVOLVED?

The research procedures will be conducted at the University of Kentucky, Medical Center.

You will have to come to the UK Center for Clinical and Translational Science (CCTS), 5th floor, close to the elevator C 4-6 times during this part of the study. A map will be given to you and research personnel will assist you.

Those visits will take approx. 40-60 minutes. The total amount of time you will be asked to volunteer for this study is 11 to 13 hours over the course of 1 year and a follow up phone call 3 months after finishing one-year treatment.

The study visits will include blood drawing, Dual energy X-ray absorptiometry (DXA) to examine bone mineral content, and a bone biopsy (at baseline). You will also be asked to complete a survey / questionnaire either electronically through web-based platform or email; or a paper version conducted at home or in person with the study coordinator. REDCap is a secure, web-based program to capture and store data at the University of Kentucky. We will make every effort to safeguard your data in REDCap. However, given the nature of online surveys, we cannot guarantee the security of data obtained by way of the Internet.

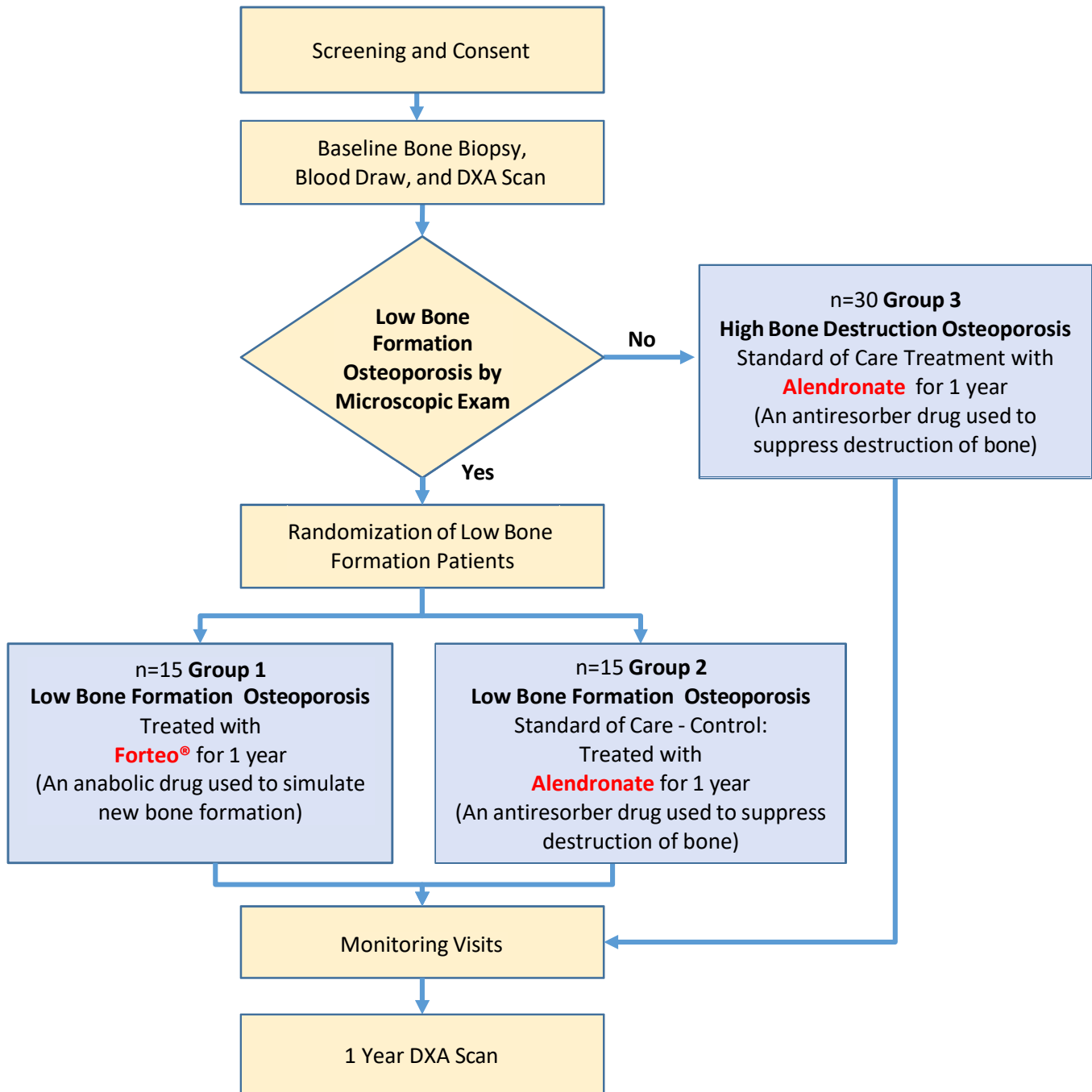
For the bone biopsy, we will ask you to take FDA (Federal Food and Drug Administration) approved antibiotics (Tetracycline and Demeclocycline) given as directed prior to your visit. These medications will help us to determine the mechanisms responsible for your bone loss.

The DXA scan and the bone biopsy (including the preparation and blood drawing) will take approx. 60 minutes. After the bone biopsy, to fully recover from the anesthesia, we ask you to stay in the CCTS unit for another 1-4

hours for observation. We ask you to have a driver available to take you home since we will administer Versed® and Fentanyl for mild sedation or Propofol for deeper sedation. Anesthesia will be administered by a faculty member in the Division of Anesthesiology, University of Kentucky.

WHAT WILL YOU BE ASKED TO DO?

We are asking you to participate in the following study protocol (replace heading?)



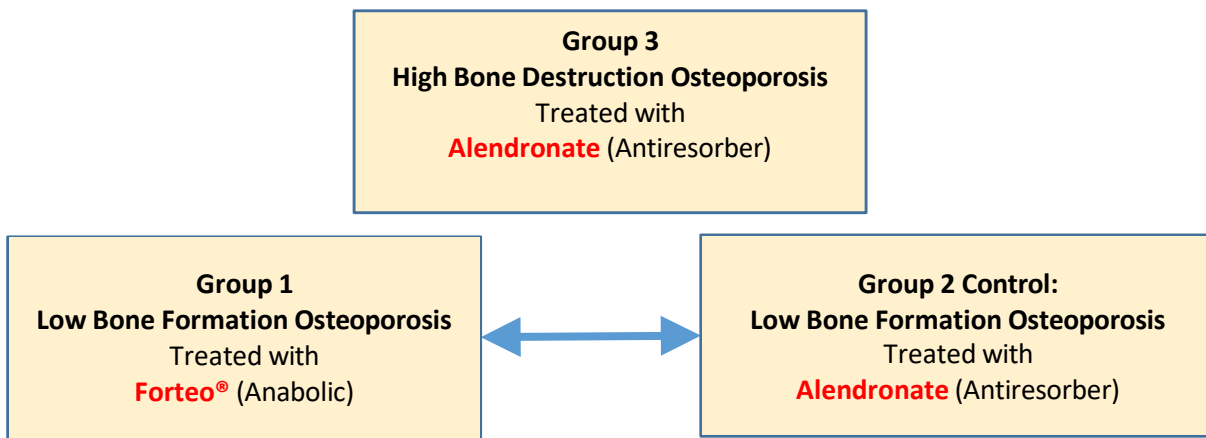
If you were found to **have low bone density by DXA scan** and **agree to participate** in this treatment study, you will have blood drawn and bone biopsy, which are also routinely offered in a standard clinical care, to determine

the mechanism for your bone loss (**assessment of bone formation versus destruction**) to determine which study group you may be a candidate for (see the Figure above).

If it is determined you are in either **group 1 or group 2** (low bone formation) you will then be assigned by chance to either treatment group **Forteo®** (simulate new bone formation) or treatment group standard of care **Alendronate** (suppress destruction of bone). You will randomly be assigned (by chance: equal probability of being assigned to any group) to one of two interventions (**Forteo®** or **Alendronate**). You will be randomized in 1:1 ratio chance using a block randomization in blocks of 5 between **Forteo®** and **Alendronate**.

If after randomization, you are assigned to Forteo® AND your DXA measurement values of the forearm are found to be lower than -3.5 T-scores, you will be offered an opportunity to sign a consent to continue to participate. If you are willing to sign the consent to continue to participate, you will be able to continue in the study. If you are unwilling to sign the consent to continue to participate, you will be excluded from the study.

Once it is determined you are in the **group 3** (High bone destruction) you will be treated with standard of care **Alendronate**. The increased bone destruction group will be filled sequentially until the goal is reached.



- **Group 1 (Low Bone Formation Osteoporosis Treated with Forteo®):**

Patients in the group 1 will be taking **Forteo®** once a day. This medication is administered by an injection under the skin by a very small needle once a day.

- **Group 2 (Low Bone Formation Osteoporosis Treated with Alendronate)**

Patients in the group 2 will be taking **Alendronate**. This medication is a pill by mouth once a week on an empty stomach with 6-8 ounces of water. After swallowing the pill, you should not lie down for 30 minutes.

- **Group 3 (High Bone Destruction Osteoporosis Treated with Alendronate):**

Patients in the group 3 will be taking **Alendronate**. This medication is a pill by mouth once a week on an empty stomach with 6-8 ounces of water. After swallowing the pill, you should not lie down for 30 minutes.

Study visits are listed below:

Visit 1:

Once enrolled in the study, you will have a bone biopsy scheduled. You will be given oral medications called **tetracycline** and **demeclocycline** to be taken at specific times before the bone biopsy. These medications are FDA approved antibiotics and will help us to determine changes in the amount of bone built in your skeleton. Tetracycline will be taken over 4 days (one pill each morning and one pill each evening). Then you will be off for 10 days then take Demeclocycline for a course of 2 days (one pill each morning and one pill each evening). You will receive a **calendar** with the days marked when to take the pills and you will also be called on the respective days by our study personnel to remind you. This will be performed only once prior to baseline. On the day prior to or on the morning of your baseline visit; you will be asked to complete a survey / questionnaire either electronically through web-based platform or email; or a paper version conducted at home or in person with the study coordinator.

Visit 2 – Baseline:

- 1) At the beginning of the study, you will first meet with the study coordinator specializing in the care of osteoporotic patients in the Center for Clinical and Translational Science (CCTS) unit located on the 5th floor of the hospital for **blood drawing** and undergo **bone density measurements (DXA)**. DXA scan is a routinely utilized procedure that uses a very weak form of X-ray for measurement of bone mineral at the hip, lower spine and the wrist in order to gain information on how strong those bone areas are. DXA scan exposes you to radiation similar to a mammogram. The radiation dose is greater than that from typical natural background exposure, but less than the limit for radiation workers and well below the levels that are considered to be a significant risk of any harmful effects. Since this scan utilizes X-ray, it requires a negative pregnancy test for women of childbearing age prior to performing the scan. Each exam takes approximately 30 minutes and requires you to lie flat.
- 2) After the DXA scan, you will undergo **bone biopsy** at the CCTS unit located on the 5th floor of the Chandler Medical Center at the University of Kentucky. Bone biopsy is the currently accepted standard for the exact diagnosis of bone disease. It is done under fully sterile conditions and under local anesthesia (numbing of the skin and bone) to the pelvic bone. You will also be given Versed® and Fentanyl for mild sedation or Propofol for deeper sedation. Anesthesia will be administered and supervised by a faculty member in the Division of Anesthesiology, University of Kentucky. Two very small bone samples (1/5 inch diameter, 2-3 cm length) will be taken from the hips by a specially trained physician who is an expert in this procedure.
- 3) You will receive from us 3 months supplies of medications at your study visits.

Visit 3:

We may ask you to return to the **CCTS unit, 1 week after the bone biopsy procedure** for routine follow-up.

Visits 4, 5 and 6:

Three, 6 and 9 months after the beginning of the study, you will meet again with the study coordinator specializing in the care of osteoporotic patients in the CCTS unit for **blood drawing**. The procedure takes less than 30 minutes.

Just prior to or on the day of your 6-month visit, you will be asked to complete a survey / questionnaire either electronically through web-based platform or email; or a paper version conducted at home or in person with the study coordinator.

Visit 7:

One year after the beginning of the study, you will meet again with the study coordinator specializing in the care of osteoporotic patients in the Center for Clinical and Translational Science (CCTS) unit located on the 5th floor of the hospital for **blood drawing** and undergo **bone density measurements (DXA)**. Each DXA scan takes approximately 30 minutes and requires you to lie flat.

Just prior to or on the day of your 12-month visit, you will be asked to complete a survey / questionnaire either electronically through web-based platform or email; or a paper version conducted at home or in person with the study coordinator.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?**Risks of Procedures****Bone biopsy**

Bone biopsies will be performed because a biopsy is the currently best test for diagnosis and determination of your bone turnover. Studies have evaluated the risks of bone biopsies and found that potential complications include bruising, nerve pain and wound infection. These complications are found in 0.36% of patients no matter whether the biopsy is part of research or part of routine management.

You will get a prescription for pain medicine after the bone biopsy.

- **Tetracycline** and **Demeclocycline** will be used for marking of the bone. These drugs are generally well tolerated--rarely observed side effects include allergic reactions and vomiting. There is also a possibility that you may experience a sensitivity to direct sunlight exposure, therefore, we recommend that you avoid extended

periods of direct exposure to sunlight while taking the antibiotics. Let your research coordinator know if you experience any side effects.

- The risks associated with **bone biopsy** include bleeding, pain, infection, superficial nerve damage, and allergic reactions to lidocaine or sedation medications. These complications are extremely rare. You will receive pain medication and sedation during the procedure and following the procedure, as needed. You will receive written instructions on postoperative wound (length 1-2 cm) care. You will also have 24-hour access to the physician who performed the biopsy through UK's answering system (UKMD) should any problems or questions arise and appropriate medical care will follow (prescription of antibiotic and wound care if necessary). The number for **UKMD is 859-257-5522**.

Blood draws

The risks associated with **blood draws** are minimal and restricted to potential discomfort during the procedure and, possibly, soreness, bruising, pain, bleeding, and possible infection at the blood drawing site. Compression after blood drawing will reduce the incidence of bruising and bleeding. Rarely, there is a possibility that you may faint.

DXA

Like all radiographic techniques the measurement of bone mass exposes you to some radiation. The radiation doses for **DXA** are small and similar to what you are exposed to everyday in the environment. The radiation dose from a typical DXA bone scan produces approximately 1/300th of the natural background radiation dose we receive each year. This radiation dose is not considered to be a significant risk of any harmful effects.

Medications

Both **Forteo®** and **Alendronate** have been used in osteoporotic patients for more than 19 and 20 years, respectively. In the experience of the PI they are generally well-tolerated. The PI, Dr. Rao, has used these medications in his osteoporosis practice in patients for over 19 years and has experience in long-term monitoring of these treatments.

There is always a chance that any medical treatment can harm you, and the investigational treatment in this study is no different. In addition to the risks listed above, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

Your bone status will be determined and there is the possibility that you may have improvement in your bone density with the medication. In addition, if you take part in this study, information learned from this study may help others with osteoporosis.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to take part in the study, you can discuss bone loss with your primary physician and continue with standard of care treatment.

WHAT WILL IT COST YOU TO PARTICIPATE?

You will not be charged for any expenses directly related to the study.

However, you and/or your insurance company, Medicare, or Medicaid will be responsible for the costs of all care and treatment that you would normally receive for any conditions you may have; these are costs that are considered medically necessary and will be part of the care you receive even if you do not take part in this study.

The University of Kentucky may not be allowed to bill your insurance company, Medicare, or Medicaid for the medical procedures done strictly for research.

Therefore, sponsor, the National Institutes of Health, will be responsible to pay all research related costs including paying for:

- the medications that you will be taking for your bone biopsy and for pain control after bone biopsy,
- the study medication **Forteo®** or **Alendronate**,
- the DXA studies and all blood tests related to the study during the time of enrollment in the research study,

- the research-related bone biopsy procedure.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

We will keep your name and other identifying information confidential.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. Your information on paper records will be kept under lock and key in the office of the study coordinators. Data on computers that are connected to a University of Kentucky Medical Center network connection have a password-protected operating system and are protected by firewalls. REDCap is a secure, web-based program to capture and store data at the University of Kentucky. We will make every effort to safeguard your data in REDCap. However, given the nature of online surveys, we cannot guarantee the security of data obtained by way of the Internet.

You should know that in some cases we may have to show your information to other people. For example, the court may require the release of your medical records.

To ensure the study is conducted properly, the National Institutes of Health and the University of Kentucky may look at or copy pertinent portions of records that identify you.

The law may require or permit us to share your information with:

- a court or agencies, if you have a reportable disease/condition;
- authorities, such as child or adult protective services, if you report information about a child or elder being abused;
- authorities or a mental health professional if you pose a danger to yourself or someone else (e.g. suicidal thoughts).

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. You may be removed from the study if:

- you are not able to follow the directions,
- we find that your participation in the study is more risk than benefit to you, or
- the agency paying for the study chooses to stop the study early for a number of scientific reasons.
- The medications may become unavailable.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

While you are part of this study, you may not participate in another study involving any therapy affecting bone. It is important to let the investigator/your doctor know if you are in another research study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

The study drugs you will be given are FDA approved medications used routinely for treatment of osteoporosis. If you believe you are hurt or if you get sick because of something that is due to the study, you should call Dr. Rao at **859-323-2637** or the Study Coordinator at **859-323-2672** or **859-619-5304** immediately.

It is important for you to understand that the University of Kentucky will not pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

Medical costs related to your care and treatment because of study-related harm

- may be paid by your insurer if you are insured by a health insurance company (you should ask your insurer if you have any questions regarding your insurer's willingness to pay under these circumstances); or

- may be paid by Medicare or Medicaid if you are covered by Medicare or Medicaid (If you have any questions regarding Medicare/Medicaid coverage you should contact Medicare by calling 1-800-Medicare (1-800-633-4227) or Medicaid 1-800-635-2570.).

It will be your responsibility if a co-payment/deductible may be needed by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs. The amount of this co-payment/deductible may be costly.

You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will be compensated for your potential discomfort, inconvenience and time commitment. You will be paid \$20 per blood draw, \$150 per DXA scan, and \$500 for the bone biopsy. Additionally, you will also receive travel reimbursement based on standard mileage rates. You should receive a check in the mail about 4 weeks after your study visit.

With a few exceptions, study payments are considered taxable income reportable to the Internal Revenue Service (IRS). A form 1099 will be sent to you if your total payments for research participation are \$600 or more in a calendar year.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?

Generally, tests done for research purposes are not meant to provide clinical information. We will provide you with individual research results at the end of the study, upon request.

Do you give permission for us to contact you about research results or incidental findings that are determined to be important to you/your family's health? (Incidental findings are unforeseen findings discovered during the course of the research that may affect you or your family's health).

☐ Yes ☐ No _____ Initials

You may also withdraw your consent to be contacted with information about research results or incidental findings by sending a written request to **Dr. Rao , Division of Nephrology, UK Medical Center, 800 Rose St, Room MN 564, Lexington, KY, 40536-0298.**

WILL WE CONTACT YOU WITH INFORMATION ABOUT PARTICIPATING IN FUTURE STUDIES?

The research staff would like to contact you in the future with information about participating in additional studies.

If so, it will be limited to **once** per year.

Do you give your permission to be contacted in the future by **Dr. Rao** regarding your willingness to participate in future research studies?

☐ Yes ☐ No Initials _____

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of 60 people to do so.

The National Institute of Health (NIH) is providing financial support and material for this study.

The information or specimens that you are providing will no longer belong to you. The research may lead to new clinical or educational knowledge, tests, treatments, or products. These products could have some financial value. There are no plans to provide financial payment to you or your relatives if this occurs.

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.

STORING AND SHARING YOUR INFORMATION OR SPECIMEN SAMPLES FOR FUTURE USE:

The researchers would like to store, use, and share your identifiable (bone biopsy and DXA results, blood samples for future tests) for future research. Having information/samples from many people helps researchers identify trends and discover better ways to diagnose, prevent, and treat many conditions. Researchers can use the stored information/samples to learn more about the best treatment for osteoporosis or research additional scientific questions.

The researchers would like to have permission to look at your medical records from time to time. Researchers would collect general information related to your health such as test results, treatments, and doctor's notes. The confidentiality section below provides details about how we will keep your information private.

Genetic studies help explain why traits (eye color, personality, etc.) or diseases are passed down in families. Results of genetic studies may also reveal information about your family members. Researchers may use genetic material in your sample to learn about the role they play in health and disease. Even if researchers do this type of research, the results will not be put into your health record.

Your complete set of your genetic information is called your "genome". Your genome is completely unique to you. Researchers may analyze sections or all of your genome. They may also analyze genomes from many different people to look for differences which may help predict what makes people more or less likely to inherit a trait or get a certain disease or condition.

To advance scientific discovery, researchers share genomic data. Your genomic and health information may be put into scientific databases along with information from other people. Your name or information that could directly identify you will never be included. Researchers who want to study the information must apply for and get permission to use the data. Summary results (trends or findings) may be placed in databases that are publicly available.

WHERE WILL INFORMATION OR SPECIMEN SAMPLES BE STORED AND FOR HOW LONG?

The information and samples collected will be stored **indefinitely** at the Bone Diagnostic and Research Center, Bone Registry. This repository is a clinical laboratory within the **Division of Nephrology, UK Medical Center, 800 Rose St, Room MN 571, Lexington, KY.**

ARE THERE RISKS FROM ALLOWING YOUR INFORMATION OR SPECIMEN SAMPLES TO BE STORED FOR FUTURE RESEARCH?

Privacy and Social/Psychological:

There is a risk that someone could get access to the stored information or samples. In spite of the security measures and safeguards we will use, we cannot guarantee that your identity will never become known.

Include if genetic or genomic testing is possible:

Even without your name or identifiers, genetic information is unique to you. The results of genetic research apply to both you and your family members. Genetic information used improperly to discriminate or support negative stereotypes could cause you or your family distress. We do not know whether future technology will make it possible for someone to trace your genetic information back to you.

There is a federal law called the Genetic Information Nondiscrimination Act (GINA). Generally, GINA makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Be aware that GINA does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. It also does not prohibit discrimination on the basis of an already known genetic disease.

HOW WILL YOUR PRIVACY AND CONFIDENTIALITY BE PROTECTED?

Researchers will take careful steps to keep your information confidential.

Your identifiable information on paper records will be kept under lock and key in the office of the study coordinators. Data on computers that are connected to a University of Kentucky Medical Center network connection have a password-protected operating system and are protected by firewalls.

Researchers will remove your name or other direct identifiers from your information or samples. We will label your information or samples with a code and will store the key separately from the master code list. Only select staff will have access to the list that links the code to you.

HOW WILL WE SHARE YOUR INFORMATION OR SPECIMEN SAMPLES WITH OTHER RESEARCHERS?

Your de-identified information or samples may be shared with other researchers without your additional informed consent, provided an Institutional Review Board (IRB) has approved this action. An IRB is a committee that reviews ethical issues, according to federal, state and local regulations on research with human participants. If a researcher requests your information or samples with identifiable information, an IRB will decide if the research may be conducted with or without your additional consent.

WHAT IF YOU CHANGE YOUR MIND AND WANT TO WITHDRAW YOUR INFORMATION OR SPECIMEN SAMPLES?

You may withdraw your permission to allow your information or samples to be used for future research. To do so, you must send a written withdraw request to **Dr. Rao, Division of Nephrology, UK Medical Center, 800 Rose St, Room MN 564, Lexington, KY, 40536-0298.**

Any remaining information and samples will be destroyed. In addition, it may be possible to destroy the code that links you with your information and specimen samples. However, the information and samples that have already been used or shared may not be withdrawn.

WILL YOU RECEIVE ANY COMMERCIAL PROFIT FROM FUTURE RESEARCH DISCOVERIES?

The information and samples that you provide will no longer belong to you. The research may lead to new medical knowledge, tests, treatments, or products. These products could have some financial value. There are no plans to provide financial payment to you or your relatives should this occur.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE FUTURE RESEARCH TESTS?

Tests done for research purposes are not meant to provide clinical information or help care for you. The results are only important for research. Therefore, the results of tests done with your information and samples will not be provided to you. In the rare event that a finding might affect the health of you or your family, we will contact you and you can choose whether to receive or refuse the information.

OPTIONAL FUTURE USE

Do you give permission for your identifiable information/specimens to be shared for future research?

☐ Yes ☐ No Initials _____

Remember, you can still be in the main study even if you do not wish to allow your information shared for future research.

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information.

Your health information that may be accessed, used and/or released includes:

- Name
- Demographics
- Date of birth

- Social Security Number
- Dates of visit at the UK hospital
- Medical history
- Medications
- Results of laboratory tests
- Results of bone X-rays
- Death Certificates
- Hospital and Clinic Notes
- Results of bone biopsy

The Researchers may use and share your health information only with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity;
- Law enforcement agencies when required by law;
- University of Kentucky representatives;
- UK HealthCare and their representatives;
- Health systems outside of UK for which you have a patient relationship;
- The National Institute Health (NIH) and its authorized representatives, who is funding this research;
- Center for Clinical and Translational Science (CCTS);
- Your primary physician will be contacted if the researcher, in the course of the project, learns of a medical condition that needs immediate attention.

The researchers agree to only share your health information with study personnel referred to in this document.

Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information is regulated by applicable federal and state laws.

You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form, it will not affect your:

- Current or future healthcare at the University of Kentucky;
- Current or future payments to the University of Kentucky;
- Ability to enroll in any health plans (if applicable); or
- Eligibility for benefits (if applicable).

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:

- Send a written letter to: **Dr. Rao, Division of Nephrology, UK Medical Center, 800 Rose St, Room MN 564, Lexington, KY, 40536-0298** to inform him of your decision.
- Researchers may use and release your health information **already** collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).

The use and sharing of your information have no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky's Privacy Officer between the business hours of 8am and 5pm EST, Monday-Friday at (859) 323-1184.

Appendix: Study Visits/Procedures

| Activity | DXA | Bone Biopsy | Safety and Monitoring Blood Draw | Wound Checkup |
|--|-----|-------------|-------------------------------------|---------------|
| Visit 1: Screening | X | | | |
| Visit 2 - Baseline DXA, Biopsy and Blood Draws | X | X | X | |
| Visit 3 – 1 Week | | | | X |
| Visit 4 –Monitoring 3 Months | | | X | |
| Visit 5 – Monitoring 6 Months | | | X | |
| Visit 6 – Monitoring 9 Months | | | X | |
| Visit 7 – End 12-Months | X | | X | |

Appendix: Risks

Bone Biopsy

| Possible Risk/Side Effect | How often has it occurred? | How serious is it? | Can it be corrected? |
|---|----------------------------|--------------------|----------------------|
| Blood Drawing | | | |
| Bruising | Common | Minimal | Yes |
| Soreness | Rarely | Minimal | Yes |
| Pain | Rarely | Minimal | Yes |
| Infection at blood site | Rarely | Can be serious | Yes |
| Possible fainting | Rarely | Minimal | Yes |
| Bleeding | Common | Minimal | Yes |
| Bone Biopsy | | | |
| Broken bone | Extremely rare | Can be serious | Yes |
| Bone infection | Extremely rare | Can be serious | Yes |
| Discomfort/Bruising | Fairly common | Minimal | Yes |
| Allergic reaction to medication/Vomiting/photosensitivity | Rarely | Moderate | Yes |
| Anesthesia | | | |
| Allergic reaction to Lidocaine, sedative or pain medications | Rarely | Moderate | Yes |
| Breathing problems or heart/circulatory problems (irregular heartbeats, heart attack, stroke) with sedative medications | Very rarely | Can be serious | Yes |

Alendronate

| Possible Risk/Side Effect | How often has it occurred? | How serious is it? | Can it be corrected? |
|--|--|--------------------|--|
| GI complaints (abdominal pain, nausea, dyspepsia(heartburn), constipation, diarrhea, and flatulence) | Occasionally | Minimal | Yes, by stopping the medication |
| More Severe GI Complaints; (Regurgitation, esophageal ulcer, vomiting, dysphagia (difficulty swallowing), abdominal distention, and gastritis) | Less Often | Can be serious | Yes, by stopping the medication but in some instances may require treatment. |
| Taste Perversion | Rarely | Minimal | Yes, by stopping the medication |
| Low blood levels of calcium and phosphorus | Occasionally, usually transient | Mild, asymptomatic | Yes, by stopping the medication |
| Bone, muscle, or joint pain | 4% of patients | Minimal | Yes, by stopping the medication |
| Osteonecrosis of the Jaw | Rarely | Serious | May require treatment |
| Femur and subtrochanteric insufficiency (spontaneous thigh bone) fractures | Rarely and is associated with long term use of more than 6 years | Serious | May require treatment |

Forteo®

| Possible Risk/Side Effect | How often has it occurred? | How serious is it? | Can it be corrected? |
|---------------------------|----------------------------|--------------------|---------------------------------|
| Arthralgia/pain | Occasionally | Minimal | Yes, by stopping the medication |
| Nausea | Occasionally | Minimal | Yes, by stopping the medication |
| Dizziness | Occasionally | Minimal | Yes, by stopping the medication |
| Leg cramps | Occasionally | Minimal | Yes, by stopping the medication |
| Injection site reaction | Occasionally | Minimal | Yes, by stopping the medication |
| High blood calcium | Rarely | Can be serious | Yes, by stopping the medication |

INFORMED CONSENT SIGNATURES

This consent includes the following:

- Key Information Page
- Detailed Consent
- Appendices:
 1. Study Visits/Procedures
 2. Appendix: Risks

You will receive a copy of this consent form after it has been signed.

| | |
|--|---|
| <div style="border-bottom: 1px solid black; margin-bottom: 5px;"></div> Signature of research subject | <div style="border-bottom: 1px solid black; margin-bottom: 5px;"></div> Date |
| <div style="border-bottom: 1px solid black; margin-bottom: 5px;"></div> Printed name of research subject | |
| <div style="border-bottom: 1px solid black; margin-bottom: 5px;"></div> Printed name of person obtaining informed consent and HIPAA authorization | |
| <div style="border-bottom: 1px solid black; margin-bottom: 5px;"></div> Date | |
| <div style="border-bottom: 1px solid black; margin-bottom: 5px;"></div> Signature of Principal Investigator or Sub/Co-Investigator, | <div style="border-bottom: 1px solid black; margin-bottom: 5px;"></div> Date |