Fractures and Bone Disease in Living Kidney Donors

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MAYO CLINIC

Name and Clinic Number

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RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Fractures and Bone Disease in Living Kidney Donors

IRB#: 20-004432

Principal Investigator: Dr. Rajiv Kumar and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.	
It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research is to compare the bone health of living kidney donors and compare them to non-kidney donors to learn if living kidney donors have a higher risk of bone fractures (breaks) after kidney donation. You have been asked to take part in this research because you previously donated a kidney, or you are similar to someone who had donated a kidney and you are 50 years of age or older.
What's Involved	Study participation involves a 6-8-hour study visit. During this time, your blood and urine will be collected for lab tests to measure your kidney function and bone health, and you will have scans of your hips, arms, legs and spine to assess bone strength.

Key Information	• You will not need to pay for any of the study tests. • During the bone scans, you will be exposed to small amounts of radiation. • During the kidney function test, you will have an injection of a contrast material under your skin. You should notify the doctor if you have ever had an allergic reaction to contrast material, iodine, or shellfish. • You will receive $250 for your time in the study. • This study is only being done for research, you won't benefit from participating in this study.
Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep. A copy of this form will be put in your medical record.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator:** Rajiv Kumar, M.D. **Phone:** (507) 266-1045 **Study Team Contact:** Adam Miller **Phone:** (507) 266-8147 **Institution Name and Address:** Mayo Clinic 200 1st St SW Rochester, MN 55905
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Participant Advocate (RPA)** **(The RPA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** ResearchParticipantAdvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

Other Information:
A description of this study will be available on http://www.ClinicalTrials.gov. 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.

Why are you being asked to take part in this research study?

You are being asked to take part in this study because you either donated a kidney at least 10 years ago, or you are similar to someone who donated a kidney, and you are 50 years of age or older.

Why is this research study being done?

This research study is being done to measure bone health in living kidney donors and compare them to non-kidney donors to learn if living kidney donors have a higher risk of bone fractures (breaks) after kidney donation. Certain chemicals in the body that help maintain bone health were shown to have changed after kidney donation in living donors, whether or not these changes lead to a decrease in bone quality and increase the risk of fractures is not known.

The purpose of this study is to compare the bone health of living kidney donors with the bone health of non-kidney donors. This information will be helpful in informing future kidney donors of the risks of donation and in creating treatments to help prevent these complications.

Information you should know

Who is Funding the Study?
The National Institutes of Health (NIH) is funding the study. The NIH will pay Mayo Clinic to cover costs related to running the study.

Information Regarding Conflict of Interest:
Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

How long will you be in this research study?

You will be in this study for 1 day (about 6-8 hours total). Prior to your visit you will be provided a urine collection kit that will be mailed to your home in which you will collect your urine for 24 hours immediately prior to coming to your visit. You will bring the collection with you on the day of your visit.

What will happen to you while you are in this research study?

If you agree to take part in this study, you will first be asked to sign this Informed Consent Form before any study procedures take place. The study team upon receiving your signed consent will mail you a 24 hour urine collection kit that you will collect the day prior to your visit. You will be asked to fast (not eat or drink anything other than water) overnight (12 hours), and when you arrive in the morning, you will meet with a study coordinator to review the study procedures. You will present the 24 hour urine collection to the study team and begin with the testing.

During your visit, the study coordinator will review your medical history with you and collect information about your current medications. After you meet with the study coordinator, you will report to the Clinical Research and Trials Unit (CRTU) in the Charlton Building around 8:00 am, and you will have the following tests and procedures:

- **Random urine collection (possible)**
  - You may be asked to provide a random urine sample if needed.
- **Blood Collection:**
  - Lab tests: Complete blood count (CBC), electrolytes, calcium, phosphate concentrations, creatinine, blood urea nitrogen (BUN) and albumin
  - Bone biomarkers (bone biomarkers are specific measures that can indicate the condition of your bones)
  - The total amount of blood that will be withdrawn for this study is about 20 mL (4 teaspoons)
- **Dual-energy x-ray absorptiometry (DXA Scan)**
  - You will have a DXA scan of your hips, forearms, and spine.
  - A DXA scan (or DEXA scan) is also called a bone density scan. A DXA scan uses a small dose of radiation (like an x-ray) to measure the density of your bones (how strong your bones are). The information from the DXA scan can help to measure your risk of developing bone fractures.

- A DXA scan takes about 15-30 minutes. During this time, you will lay on a padded table while a mechanical arm passes over your body.

- **High resolution peripheral quantitative computed tomography (HR-pQCT)**
  - Measurements of your wrist and tibia (lower leg bone) will be collected by HR-pQCT
  - HR-pQCT uses low-dose radiation to create 3D images of bones and measures of bone density
  - During the HR-pQCT scan, you will sit in front of a machine that looks like a large washing machine with an opening in the front. You will place your wrist in the opening of the machine and a picture will be taken. After this measurement, your ankle will be placed in a similar manner.
  - These scans will take a total of about 10 minutes.
- **AGE Reader®**
  - Your skin will be assessed using an AGE (Advanced Glycation End products) Reader®. For this scan you will sit in a chair and rest your forearm on a small tabletop device. The device sends out a small amount of UV light to your skin to measure certain products in your tissue. These measurements can give the researchers information about your health. This scan will take less than 1 minute.
- **Glomerular filtration rate (GFR)**
  - GFR measures your kidney function
  - GFR will be determined using a short iothalamate clearance protocol and will be done in the Renal Studies Unit. This test takes about 2 hours.
  - During this time, you will be given an injection of a contrast material called iothalamate. Let your doctor know if you have ever had an allergic reaction to contrast material, iodine or shellfish. You will have your GFR measured a different way.
  - You will then be asked to sit in your room for about 1 hour while you drink water. After this, you will be asked to urinate, and a nurse will do a bladder scan (a painless ultrasound) to confirm that your bladder is empty. If your bladder is empty, the nurse will draw blood from your arm. You will then be asked to wait 45 minutes, during which time you will again drink water, and the process will be repeated.
  - If you aren't able to completely empty your bladder, a temporary urinary catheter may be placed by a nurse in the Renal Studies Unit. Information about this procedure will be shared with you at that time.

The results of this testing will be shared with you and put into your medical record. If you decide to follow up and further medical testing or care is needed, the costs will be billed to you or your insurance.

What are the possible risks or discomforts from being in this research study?

Blood Draw: The risks of drawing blood include pain, bruising, lightheadedness, and/or fainting, or rarely, infection at the site of the needle stick. The total amount of blood that will be withdrawn for this study is about 20 mL (4 teaspoons).

Radiation: You will be exposed to radiation from the measures in this study (DXA scan & HR-pQCT scan). The amount of radiation has a low risk of harmful effects.

Short Renal Clearance Test: Complications are rare, however, if an allergic reaction to the contrast occurs, this may lead to anaphylaxis, which is a severe, potentially life-threatening reaction. If a temporary catheter is placed, risks include damage to the urethra or bladder, risk of urinary tract or bladder infection, or rarely, the bladder wall may be punctured.

AGE Reader® test: There are no known risks associated with the AGE (Advanced Glycation End Products) testing.

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time:

- Study is stopped.
- If it is in your best interest.
- If you don't follow the study procedures.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

What if you are injured from your participation in this research study?

Where to get help:
If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries?
Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. Treatment costs for research-related injuries not covered by your insurance will be paid by Mayo Clinic.

What are the possible benefits from being in this research study?

You won't benefit from taking part in this research study. It is for the benefit of research.

What alternative do you have if you choose not to participate in this research study?

This study is only being done to gather information. You may choose not to take part in this study.

What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- Urine collection container and urine tests
- Blood tests done for the study (CBC, electrolytes, calcium, phosphate (Pi) concentrations, creatinine, BUN and albumin)
- DXA scan done for the study (forearms, hips and spine)
- HR-pQCT scans done for the study (wrist and tibia)
- AGE Reader® scan
- eGFR (short iothalamate clearance, kidney function test)
- Temporary urinary catheter and placement (if needed for the kidney function test)

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

You will receive $250 for completing the study visit. If you aren't able to complete the whole study visit, you will be paid for the portion of the visit that you do complete.

Payment for participation in research is considered taxable income and reportable to the Internal Revenue Service (IRS). Accounts Payable at Mayo Clinic will be given your name, address and Social Security number in order to issue a check for your study participation. If you receive research payments totaling $600 or more in a calendar year, a tax Form 1099 will be sent to you. For Mayo Clinic employees, research payments are included in your paycheck with applicable taxes withheld and reported on your Form W2 after calendar year-end.

There is a very small chance that some commercial value may result from the use of your samples or information. This could include new products like a drug or a test to diagnose a disease. If that happens, you will not be offered a share in any profits.

Will your information or samples be used for future research?

Unless you give your permission below, your information or samples collected for this study will not be used or shared for future research, even if the identifiable information such as your name, Mayo Clinic number or date of birth is removed.

We would like to keep your information and samples for future research. You can still take part in this current study even if you don't want your information or samples used for future research.

Researchers at Mayo Clinic who aren't involved with this study may ask to use your information and/or samples for future research. Researchers at other institutions may also ask for a part of your information and/or samples for future studies. Unless you indicate otherwise, the future research may be on any topic. No direct benefits to you are expected from the future research. Your information and/or samples will only be shared consistent with your consent, and with all applicable laws and regulations.

If you approve release of your information and/or samples by checking 'yes' below, Mayo may send the information and/or samples to researchers who request them, but Mayo will not send your name, address, phone number, social security number, or any other identifying information with the information and/or samples. Your information and/or samples may be sent with a code, and only the researchers for this study at Mayo Clinic would be able to link the code to you.

Some future studies may examine your DNA, the genetic information you inherited from your parents (genetic testing). If there are findings which may be useful for your health care, the researchers may contact Mayo Clinic, so Mayo Clinic can give you the option of learning the results. You would be given general information on the potential risks, benefits, and costs of choosing to learn about the findings.

To support future research, de-identified genetic information may be placed in databases accessible by the internet. Some of the information may be available to anyone using the internet, and some will be released only to approved researchers. Combined study information (including genomic summary results) may be published, but the information will not identify you.

Even though information traditionally used to identify you will not be shared, people may develop ways in the future to allow someone to link your genetic information back to you. For this reason, confidentiality cannot be guaranteed. It is also possible that reidentified information could be used in discriminating ways, and there could be additional unknown risks. We will make every effort to protect your confidentiality.

Privacy protections given by the Certificate of Confidentiality for this study do not apply to combined study results, however they do apply to your individual information. (See separate section for information about the Certificate of Confidentiality.)

Please read the following statements and mark your choices:

1. I permit my information and samples to be stored and used in future research of kidney donation at Mayo Clinic:

   ☐ Yes ☐ No Please initial here: _____Date: _____

2. I permit my information and samples to be stored and used in future research at Mayo Clinic to learn about, prevent, or treat any other health problems:

   ☐ Yes ☐ No Please initial here: _____Date: _____

3. I permit Mayo Clinic to give my information and samples to researchers at other institutions:

   ☐ Yes ☐ No Please initial here: _____Date: _____

You may withdraw your consent for future use of your information and/or samples at any time, by writing to the Principal Investigator at the address provided in the "Contact Information" section of this consent form.

Your information and/or samples would be removed from any repository where they are stored, if possible. Information and/or samples already distributed for research use will not be retrieved.

How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. All electronic data will be kept in a secured database/server accessible only by study personnel as authorized by the investigator, and all printed data will be stored securely in a locked file cabinet. Your identifiable information will not be shared outside of Mayo Clinic. Any information that is shared outside of Mayo Clinic will be identified by a code, and not your name or clinic number.

We have obtained a **Certificate of Confidentiality** from the National Institutes of Health (NIH). The Certificate is designed to prevent us from being forced to disclose identifying information for use in any federal, state, or local civil, criminal, administrative, legislative, or other court proceeding, even if faced with a court subpoena. You should understand, however, that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. We may not withhold information if you give your insurer or employer or a law enforcement agency permission to receive information about your participation in this research. This means that you and your family must also actively protect your own privacy.

The Certificate does not prevent us from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. Such disclosures will be made as described below.

The research team may share your information with:

- NIH, to complete federal responsibilities for audit or evaluation of this research;
- Public health agencies, to complete public health reporting requirements;
- Mayo Clinic representatives, to complete responsibilities for oversight of this study;
- Your primary care physician if a medical condition that needs urgent attention is discovered;
- Appropriate authorities to the extent necessary to prevent serious harm to yourself or others.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- Other Mayo Clinic staff involved in your clinical care.
- Researchers involved in this study at other institutions.
- The sponsor(s) of this study and the people or groups hired by the sponsor(s) to help perform this research.
- The Mayo Clinic Institutional Review Board that oversees the research.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- A group that oversees the data (study information) and safety of this research.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you, but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
201 Building 4-60
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Participant Advocate at: ResearchParticipantAdvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts until the end of this study, unless you cancel it. The study does not end until all data has been collected, checked (or audited), analyzed, and reported. Because research is an ongoing process, we cannot give you an exact date when the study will end. Sometimes this can be years after your study visits and/or activities have ended.

Mayo Clinic will store your coded samples indefinitely.

Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature