RANDOMIZED CONTROLLED TRIAL TO EVALUATE THE EFFECT OF LOST WAGE REIMBURSMENT TO POTENTIAL IDNEY DONORS ON LIVING DONATION RATES (DONOR LOST WAGES STUDY)

NCT NUMBER: 03350269

INFORMED CONSENT FORM

MAY 11, 2017

SAMPLE CONSENT TEMPLATE FOR KIDNEY TRANSPLANT RECIPIENTS

EACH PARTICIPATINGTRANSPLANT CENTER MUST ADAPT TO FULFILL THE LOCAL IRB REQUIREMENTS

INFORMATION ABOUT THIS FORM

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title:
Randomized Controlled Trial to Evaluate the Effect of Lost Wage Reimbursement to Potential Kidney Donors on Living Donation Rates (Donor Lost Wages Study)

1.2 Company or agency sponsoring the study:
Laura and John Arnold Foundation

1.3 Names, degrees, and affiliations of the researchers conducting the study:
SITE SPECIFIC

2. PURPOSE OF THIS STUDY

2.1 Study purpose:
This research study is being done to learn if offering to reimburse kidney donors for wages they wo uld lose by being off work during the donation evaluation and surgery process increases your likelihood of receiving a living kidney transplant within one year.

3. INFORMATION ABOUT STUDY PARTICIPANTS

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?
All potential kidney transplant recipients who:

- Are at least 18 years old
- Do not need more than one organ transplanted (kidney-only transplant; if you plan to have a pancreas transplant after a living donor kidney transplant you can still participate in this study)
- Have not received a transplant (of any organ) before

3.2 How many people (participants) are expected to take part in this study?
2,750 people are expected to participate, XXX AT YOUR SITE, and the remainder at other sites around the United States.

4. INFORMATION ABOUT STUDY PARTICIPATION

Study ID Number
IRB Approval Date:
(IRB Use Only)

4.1 What will happen to me in this study?

After you have signed this consent form, we will randomly assign you to one of two groups. You have an equal chance of being assigned to each group. The study computer will do the equivalent of a coin toss to decide what group you will be in. If you are assigned to the treatment group, we will be able to provide your living donor, if you have one, with reimbursement of wages they lose as a result of the donor evaluation and surgery. If you are assigned to the control group, you will receive all of your normal care, as will any living donors that come forward on your behalf. However, your living donor, if you have one, will not be reimbursed for lost wages.

While you're here for your visit, we will review your medical record and collect some basic information about you, including:

- Dialysis information (if you are already on dialysis)
- Income information and household size
- Information about any possible kidney donors known at the time of your first visit

Six months and one year after we've collected the information above, we'll collect additional information from your medical records about whether you've started on dialysis (if you weren't on it before), you've had a transplant or not, and if you haven't had a transplant, the reasons why.

4.2 How much of my time will be needed to take part in this study?
Participation in this study may increase the time spent at your evaluation visit by 15-20 minutes. Information required for the six-month and one-year follow-up will be gathered from your medical record and will not require you to come to the transplant program.

4.3 When will my participation in the study be over?
Your participation will end no later than one year after the first study visit.

5. INFORMATION ABOUT RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?
There is the possibility of a breach of confidentiality and your participation could become known outside the research study. Once you are enrolled into this research study, you are assigned a unique Study ID Number. All information will be labeled with this Study ID number; your name and any other identifying information will not be recorded. Only the research team at XXX YOUR SITE will know your name and study ID number. The Data Coordinating Center will only use the de-identified Study ID number.

The investigator is willing to discuss any questions you might have about this risk.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 "Contact Information" (below) about any problems that you have during this study.

5.3 If I take part in this study, can I also participate in other studies?
Yes.

5.4 How could I benefit if I take part in this study? How could others benefit?

Study ID Number
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You may not receive any direct personal benefits from being in this study. Possible benefits of the research for future people with kidney disease include increasing the number of people who are willing to donate a kidney to someone who needs a kidney transplant. You may indirectly benefit if you are assigned to the treatment group and receive a living donor transplant from a person who could not have donated without the lost wage reimbursement.

6. OTHER OPTIONS

6.1 If I decide not to take part in this study, what other options do I have?
Participation in this study is completely voluntary and your alternative is not to participate. You will receive the same medical treatment from your doctors whether or not you take part in this study, and there will be no penalty or loss of benefits to which you are entitled.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information" (below). Even if you decide to leave the study early, we will review your medical chart at six months and one year later, unless you specifically request us not to do so.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
No.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- ✓ The researcher believes that it is not in your best interest to stay in the study.
- ✓ You become ineligible to participate.
- ✓ Your condition changes and you no longer need a kidney transplant
- ✓ You do not follow instructions from the researchers.
- ✓ The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?
There are no costs or billing for this study. There will be no cost to you or your insurance company for any study-related activities.

You or your health insurance company will be responsible for costs related to the evaluation, surgery and follow-up of your kidney transplant.

It is important to understand that some insurance companies may not cover all of the above listed costs. If your insurance company does not cover a treatment or procedure, you may be required to pay for it.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?
No.

8.3 Who could profit or financially benefit from the study results?
No person or organization has a financial interest in the outcome of the study.

Study ID Number
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9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how your privacy and the confidentiality of your research records will be protected in this study. Protected Health Information (PHI) is any health information through which you can be identified. Protected Health Information is protected by federal law under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). A decision to participate in this research means that you agree to let the research team use and share your PHI for the study explained above. Study PHI will be kept in your research record and only the research team will have access to this information.

9.1 How will the researchers protect my privacy?
Once you are enrolled into this research study, you are assigned a unique Study ID Number. All information will be labeled with this de-identified number (Study ID number). Only the research team at XXX YOUR SITE will know your name and study ID number. Information sent to the Data Coordinating Center will only use the de-identified number study ID. This way only the research team at this clinical site will be able to identify you. You will not be identified in any reports or publications that arise from this study. We will take every precaution to protect your confidentiality.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?
Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care.

Information about you may include information about health and medical care before and during the study, even if that information wasn't collected as part of this research study. For example:

- Hospital/doctor's office records
- All records relating to your kidney disease and transplant, including information about your living donor candidates
- Financial information

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or study monitors, may need the information to:
    - Check that the data you provide is being recorded correctly
    - Make sure the study is done safely and properly
    - Analyze the results of the study
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study may be published in an article in a medical journal, but would not include any information that would let others know who you are.

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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.

9.3 What happens to information about me after the study is over or if I cancel my permission?
Your participation is voluntary; you may choose not to participate in this research study or withdraw at any time. Your choice will not affect the commitment of your health care providers to care for you and there will be no penalty or loss of benefits to which you are otherwise entitled. If you decide to end participation in the study, please contact the investigator.

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over. Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help hospital, sponsor and government officials make sure that the study was conducted properly
- As required by applicable Federal or state law. For example, if you withdraw from the study at any time, a record of your withdrawal and the reasons you gave for withdrawing will be kept as part of the study record. In addition, government officials who are responsible for oversight and review of clinical t rials may require certain disclosures.

Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission expire?
Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below).

10. CONTACT INFORMATION

10.1 Who can I contact about this study?
Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator:
Mailing Address:
Telephone:
Study Coordinator:
Mailing Address:
Telephone:

Study ID Number
IRB Approval Date:
(IRB Use Only)

Insert PI and study coordinator names, addresses, and phone numbers. Duplicate and/or edit the contact information headings as necessary to include all appropriate contact personnel.

You may also express a concern about a study by contacting the Institutional Review Board listed below.

INSERT SITE'S IRB INFORMATION HERE

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the INSTITUTION'S PRIVACY OFFICER at CONTACT INFORMATION.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRB number (located INDICATE LOCATION OF IRB NUMBER ON CONSENT FORM), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular medical record.)*
- A sealed packet of information to provide to your kidney donor candidate(s)

12. SIGNATURES

Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with {Study Team Member Name/s}. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research participant, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Study ID Number
IRB Approval Date:
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Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Study ID Number
IRB Approval Date:
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