

Official Title: System Interventions to Achieve Early and Equitable Transplants (STEPS) Study

NCT05014256

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Attachment B – Script for Screener and Verbal Consent

Hello, may I speak with <Title. First Name Last Name>?

If not available, say:

- When is a better time for me to call <Title. Last Name> back?

Record the date and time. Thank you for the information. Goodbye.

If you get voicemail, say:

Hello, this message is for <PARTICIPANT NAME>. This is <INTERVIEWER NAME> calling on behalf of <DUKE UNIVERSITY MEDICAL CENTER/UNIVERSITY OF MISSISSIPPI MEDICAL CENTER/GEISINGER >. This is not a sales call. We are calling because we recently mailed you a letter about the STEPS study. If you participate you will be paid for your time. Could you please give us a call at <PHONE NUMBER> if you are interested? Thank you.

If available, say:

Hello, my name is <INTERVIEWER NAME> I am calling on behalf of <DUKE UNIVERSITY MEDICAL CENTER/UNIVERSITY OF MISSISSIPPI MEDICAL CENTER/GEISINGER HEALTH SYSTEM> for the STEPS study. How are you today? [Pause, exchange pleasantries]

NEW or UNABLE TO REACH:

MAILED LETTER

- We recently mailed you a letter describing an important new study to help people with kidney disease. Do you have a few minutes to talk about the study? **If they do not recall receiving, say:**
- Let's go over what was in the letter now. If you would still like to receive the letter at the end of our call, you can let me know and I will re-send.

The STEPS study is for anyone who would like to learn more about kidney health and kidney treatments. This study is not just for people who need kidney treatments today, but for anyone whose kidneys may need treatment later. There is a special focus in this study on helping people understand how to get a kidney transplant.

I am calling you today because this study will help improve the care of people with kidney disease and help them understand treatment options and how to get them. We are calling you today because you are a patient at <DUKE UNIVERSITY MEDICAL CENTER/UNIVERSITY OF MISSISSIPPI MEDICAL CENTER/GEISINGER HEALTH SYSTEM> and you may be eligible to participate. If you participate, you will be paid for your time.

Do you have a few minutes for me tell you more about the study?

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If no, ask:

- What is a better time for me to call you back and tell you more about the study?

If willing to schedule a time, record date(s) and time(s) for call back, and say: Thank you for your time. We look forward to talking to you soon. Goodbye.

If not willing to schedule a time, say: May I ask why you don't want to hear more about the study?

SEE APPENDIX FOR RESPONSES

Continue:

Let me tell you more about the study. Feel free to ask questions.

- This study is funded by the National Institutes of Health and the Patient Centered Outcomes Research Institute.

We are doing this study to understand how patients with kidney disease and their families decide what treatments are best.

- We also want to know if education can help patients learn more about kidney transplant even if they don't need it.
- This will help doctors and others improve the care that patients with kidney disease receive.
- Around 1,150 patients with kidney disease will be asked to join this study.
- The study team includes researchers from Duke University Medical Center, the University of Mississippi Medical Center, Geisinger Health System, Atrium Health Wake Forest Baptist and Northwell Health.
- This study does not require doctor office visits. You can participate by phone if you like. There is no testing, such as blood tests or urine tests.

Before I tell you more, I'd like to check to see if you qualify for the study. Is that okay??

- ☐ **Don't Know/Not Sure**
- ☐ **No**
- ☐ **Yes**

If Yes, interested in taking part, go to section below "Eligibility and Consent".

If No, not interested in taking part, ask:

- Can I ask why you aren't interested? **SEE APPENDIX FOR RESPONSES**

If Don't Know/Not Sure if interested in taking part, ask:

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- Do you have any questions that I can answer about the study? **If yes (has questions), answer questions and ask:** Would it be okay for me to call you back in a couple days so you can think about it?

If yes, say: Ok, when is a good time? **(SCHEDULE TIME)** Thank you for your time. We look forward to talking to you soon.
Goodbye.

If no, say: I understand but we really do need your help. You can help us improve care. Would you be interested in doing the survey?

Responses:

- a) **If Yes: Continue to next section “Eligibility and Consent”.**
- b) **If No:** Thank you for your time. You can call us anytime if you change your mind, have any questions or want to learn more about the study.

If no (no questions), say: Would it be okay for me to call you back in a couple days so you can think about it?

If yes, say: Ok, when is a good time? **(SCHEDULE TIME)**
Thank you for your time. We look forward to talking to you soon.
Goodbye.

If no, say: I understand but we really do need your help. You can help us improve care. Would you be interested in doing the survey?

Responses:

- a) **If Yes: Continue to next section “Eligibility and Consent”.**
- b) **If No:** Thank you for your time. You can call us anytime if you change your mind, have any questions or want to learn more about the study.

ELIGIBILITY AND CONSENT

- Great. Let me first ask you 5 quick questions to make sure you can take part in the study.

1. First, how old are you?

Refused.....-997

Don't Know.....-999

(If Q1 < 18yrs of age OR > 74 years, Refused or Don't Know then ineligible.)

- **If ineligible say:** Thank you. I'm sorry, but it looks like you are not eligible to participate in our study. Thank you very much for your time.
- **If eligible, continue.**

2. Are you currently on dialysis?

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If yes, Thank you. I'm sorry, but it looks like you are not eligible to participate in our study. Thank you very much for your time. **If no, continue.**

3. Have you been diagnosed with a terminal illness or on hospice care?

If yes, Thank you. I'm sorry, but it looks like you are not eligible to participate in our study. Thank you very much for your time. **If no, continue.**

4. Have you ever had a kidney transplant?

If yes, Thank you. I'm sorry, but it looks like you are not eligible to participate in our study. Thank you very much for your time. **If no, continue.**

5. Are you currently on a kidney transplant waitlist at any transplant center (this would mean that you have gone to the transplant center, been evaluated by a medical team, passed all the tests that you needed, received a letter or phone call from the transplant center telling you that you have finished all steps, and that you are on the transplant list)?

[If yes, ask:] At which transplant center have you been listed? ____

[If at current institution (Duke, UMMC, Geisinger):] If you are on the waitlist, you may not be eligible, we are going to confirm your eligibility and get back to you.

[Eligible after chart review:] "Hello, Ms./Mr. [name]. I am calling back from the STEPS study to let you know that you are eligible to be in the study. Would you like to hear more about the study now?" continue to study description, consent, questionnaire.

[Not eligible after chart review:] "Hello, Ms./Mr. [name]. I am calling back from the STEPS study to let you know that you are not eligible to be in the study at this time. We appreciate your time and interest. Have a good day." Mark as ineligible.

[If outside site, **ineligible:**]

Thank you. I'm sorry, but it looks like you are not eligible to participate in our study. Thank you very much for your time. **If no, continue.**

I've confirmed that you qualify for this study. _____

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Here is what will happen if you want to be a part of this study:

[For everyone]

Everyone in the study will be asked to do the following things:

[Survey/Medical Record]

- We may send you text messages.
- We will ask you questions over the phone today and every 6 months for up to 18 months.
- These questions will be about you and your kidney disease.
- It will take 40 minutes now to answer the questions, and 25 minutes for follow up calls.
- We will send you \$50 each time you finish the questions. In order to send you the \$50 check, we will ask for your Social Security Number.
- We will review your medical records at [Duke/Geisinger/UMMC] to get information related to your care, such as lab tests and visits with your doctor.
- Your answers to these questions along with information in your medical records will help us learn about the care you receive. Information will only include a unique code to identify you and will not include your name, address or any other information that identifies you.
- We will also place you into one of two groups by chance, like flipping a coin.

[Description of Group 1: Usual Care]

- **If you are put into group 1**, you will continue with your usual health care at <Duke/GHS/UMMC>.
- At the end of the study, we will send you a video and a booklet for people with kidney disease.

[Description of Group 2: STEPS]

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- **If you are put into group 2**, we will ask you to watch a video and read a booklet for people with kidney disease
- Then, we will schedule a time for you to meet with a trained study team member to talk about the video and booklet and answer questions.
- This will be scheduled at a time that works best for you.

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- The meeting can take place by phone or in person and would take about 30 minutes to 1 hour of your time.
- We will schedule a second meeting with you. You can also bring family or friends to this meeting.
- We will take notes about the meetings. We will use this to study what happens during the meetings.
- If during the study you and your doctor think you may need a kidney transplant, you may also be contacted by a trained study team member to talk more about the steps to transplant.
- The study team member will help you walk through the steps. For example, they may help you create a plan, make phone calls, and complete any paperwork.

Do you have any questions?

Now here is some more information about the study:

[Voluntary]

- Taking part in this research study is voluntary.
- Some questions we ask you may make you feel uncomfortable or bring up concerns you may need help with. You are free to skip questions or stop answering questions at any time. If you need help, please contact your doctor.

[Record Keeping]

- We will keep your information for at least six years after the study is done. After six years, we will remove all information identifying you and keep your data.

[NIDDK Central Repository]

- Our study sponsor requests that information we collect from this study is shared for future research. We will send information to the NIDDK which is part of the National Institutes of Health who is paying for the study. All information that directly identifies you will be removed. The NIDDK provides valuable information that can help researchers to develop new diagnostic tests, new treatments, and new ways to prevent diseases. The NIDDK will take measures to protect your privacy.

Although no guarantee of confidentiality can be certain, they are trained in handling private medical information and have appropriate safeguards in place.

[Risk]

- There are no physical risks in taking part in this study.

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- There is a slight risk of loss of confidentiality, but this is lowered by the fact that the study researchers are experienced and trained in handling private medical information and have appropriate safeguards in place.

[Benefit/Cost]

- There is no cost to take part in this study.
- There is no direct benefit to you for taking part in this study; however, we hope that the information we learn from you will help improve care for people who need kidney care in the future.

[Voluntary]

- If you take part in the study, you can withdraw at any time. If you choose to stop taking part in the study, we will not collect new information about you, but we will record why you stopped taking part and keep any information already collected. Your decision not to take part or to withdraw from the study will not involve any penalty or loss of benefit. It will not affect your health care at <DUKE/UMMC/GHS>.
- We describe the study online at <http://www.ClinicalTrials.gov>. This is required by law. The Web site tells about the study. It does not include information about you.
- If you wish to withdraw from the study or have questions at any time, please contact the <DUKE Principal Investigator for the study, Dr. Ranee Chatterjee at PHONE NUMBER>/<UMMC Principal Investigator for the study, Dr. Pradeep Vaitla at PHONE NUMBER>
<Geisinger Principal Investigator for the study, Dr. Jamie Greene at PHONE NUMBER>, or by email at <DUKE EMAIL/UMMC EMAIL/GEISINGER EMAIL>.
- For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Wake Forest University Health Sciences Institutional Review Board, who is overseeing this study at [REDACTED] or the Research Subject Advocate at Wake Forest at [REDACTED].
< DUKE [You can also contact Institutional Review Board at the Duke University Health System at [REDACTED]]>
<UMMC [You can also contact the Institutional Review Board at the University of Mississippi Medical Center at [REDACTED]]>

Can you please tell me now, yes or no, **would you like to join this study?**
(Date, time, interviewer initials recorded in REDCap/tracking system for consent.)

- ☐ **No**
- ☐ **Yes**

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If no, does not want to take part, say: Thank you for your time and interest in our study. You can call us anytime if you have any questions or decide to take part later. Thank you again. Goodbye.

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If yes, would like to take part, say: Great. First, I'd like to confirm the spelling of your first and last name.

Will you spell your first name for me please? _____

Will you spell your last name for me please? _____

_____ Thank you for joining the study.

[Text Messaging]

We would like to send you text messages to remind you about the phone surveys that are done every six months while you are in the study. A system called Twilio uses your mobile phone number to send these messages that are one-way only, so you cannot reply. Texting is not completely secure or private. Your phone number may be kept by Twilio and shared with their partners. If you do not wish to receive text messages, we will only contact you by telephone. You can contact the study team if you have any questions about text messaging.

Would you like for us to send you text message reminders? Message and data rates may apply.

☐ Yes ☐ No

Now, let's move on to the survey questions. This will take about 40 minutes. We will mail you a check for \$50 after you complete all of the questions.

Ask about re-mailing the letter:

Now that we have reviewed the study information, would you still like us to re-send the letter?

Interviewer: Did the patient request to re-mail the recruitment letter?

☐ Yes ☐ No

If yes, confirm their mailing address.

If doesn't want to complete the survey now:

What is a better time for me to call you back? **(SCHEDULE TIME) If willing to schedule a time, record time and date for call back and say:** Thank you for your time. We look forward to speaking with you soon.

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If not willing, say: We will call back in a few days. Thank you for your time. Goodbye.

CLOSING STATEMENTS

[SRTR linkage]

As an additional part of this study we would like to obtain information about people getting transplants now or in the future from the Scientific Registry of Transplant Recipients which is also called SRTR. SRTR keeps track of information when people are listed or have a transplant in the US. We would like to look up your transplant information in the SRTR registry using your name and date of birth.

Providing this information is voluntary and will not affect whether or not you can take part in the study. Your information will be handled with the strictest precautions for privacy.

Do agree to us sharing your name and date of birth with SRTR for our study?

Yes

No

If No: "This is not required to take part in the study so we thank you for agreeing to continue to take part."

It is important while you are in the study that we are able to follow-up with you by telephone. We know that sometimes peoples phone number change or things come up and they may be hard to reach. We would like to collect the name and number of someone you usually keep in contact with who we can call in case we have trouble reaching you. We would like to collect the contact information of one person who lives with you and one person who does not live with you. They can be a family member and/or friend.

Can you provide us with the contact information of those individuals?

Yes No

If yes, complete below:

Contact Person **who lives at home** with participant:

Name

Telephone Number

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Contact Person **who does not live at home** with participant:

Name

Telephone Number

If no say:

Okay, you can still be in this study. If your phone number changes, please be sure to contact us at [study phone number] to let us know.

If completed survey:

Thank you so much for taking the time to talk to me today. Let's complete the information so we can mail you \$50 within the next few weeks.

(COMPLETE DUKE DATA DISCLOSURE FORM)

Thank you so much for taking the time to talk to me today. You should receive your check in the mail within 4-6 weeks. Let's now move on to the randomization section.

Randomized to Group 1 Usual Care:

Thank you so much for the important information you provided us. We are very grateful. You have been assigned to Group 1, which means we will call you again in 6 months to ask you questions like we did today and will pay you \$50 again

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Randomized to Group 2 STEPS:

Thank you so much for the important information you provided us. We are very grateful. You have been assigned to Group 2. The next step is that you will receive a call from [Social Worker name] a kidney social worker to talk with you more and give you more information about what you will be doing as part of the study. [Social Worker name] will call you from this phone number: [Social worker phone number]. When are the best days and times to reach you?

We will also be sending you a letter to confirm your enrollment in the study. Along with the letter will be a workbook called "Living with Kidney Disease: All the Facts". The nephrology social worker will review this with you when you meet with her. We will also call you again in 6 months to ask you questions like we did today and will pay you \$50 again.

If did not complete all of survey and did not withdraw:

Let's schedule a time to complete the rest of the questions. We must complete them before I can send you the \$50. What is a good time for me to call you back?

(SCHEDULE TIME) If willing to schedule a time, record time and date for call back and say: Thank you for your time. We look forward to speaking with you soon. **If not willing, say:** We will call back in a few days. Thank you for your time. Goodbye.

Appendix:

Do not read responses. Select their response and respond accordingly.

- 1) Not interested
- 2) Too busy/Study is too long/Takes too much time

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- 3) Don't trust research**
- 4) I don't think I have a kidney problem**
- 5) I don't want a transplant**
- 6) Doesn't trust giving Social Security Number 7) If other, please specify_.**
- 8) REFUSED**
- 9) DON'T KNOW**

1) NOT INTERESTED

I understand but we really do need your help. You can help us improve care. Would you be willing to hear more about the study?

Responses:

a) If Yes: Continue to next section.

b) If No: Thank you for your time. You can call us anytime if you change your mind, have any questions or want to learn more about the study.

2) TOO BUSY

I understand that you are busy and we value your time. We really do need your help. We can really improve care with your input. Would you be willing to hear more about the study?

Responses:

a) If Yes: Continue to next section.

b) If No: Thank you for your time. You can call us anytime if you change your mind, have any questions or want to learn more about the study.

3) DON'T TRUST RESEARCH

All information collected during this study will be kept strictly confidential. Information will never be reported in such a way that individuals can link information with names or addresses. We hope that the information we learn from you will improve your care and the care of other patients with kidney disease. Would you be willing to hear more the study?

Responses:

a) If Yes: Continue to next section.

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- b) **If No:** Thank you for your time. You can call us anytime if you change your mind, have any questions or want to learn more about the study.

4) I DON'T THINK I HAVE A KIDNEY PROBLEM

We are asking you to take part in the study because your kidney tests were not normal. We encourage you to talk with your doctor about those tests. Would you be willing to hear more about the study?

Responses:

- a) **If Yes: Continue to next section.**
- b) **If No:** Thank you for your time. Would it be okay for us to call you back after you have spoken with your doctor?

5) I DON'T WANT A TRANSPLANT

For this study, you do not need to have a kidney transplant. We want to know if education can help patients understand the process of kidney transplant even if they don't need it.

Would you be willing to hear more about the study?

Responses:

- a) **If Yes: Continue to next section.**
- b) **If No:** Thank you for your time. You can call us anytime if you change your mind, have any questions or want to learn more about the study.

- 6) **Doesn't trust giving Social Security Number** I understand you would have concerns. We have to follow the rules of the IRS that require us to document the social security number for research study payments by check. This is why we have to collect this information. Once we process a check for you, we would destroy the information. We can also offer you the option of completing the study and not receive payment. Would you be willing to take part in the study?

Responses:

- a) **If Yes: Continue to next section.**
- b) **If No, still has concerns:** Ok, I understand you have concerns. Thank you for your time. You can call us anytime if you change your mind, have any questions or want to learn more about the study.

7) OTHER

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INTERVIEWER: Answer to the best of your ability and ask if they'd be willing to hear more or complete at a later time.

INTERVIEWER: If at any time a potential participant says this is not a good time, please let them know you would glad to set up a time that is more convenient for them. Schedule this date/time and document any notes in comments.