CommunityRx-Kidney Health

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University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: March 10, 2026
IRB Study #: 24-2006
Title of Study: CommunityRx-Kidney Health
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Concise Summary of the Research Study
CommunityRx-Kidney Health aims to create new ways for people to find resources in their community. These resources can support basic needs and health goals. If you join this study, you will complete 5 surveys over 12 months about taking care of your kidney health.

The National Institute of Diabetes and Digestive and Kidney Disease (NIDDK) at the United States National Institutes of Health (NIH) funds this study.

What general things should you know about research studies?
We invite you to join CommunityRx-Kidney Health. Joining is your choice. You can join now and leave later for any reason without penalty.

Research studies help us learn new things that may help people in the future. You might not directly benefit from this research study. This study has very little risk. Deciding not to join the study or leaving before it ends will not affect your relationship with our research team, your medical provider, or the University of North Carolina at Chapel Hill. You do not have to join the study to get health care. Goshen Medical Center will continue providing your usual care regardless of whether you participate in this study.

You will get a $10 gift card for completing each of five surveys, up to $50 total.

This form explains the study. It is important that you understand this information before you decide to participate in this study. You will get a copy of this form. If you have questions, please contact the research team using the information at the top of this form.

What is the purpose of this study?
People with kidney problems and related health issues like diabetes, high blood pressure, or heart disease may have needs that impact their health. Connecting with community resources may make it easier to manage the condition. This study looks at two ways in which patients get information about these resources. We want to learn which way works better.

What will happen if you join the study?

If you join the study, the research team will label your data with a unique number. This allows us to store research data separately from your identity.

We will place you in one of two groups at random. You have a 50/50 chance of being in either group. Both groups will continue getting their usual care at Goshen Medical Center, which may include information about community resources. One group will receive more communications about community resources than the other.

You will complete five surveys. The research team will also collect health information from Goshen Medical Center. This could include your age, sex, race, ethnicity, lab tests, health conditions, and medications.

We will store electronic data on a password-protected server at the University of North Carolina, Chapel Hill. If you choose to complete surveys on paper, we will transfer the data to our online data system and store hard copies in a locked cabinet at the University of North Carolina at Chapel Hill.

The National Institutes of Health (NIH) funds this study. At the end of the study, we will send de-identified study data to a secure database at the NIH. Other researchers can access this database. They will not know who you are, so you will not get results of any future studies that use your information.

The research team may publish results from this study. These publications will not include your name or other personal information.

Research sometimes leads to inventions. A company may sell products or services made using study data. If this happens, a company might pay the researchers or the organizations conducting this study. You would not get money from such discoveries, nor would the NIH.

Are there any reasons you should not be in this study?

You should not be in this study if you are:

- Under the age of 18
- Living with end-stage kidney or liver disease
- Receiving treatment for cancer
- Living in a skilled nursing facility
- Living with dementia or other significant cognitive impairment

How many people will take part in this study?

A total of 634 people will take part in this study.

How long will your part in this study last?

You will be in the study for 12 months.

What are the possible benefits of being in this study?

You might not directly benefit from this study. If you are placed in the group that gets more frequent information about community resources, you may:

- Learn more about kidney health.
- Find helpful services in your community, like food or housing assistance.

- Use more resources to take care of your health and daily needs.

Your participation may help researchers learn how to better support people's kidney health in the future.

What are the possible risks or discomforts involved from being in this study?
This research has very little risk. There is a small chance that someone could access your data without permission. We reduce this risk by storing all information in a password-protected database and locked cabinets accessible only to study staff.

None of the 114,000 participants in other CommunityRx studies have experienced a reportable serious adverse event.

If you choose not to be in the study, what other treatment options do you have?
You will continue to get your usual care from Goshen Medical Center regardless of whether you join this study. Your usual care might include referrals to community resources.

How will we protect your information?
Federal or state law may sometimes require us to share study records, including personal information. If this happens, UNC will follow laws to protect your privacy. University representatives, research sponsors, or government agencies may review your information to make sure the study is safe and done correctly.

We work hard to protect your identity:
- We will remove your name and other personal details from your data prior to analysis.
- We will not print your name or private information in any reports or publications.
- We will store the list that matches names and codes on a secure private server hosted at the University of North Carolina at Chapel Hill.
- We will store all electronic data on a secure, password-protected computer system at the University of North Carolina at Chapel Hill. Only approved research staff can access it.
- We will keep any paper records in a locked cabinet at the University of North Carolina at Chapel Hill. Only approved research staff can access the cabinet.
- We will ask you to sign a separate form allowing us to review your medical records.

What is a Certificate of Confidentiality?
This study has a Certificate of Confidentiality. This means researchers cannot share or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States without your permission.

The Certificate does not prevent federal or state agencies from receiving information as part of an audit, evaluation, or to meet the federal requirements. The Certificate does not prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, infectious diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirements under applicable law. The Certificate also does not cover disclosures for different scientific research, as allowed by federal regulations protecting research subjects, or for any purpose you have agreed to in this informed consent document.

A Certificate of Confidentiality does not stop you from sharing your own information. If you give written permission to share your own information with an insurer, employer, or other entity, we cannot use the Certificate to block that.

By signing this informed consent document, you agree that some study information and this consent form may go into your medical record. Your medical providers may see this information. Your medical providers may also share this information with your insurer if needed for billing.

North Carolina law requires researchers to report the abuse or neglect of a child or disabled adult to local or state authorities. The researchers must also report certain infectious diseases, such as tuberculosis, HIV, and hepatitis, to state authorities.

What will happen if the study injures you?
This research has very little risk. However, all research involves a chance that something might happen to you. If you are hurt or get sick because of this study, the research team will help you get medical care. UNC has not set aside money to pay you for injuries, illnesses, reactions, or related medical care. You or your insurance company would be billed and you may have co-payments. Your insurance might not cover the costs of study-related injuries. If you are injured, call the study team member using the phone number on this consent form. Signing this form does not take away your right to seek payment or pursue other actions if this study harms you.

What if you want to leave the study?
You can leave this study at any time without penalty. The researchers can also stop your participation at any time. If you leave, we will keep the information collected up to that point, but we will not ask for more.

Will you get anything for being in this study?
You will get $10 for completing each of the study's five surveys, up to $50 total. Payments may be subject to taxes. UNC may share your name and contact information with third parties that process payments on the University's behalf. If you do not agree to share your information, you cannot be paid.

Your data may help create new tests, drugs, devices, or other products or services with commercial value. Companies could sell these products or services, but would not pay you.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

What if you are a UNC student or employee?
You may choose not to join the study or leave before it ends. This decision will not affect your class standing, grades, or job at UNC. You will not get special consideration for joining this study.

Who sponsors this study?
The National Institute of Diabetes and Digestive and Kidney Diseases at the National Institutes of Health funds the research team to conduct this study. The researchers do not have a direct financial interest in the sponsor or the study's results.

What if you have questions about this study?
You have the right to ask any questions about this study. If you have questions about the study, complaints, concerns, or if a research-related injury occurs, please contact the research team members listed on the first page of this form.

What if you have questions about your rights as a research participant?
UNC's Institutional Review Board reviews all research on human volunteers. They protect your rights and welfare as a research participant. If you have questions or concerns about your rights as a research participant, contact the Institutional Review Board at (919) 966-3113 or email IRB_subjects@unc.edu.

Unencrypted (Un-Protected) Communication
The research team will email and text you. These messages may include community resource information and survey reminders. We might also ask you to contact us.

The research team will send emails from UNC email accounts. We will send text messages using a service called Mosio.

You will stop getting messages when the study ends or if you leave the study.

Participant's Agreement:
I have read the information provided above and have asked all my questions. I voluntarily agree to participate in this research study.

_____	_____
Signature of Research Participant	Date
_____	____:____
Printed Name of Research Participant	Time
_____	_____
Signature of Research Team member Obtaining Consent	Date
_____	____:____
Printed Name of Research Team Member Obtaining Consent	Time