Informed Consent Form

TITLE: A Pilot Trial of UrApp, a Novel Mobile Application for Childhood Nephrotic Syndrome Management

NCT NUMBER: NCT04075656

IRB APPROVAL DATE: May 20, 2024

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 60 people who are being studied, at Emory and elsewhere.

Why is this study being done?

This study is being done to answer the question: Will utilizing a mobile app for nephrotic syndrome improve disease management for families? You are being asked to be in this research study because we aim to understand your perspectives as a parent user of the new app and seek insights on how to enhance its design.

Do you have to be in the study?

It is your choice to join this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you choose, take time to learn about the study.

What do you have to do if you choose to join this study?

If you are eligible and want to be part of the study, you will participate for 12 months. The researchers will ask you to do the following:

- Fill out surveys today and in 6 and 12 months.
- Check your child's urine for protein every day.
- Download a nephrotic syndrome mobile app onto your phone (if assigned).
- Be interviewed for your opinion of the mobile app in 6 and 12 months (if assigned).

All of these procedures will be paid for by the study.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question.

What are the risks or discomforts you should know about before deciding?

The study will take time. The mobile app that is being tested may not work any better than regular care. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include loss of privacy and breach of confidentiality. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

Alternatives to Joining This Study
Since this is not a treatment study, the alternative is not to participate

Costs
There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

There is more information in the “Costs” section further below.

What Should You Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions such as how much time you will have to spend on the study, any words you do not understand and more details about study procedures. Take time to think about this and talk about it with your family and friends.

Emory University and Children's Healthcare of Atlanta
Consent to be a Research Subject / HIPAA Authorization

Title: A Pilot Trial of UrApp, a Novel Mobile Application for Childhood Nephrotic Syndrome Management

IRB #: IRB00108912

Principal Investigator: Chia-shi Wang, MD, MS

Study Supporter: National Institute of Diabetes and Digestive and Kidney Diseases

Introduction
You are being asked to be in a medical research study. This form tells you what you need to think about before you choose if you want to join the study. **It is your choice. If you choose to join, you can change your mind later and leave the study.** Your choice will not cause you to lose any medical benefits. If you choose not to join this study, your doctor will still treat you.

Before you decide:
- Read this form or have it read to you
- Listen to the study doctor or study staff explain the study to you
- Ask questions about anything that is not clear

You will get a copy of this form. Take your time to think about joining the study. You may wish to discuss it with family or friends. Do not sign this form if you still have questions or something does not make sense to you. By signing this form, you will not give up any legal rights.

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.

What is the purpose of this study?
The purpose of this study is to find out if using a nephrotic syndrome mobile app will help families manage this disease. We will also find out what parent users think about the new app and how we can improve the design of the app.

What will you be asked to do?
If you choose to participate, you will be randomly assigned to Group A or Group B. The chances of being in Group A or Group are 50/50, like flipping a coin. The total study participation time is one year. If you are assigned to Group A, we will provide you with a folder of educational material on nephrotic syndrome and free urine test strips. We will show you how to check your child's urine for protein at home and ask you to check the urine every day. We will ask you and your child to complete surveys on how you feel about managing nephrotic syndrome when you enter the study, and at 6 and 12 months. We will also contact you by phone in 1-3 months to see if you have any questions about nephrotic syndrome management. If you are assigned to Group B, your tasks will be the same as Group A participants. In addition, you will also be asked to download a nephrotic syndrome mobile app. We will show you how to use the app and answer any questions you may have about the app. We will call you in 1-3 months to see if you have any problems with the app. At 6 and 12 months, we will also interview you to find out what you think about the app.

OPTIONAL STUDY:
If you are assigned to Group B, you will have an opportunity to become a Stakeholder Committee member after you have participated in the study for at least 6 months. The Committee will be comprised of other study participants like yourself, pediatric nephrologists, and mobile app engineers. The Committee will review the study data. Members will provide their opinions on how well the mobile app works and how the app may be improved. The Committee will meet every 4-6 months for a total of 4 meetings.

Who owns your study data and samples?
If you join this study, you will be donating you and your child's study information. You will not receive any compensation if your information is used to make a new product. If you withdraw from the study, data and samples that were already collected may be still be used for this study.

What are the possible risks and discomforts?
There may be side effects from the study device or procedures that are not known at this time.
The most common risks and discomforts expected in this study are:
1) The mobile app reads the urine test strips inaccurately;
2) The mobile app failed to transmit the urine testing results to your provider;
The less common risks and discomforts expected in this study are:
1) You may feel uncomfortable sharing your thoughts on the surveys or during the interviews;
2) You and your child's information may be breached accidentally;
3) You may feel uncomfortable sharing your thoughts during stakeholder meetings.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will you benefit from the study?
This study is not designed to benefit you directly. You may find that the mobile app is helpful for managing your child's nephrotic syndrome, or you may not. This study is designed to learn more about how we can best help families manage their nephrotic syndrome. The study results may be used to help others in the future.

Will you be paid for your time and effort?

If you are in Group A, you will get $20 for each time you and your child complete surveys, to compensate you for your time and effort. If you do not finish the study, we will compensate you for the times you have completed the surveys.

If you are in Group B, you will also get $20 for each time you and your child complete surveys. In addition, you will get $50 each time you complete an interview.

OPTIONAL STUDY:

Stakeholder Committee members will receive $75 for each completed meeting.

You may be asked to fill out a tax form, including your Social Security or Taxpayer Identification Number, in order to be reimbursed, depending on the amount and method of payment. Some payment methods involve mail coming to your

house, which may be seen by others in your household. You can decline payment if you are concerned about confidentiality, or you can talk to the study team to see if there are other payment options.

What are your other options?

If you choose not to join this study, you can get care outside of this study. The study doctor will discuss these with you. You do not have to be in this study to be treated for your condition.

If you choose to join this study, you may not be able to join other research studies. Discuss this with the researchers if you have concerns. You may wish to look on websites such as clinicaltrials.gov and ResearchMatch.org for other research studies you may want to join.

How will your private information be protected?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory and Children's Healthcare of Atlanta will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory and Children's Healthcare of Atlanta received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

We will store all the data that you provide using a code. We need this code so that we can keep track of your data over time. This code will not include information that can identify you (identifiers). Specifically, it will not include your name, initials, date of birth, or medical record number. We will keep a file that links this code to your identifiers in a secure location separate from the data.

We will not allow your name and any other fact that might point to you to appear when we present or publish the results of this study.

Your data may be useful for other research being done by investigators at Emory or elsewhere. We may share the data, linked by the study code, with other researchers at Emory and Children's Healthcare of Atlanta, or with researchers at

other institutions that maintain at least the same level of data security that we maintain at Emory and Children's Healthcare of Atlanta. We will not share the link between the study code and your identity.

In general, we will not give you any individual results from the study of the samples you give us. If we find something of urgent medical importance to your child, we will inform you and your child's provider (for example, a new disease relapse).

Medical Record

If you have been an Emory and Children's Healthcare of Atlanta patient before, then you already have an Emory and Children's Healthcare of Atlanta medical record. If you have never been an Emory and Children's Healthcare of Atlanta patient, you do not have one. An Emory and Children's Healthcare of Atlanta medical record will be made for you if an Emory and Children's Healthcare of Atlanta provider or facility gives you any services or procedures for this study.

Emory and Children's Healthcare of Atlanta may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory and Children's Healthcare of Atlanta medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

The results of some study tests and procedures will be used only for research purposes and will *not* be placed in your medical record. For this study, those items include:

- Urine test results collected by UrApp
- Survey and interview results

Tests and procedures done at non-Emory and Children's Healthcare of Atlanta places may not become part of your Emory and Children's Healthcare of Atlanta medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

For your safety, however, you should consider the study doctor's advice about how to go off the study treatment. If you leave the study before the last planned study visit, the researchers may ask you to complete some of the final steps such as surveys, interviews or sharing historical data from the app.

The researchers also have the right to take you out of the study without your consent for any reason. They may do this if they believe it is in your best interest or if you do not agree to changes that may be made in the study.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. As part of this study, we will get your protected health information (PHI) from health care entities who are covered by the Health Insurance Portability and Accountability Act and regulations (HIPAA). Because the health care entities are covered by HIPAA, we must have your authorization to get your PHI from them. However, once we get your PHI from the health care entities, it changes from PHI to individually identifiable information (IIHI) and is no longer covered by HIPAA. We will put your IIHI in a separate research record that is not a part of your medical record. IIHI placed in the separate research record is not covered by HIPAA.

Main Study
This study involved research-related treatment that will not be electronically billed to any insurance company or government benefits program (e.g., Medicare, Medicaid). You may not receive the research-related treatment unless you sign this authorization. You may receive any non-research related treatment whether or not you sign this form.

IIHI that Will be Used/Disclosed:

The IIHI that we will use or disclosed for this study includes:

- Medical information about your child including his/her medical history and present/past medications.
- Results of exams, procedures and tests that your child has had before and during the study.
- Laboratory test results.

Purposes for Which Your IIHI Will be Used/Disclosed:

- To conduct this research study
- To evaluate the safety and effectiveness of the drug, device and/or other intervention being studied and ensure integrity of the data
- To provide study-related treatment
- To conduct healthcare operations
- To ensure compliance with state and federal regulations and provide oversight of the study
- To determine your health, vital status or contact information should you be unreachable during the study
- For the administration and payment of any costs relating to subject injury from the study

In certain cases where a researcher moves to a different institution, your IIHI may be disclosed to that new institution and their oversight offices. The IIHI will be disclosed in a secure manner and under a legal agreement signed by both institutions to ensure it continues to be used under the terms of this consent and authorization.

Expiration of Your Authorization
Your HIPAA authorization will expire once no more PHI is needed from your medical records for this study.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your IIHI. If you want to do this, you must contact the study team at: [redacted]

At that point, we will stop collecting your IIHI. We may use or disclose the IIHI already collected so we can follow the law, protect your safety, make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy

Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. HIPAA does not apply to the research records for this study because the study does not include treatment that is billed to insurers or government benefit programs. Your information collected for this study may be disclosed to others without your permission. The researchers, Sponsor, and people and companies working on this study are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

To maintain the integrity of this research study, you generally will not have access to your IIHI related to this research until the study is complete. When the study ends, and at your request, you generally will only have access to your IIHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. You will not have a right of access to IIHI kept in a separate research record used only for research purposed. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your IIHI. Information without identifiers is not subject to HIPAA and may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

If you have questions about the study procedures, appointments, research-related injuries or bad reactions, or other questions or concerns about the research or your part in it, contact [redacted]

This study has been reviewed by an ethics committee to ensure the protection of research participants. If you have questions about your **rights as a research participant**, or if you have **complaints** about the research or an issue you would rather discuss with someone outside the research team, contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu.

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at **https://tinyurl.com/ycewgkke**.

If you are a patient receiving care at Children's Healthcare of Atlanta and have a question about your rights, please contact the Children's Institutional Review Board at 404-785-7477.

Consent and Authorization

Print your name, **sign**, and **date** below if you choose to be in this research study. You will not give up any of your legal rights by signing this form. We will give you a copy of the signed form to keep.

_____

Name of Child

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

_____

Authority of Legally Authorized Representative or Relationship to Subject

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TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**

OPTIONAL STUDY

Optional Study: Stakeholder Committee Participation

Authorization for This Use of PHI is Required to Participate in Optional Study, but Not in Main Study:
You do not have to authorize the use and disclosure of your child's PHI for the optional study. If you do not authorize the use and disclosure of your PHI for the optional study, then you may not participate in the optional research study, but you can still be in the main research study.

Expiration of Your Authorization
Your child's PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use you and your child's information. If you want to do this, you must contact the study team at: [redacted]

At that point, the researchers would not collect any more of your child's PHI. But they may use or disclose the information you already gave them so they can follow the law, protect you and your child's safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the main study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your child's information to people who are not covered by the Privacy Rules, including HIPAA, then your child's information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your child's information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your child's PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your child's PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your child's health care providers use to make decisions about him/her. If it is necessary for your child's health care, your child's health information will be provided to his/her doctor.

We may remove identifying information from your child's PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study

Consent and HIPAA Authorization for Optional Study/Studies:
Please initial below if you opt to participate in and authorize use and disclosure of your child's PHI in the optional study/studies previously described:

Stakeholder Committee Participation _____Initials