Official title of study	Urological and Renal Disease Engaging Adolescents in Adherence Collaborative Trial
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The Children's Hospital *of* Philadelphia®

Informed Consent/Assent Form and HIPAA Authorization

Study Title: U-REAACT study (Urological and Renal disease Engaging Adolescents in Adherence Collaborative Trial)

Version Date: March 22, 2019

Principal Investigator: Sandra Amaral, MD, MHS Telephone: (215) 590- 2449

You, or your child, may be able to be in a research study. This form gives you important information about the study. It describes the purpose, risks and possible benefits of participating.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. You can leave the study at any time.

In the sections that follow, the word "we" means the study staff. If you are a parent or legal guardian who is giving permission for a child, please note that the word "you" refers to your child.

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

You are being asked to be in this study because you are between the ages of 12-24 years and have received a kidney transplant greater than 3 months ago or have spina bifida and perform daily Clean Intermittent Catheterization as part of your treatment regimen.

What is the purpose of this research study?

The purpose of this study is to see if our intervention program, which includes weekly financial rewards for each participant, improves the way patients take medications or complete catheterization.

How many people will take part?

Approximately 400 teens and young adults and 800 parents/legal guardians will take part in this study.

What is involved in the study?

In this study, we will collect data about your medical care. You will get text reminders about your treatment regimen and access to an online portal with educational materials. We will ask you to respond to those text messages with a picture of your treatment (catheter or pills) at the time you usually use your catheter or take your pills. You will be randomly selected (like flipping a coin) to receive a certain amount of compensation for doing this. When you are randomly selected, you will only be told how much money you will receive. You will not know what other participants will be paid. Neither the study team nor you will know ahead of time which group you will be in.

No matter which group you are in, you will get access to the Way to Health Platform, an online tool designed to help you take your medicine or complete catheterization. This platform will send you messages to remind you to take your medicine or do your

catheterization. You will need to take daily photos of your adherence behaviors (medication or catheterization) displayed in your hand over the course of the study. You will also answer 5 online surveys, multiple times, for the study.

How long will you be in this study?

If you agree to take part, your participation will last for a total of 12.5 months.

What are the study procedures?

Some of the procedures in this study will be repeated several times. Tests that are part of your regular, routine medical care will continue to be performed.

- **Interviews:** A team member will take your medical history, along with a listing of any medications you are taking. Throughout the study you will be asked to report if you think that anything bad has happened as a result of the study.
- **Medical Record Review:** Throughout the study, we will review your medical records, first to determine your eligibility for the study, and then to collect data related to your kidney transplant or spina bifida care. You may be asked to sign a medical record release form if you transfer your care to a new provider outside of CHOP.
- **Questionnaires:** You will complete 5 surveys that ask questions about your medication/catheterization habits, your confidence and more at three different times throughout the study. You can complete these from home via the Way to Health portal. At the end of the study, you will be asked to complete an Exit Survey which asks about your experience in our study. If you should leave the study before the end of the study you will be given the option to complete an Exit Survey immediately.
- **Photographs:** You will text pictures of your medication or catheter in hand when you normally take your medicine or use your catheter, every day.
- **Text Message Reminders:** You will receive daily messages by text related to the study. On most days, you will receive no more than 4 messages from the study.

Study Schedule

Parts	Start of Study	Intervention	Follow-up Period
How long will this part be?	2 weeks	6 months	6 months
Your procedures	*Create username and profile on Way to Health. *Complete surveys. *Text pictures of your medicine or catheter when you normally take or use them.	*Complete surveys. *Receive daily reminder text messages from Way to Health. *Text pictures of your medicine or catheter when you normally take or use them.	*Complete surveys. *Text pictures of your medicine or catheter when you normally take or use them.

What are the risks of this study?

Taking part in a research study may involve risks. If you have any questions about the possible risks, you should talk to the study team or your health care provider.

Interviews, Medical Record Review, Photographs, and Questionnaires: There are no physical risks but you might experience momentary embarrassment or discomfort. You do not have to answer any questions that make you too uncomfortable.

Breach of Privacy and Confidentiality: As with any study involving collection of data, there is the possibility of breach of confidentiality of data. Every precaution will be taken to secure participants' personal information to ensure confidentiality.

At the time of participation, each participant will be assigned a study identification number. This number will be used on data collection forms in the database instead of names and other private information. A separate list will be maintained that will link each participant's name to the study identification number for future reference and communication.

If you are overly non-compliant with your treatment regimen or show signs of depression, the investigator will contact your care team.

Are there any benefits to taking part in this study?

The knowledge gained from this study may help your health care team learn whether this program is helpful for improving adherence to treatment schedules in teens and young adults. You may improve the way you take your medications or the frequency of your catheterization. However, we cannot guarantee or promise that you will receive any direct benefit by participating in this study.

Do you need to give your consent in order to participate?

If you want to be in the study, you must sign this form. A copy will be saved on the Way to Health platform for you to revisit at any time.

What are your responsibilities?

Please consider study time commitments and responsibilities as a research subject when making your decision about participating in this study.

What happens if you decide not to take part in this study?

Your participation is voluntary. You do not have to take part in order to receive care at CHOP. If you decide not to take part or if you change your mind later, there will be no penalties or loss of any benefits to which you are otherwise entitled.

Can you stop your participation in the study early?

You can stop being in the study at any time. You do not have to give a reason.

Can the study team take you out of the study early?

The study team may take you off the study if you cannot meet the study requirements or if new information suggests that being in the study is not in your best interest.

What choices do you have other than this study?

There are options for you other than this study including:

- Mobile apps and other similar technologies that will help you with taking your medicine or cathing on time
- Not participating in this study.
- You may discuss other options available to you with your doctor.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about you will be collected. This will include information from the surveys you fill out, the pictures you send, and other medical information. Information related to your medical care at CHOP will go in your medical record. This could include physical exams, imaging studies (x-rays or MRI scans) or tests done in the clinical lab. Medical records are available to CHOP staff. Staff will view your records only when required as part of their job. Staff are required to keep your information private. Information that could identify you will not be shared with anyone - unless you provide your written consent, or it is required or allowed by law. We do our best to keep your information private. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at CHOP;
- Research staff from the University of Pennsylvania who run the online platform used for the study (Way to Health);
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections;
- Groups monitoring the safety of this study;
- The National Institutes of Health who is sponsoring this research.

The law makes sure that CHOP protects your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are letting CHOP use and/or release your health information for this research. Some of the organizations listed above may not have the same rules about protecting your information. If allowed by law, they may be able to share it with others without your permission.

There is no set time for destroying the information that will be collected for this study. Your permission to use and share the information and data from this study will continue

until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand 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. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing, without your consent, information that they are required by law to disclose to government authorities. For example, researchers must comply with laws requiring the reporting of suspected child abuse and neglect and communicable diseases.

Can you change your mind about the use of personal information?

You can change your mind at any time. To take back your permission to use and disclose your health information, it is preferred that you tell the investigator in writing. In the letter, state that you changed your mind and do not want any more of your health information collected. Mail your letter to

Dr. Sandra Amaral
The Children's Hospital of Philadelphia
Division of Pediatric Nephrology
34th Street and Civic Center Boulevard
Philadelphia, PA 19104

The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission, you will be withdrawn from the study.

Financial Information

While you are in this study, the cost of your usual medical care – procedures, medications, and doctor visits - will continue to be billed to you or your insurance, if applicable.

Will there be any additional costs?

There will be no additional costs to you by taking part in this study. The National Institutes of Health (NIH) is providing financial support and material for this study and all research study visits.

- If you do not have a phone capable of picture messaging or your phone plan does not cover text messaging, you will be provided with a phone for the duration of the study to be used for picture messages to the Way to Health platform.

Will you be paid for taking part in this study?

- You will be paid a minimum of $2/week for adherence reporting for the duration of the 12.5 month study. After the first month of the study, participants may receive up to, but no more than, $10/week for their adherence reporting if adherence goals are met. You will be paid monthly.
- All money will be provided through your ClinCard, similar to a MasterCard Gift Card that can be used at most stores. You will be given this card when you enter the study and will be asked to keep it throughout the time you are in the study. This card will be uploaded with the funds earned by your participation over time.
- If you receive payment using a bankcard, the bank will have access to identifiable information. The bank will not have access to any medical information.
- You will have the opportunity to earn a small prize for the timely completion of surveys at the start of study. If you complete your surveys in clinic today, you can choose a small prize to bring home with you. If you complete these surveys within five days of enrolling in Way to Health, we will mail a prize to you
- For baseline, post intervention and post follow-up surveys, for each survey set completed within 5 days of survey administration, you will receive $20 and $10 if they're completed within 6 – 10 days.
- If you choose to withdraw from the study, you can earn $10 for completing the Exit Survey within five days of receiving the survey link.

Who is funding this research study?

The National Institute of Diabetes and Digestive and Kidney Diseases, an institute within the NIH, is funding this study.

What if you have questions about the study?

If you have questions about the study, call the study's lead investigator, Dr. Sandra Amaral at 215-590-2449 and amarals@email.chop.edu. You may also talk to your own health care provider.

The Institutional Review Board (IRB) at CHOP has reviewed and approved this study. The IRB makes sure research subjects are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

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.

Documentation of Subject Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

By typing your name here, you are indicating that you have had your questions answered, you agree to take part in this research study and you are legally authorized to consent to yours/ your child's participation. You are also agreeing to let CHOP use and share yours/ your child's health information as explained above. If you don't agree to the collection, use and sharing of yours/ your child's health information, you/ your child cannot participate in this study. **NOTE:** *A foster parent is not legally authorized to consent for a foster child's participation.*

Name of Subject	
Signature of Subject (18 years or older)	Date
Name of Authorized Representative (if different than subject)	Relation to subject: ☐ Parent ☐ Legal Guardian
Signature of Authorized Representative	Date
	Contact phone number for person providing consent (if participant <18 years old)
	Contact email for person providing consent (if participant <18 years old)

Child Assent to Take Part in this Research Study

For children capable of providing assent:

I have explained this study and the procedures involved to _____ in terms he/she could understand and that he/she freely assented to take part in this study.

_____

Person Obtaining Assent

_____ _____

Signature of Person Obtaining Assent Date

This study has been explained to me and I agree to take part.

_____ _____

Signature of Subject Date