

Informed Consent Form

Project Title: Curcumin Therapy to Treat Vascular Dysfunction in Children and Young Adults with ADPKD

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Consent and Authorization Form

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COMIRB No: 15-0902

Version Date: 3/12/2020

Study Title: Curcumin Therapy to Treat Vascular Dysfunction in Children and Young Adults with ADPKD

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Some people in this study may have a medical condition or a disability that does not allow them to make important decisions for themselves. If you have been asked to decide for someone else whether they should be in this study, please read this consent form carefully.

In this form, we use the words "you" and "your." If you are reading this form and deciding for someone else, the words 'you' and 'your' refer to that other person, not to you.

Why is this study being done?

This study plans to learn more about the effects of curcumin on blood vessel function in children and young adults with autosomal dominant polycystic kidney disease (ADPKD). Curcumin is a dietary supplement and is a naturally occurring substance found in the Indian spice turmeric. Turmeric is commonly found in curry powder. You are invited to participate in this research study to determine whether curcumin can improve the function of your blood vessels.

Function of blood vessels is affected by how stiff they are and by a layer of cells called the endothelium. In a healthy blood vessel, the endothelium helps blood vessels to become wider in response to triggers.

In ADPKD, blood vessels do not function properly. The blood vessels are stiffer and do not become as wide in response to triggers. Patients with ADPKD often have increased inflammation and free radicals. Increased inflammation and free radicals may be one reason why blood vessels do not work as well.

You are being asked to participate in this research study to determine if curcumin will improve the function of your blood vessels. We will also see if curcumin can slow the growth of your kidneys.

You are being asked to participate in this research study because you are between 6-25 years of age and have ADPKD.

Other people in this study

Up to 68 children and young adults from your area will participate in the study.

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What happens if I join this study?

Screening:

Your first study visit is called the screening visit. After signing this form, we will ask questions to determine if you qualify for the study. We will review your medical history, medications, and lab work. We may draw some blood from a vein in your arm if you do not have current lab work available. You will also have a short physical exam.

You will be asked to participate for approximately a 1 year period that will involve 7 visits (ranging from ½ hour to 3 hours [if you are under 18] or 5 hours per visit [if you are 18 or older]). Participation will take place in the research space of the Division of Renal Diseases and Hypertension Clinical Research Unit at the University of Colorado Anschutz Medical campus. The MRI scans will take place at the Brain Imaging Center on the University of Colorado Anschutz Medical campus. Most visits will begin between 7 a.m. and 11 a.m.

The treatment period may be extended by several months during extenuating circumstances limiting the ability to return the University of Colorado Anschutz Medical campus (e.g., COVID-19 outbreak).

You will be required to refrain from food (water is ok), exercise, non-prescription medications, and alcohol (if applicable) prior to some of the visits. The study coordinator will review these restrictions with you.

If you live out of state, the lab work in the middle of the study will be arranged to occur elsewhere, and you will only need to come to the Anschutz Medical campus at the beginning and end of the study.

Randomization:

This study will have 2 different groups of research subjects like you. To decide which group you will be in, we will use a method of chance. This method is like flipping a coin or rolling dice. Each group will get slightly different care. One group will receive curcumin and the other will receive a placebo. A placebo is a pill or a liquid that looks like medicine but is not real. It will have no medical effect on you. In both groups, the drug or placebo will be given to you as a powder.

You will not know which treatment group you are in. Neither will your study doctor. This information needs to be kept secret so that the study is based on scientific results, not on peoples' opinions. However, we can give this information out if you have an emergency.

If you are in an emergency, make sure you tell the emergency staff about this study. They can contact us, and we will give them all relevant information.

Dosing of medication:

If you are randomized to the study drug, you will take a dose that is specific to your body weight. The number of scoops of powder will differ depending on the person. If you are in the placebo

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group you will still receive powder; but the powder will not have any medicine. No matter what group you are in, we will have you measure the powder and mix it with food.

Table of detailed visits:

The table below illustrates the detailed visits if you enroll in the study.

	Visit 1 (Screening)	Visit 2 (Baseline testing)	Visit 3 (Baseline testing)	Visit 4 (Safety Check)	Visit 5 (Safety check, testing visit if local)	Visit 6 (End of study testing)	Visit 7 (End of study testing)
Medical History	✗ (may be completed at Visit 2)	✗ (if not completed at Visit 1)					
Physical Examination	✗ (may be completed at Visit 1)	✗ (if not completed at Visit 1)				✗	
Blood Draw	✗ (may be completed at Visit 1)	✗		✗	✗	✗	
Blood pressure at rest	✗ (may be completed at Visit 1)	✗			✗ (only if you live in CO)	✗	
Urine Sample		✗				✗	
Blood Vessel Stiffness and Endothelial Function Tests		✗			✗ (only if you live in CO)	✗	
Saline and Vitamin C infusion		✗ (only if you are 18 or older)				✗ (only if you are 18 or older)	
Nitroglycerin		✗ (only if you are 18 or older)				✗ (only if you are 18 or older)	
MRI			✗				✗
Receive study drug		✗					

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You may have questions about your rights as someone in this study. You can call Dr. Nowak with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

Explanation of each session:

Visit 1 (about 1 hr):

- **Medical History and Physical Examination.** Your medical history and physical examination will be performed by a physician or nurse practitioner at the Division of Renal Diseases and Hypertension Clinical Research Unit. You will also be asked about your family history of kidney disease, cardiovascular disease, diabetes, and cancer. Your body weight will be measured using a doctor's office scale.
- **Blood Draw.** A nurse or certified medical technician will place a small tube in a vein in your arm for drawing blood and will collect a blood sample (less than ½ a tablespoon) for markers of kidney and liver function.
- **Pregnancy Test.** If you are a female of possible child-bearing age, we will perform a pregnancy test even if you are sure you are not pregnant.

Visit 2 (about 3 hours if under 18; about 5 hours if 18 or older):

- **Medical History and Physical Examination.** (If not completed at Visit 1). Your medical history and physical examination will be performed by a physician or nurse practitioner at the Division of Renal Diseases and Hypertension Clinical Research Unit. You will also be asked about your family history of cardiovascular disease, diabetes, and cancer. Your body weight will be measured using a doctor's office scale.
- **Blood Pressure at Rest.** Your blood pressure will be measured as is done in your doctor's office with a cuff on your upper arm.
- **Blood Draw.** A nurse or certified medical technician will place a small tube in a vein in your arm for drawing blood and will collect a blood sample for markers of kidney and liver function (if not completed at Visit 1; less than ½ a tablespoon of blood), measurement of study drug levels (less than ½ a tablespoon of blood), measurements of markers of inflammation and free radicals (only if you are 18 or older; about 1 ½ tablespoons of blood), and immune cells (only if you are 18 or older; about 1 ½ tablespoons of blood). If you sign the optional consent for future research, we will draw additional blood (about a tablespoon if you are 18 or older, less than ½ a tablespoon if you are under 18).
- **Urine Sample.** We will collect a sample of urine to measure markers of free radicals.
- **Blood Vessel Stiffness Test.** To test the "stiffness" of the walls of your arteries we will do two sets of measures. First, a small probe will be placed flat on the surface of your skin at four sites and will record each time your heart beats. The four sites are your carotid artery (side of neck), brachial artery (near the back of your elbow), femoral artery (upper leg/hip) and radial artery (wrist). The faster your pulse moves between these sites, the stiffer your arteries are. Second, an ultrasound will also be used on the surface of your skin to allow us to see how the size of an artery on the side of your neck (carotid artery) changes at rest. This tells us how elastic (the opposite of stiffness) your artery is.

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- Endothelial Function Test. We will place an ultrasound probe on your skin over the major artery in your upper arm. A small blood pressure cuff will be inflated tightly below your elbow cutting off the blood flow for 5 minutes. The blood flow and size of your vessel will be measured before and after inflating the cuff. This will allow us to measure your endothelial function (ability of blood vessels to dilate or get bigger). You will also have electrodes on your chest to trace the electrical activity of your heart (ECG).
- Saline. If you are 18 or older, we will infuse saline (water with salt) into an IV placed on the top of your hand for about an hour. After 20 minutes of the infusion, we will make the measurements described above (Blood Vessel Stiffness Test and Endothelial Function Test).
- Vitamin C. If you are 18 or older, we will then infuse vitamin C into the IV in your hand for about an hour. After 20 minutes of the infusion, we will repeat the measurements of blood vessel function described above (Blood Vessel Stiffness Test and Endothelial Function Test).
- Nitroglycerin. If you are 18 or older, a nitroglycerin pill will be placed under your tongue. Nitroglycerin is given to patients to relieve chest pain. This pill will cause the major artery in your upper arm to increase in size. We will look at your blood pressure and will collect ultrasound images of your blood vessel for 8 minutes after you take the nitroglycerin pill. If your blood pressure decreases, we will make sure your blood pressure returns to where it started before we let you sit up.
- Receive Curcumin. A nurse will give you your first dose of the curcumin (or placebo) and the rest of the medication for you to take home to be use during the course of the study.
- Receive Blood Pressure Monitor. A staff research coordinator will give you a blood pressure monitor and a chart to record blood pressure measurements. The coordinator will review proper blood pressure measuring technique. You will be asked to record your blood pressure once a month.

Visit 3 (about 1 hour):

- MRI scan: You will have an MRI scan of your kidneys to measure the kidney size.

Visit 4 (about 1 hour):

- Blood Draw. A nurse or certified medical technician will place a small tube in a vein in your arm for drawing blood and will collect a blood sample for markers of kidney and liver function (less than ½ a tablespoon of blood)

Visit 5 – If out you live out of state (about ½ hour):

- Blood Draw. A nurse or certified medical technician will place a small tube in a vein in your arm for drawing blood and will collect a blood sample for markers of kidney and liver function (less than ½ a tablespoon of blood)

Visit 5 – If you live local (about 1 ½ hours):

- Blood Draw. A nurse or certified medical technician will place a small tube in a vein in your arm for drawing blood and will collect a blood sample for markers of kidney and liver function (less than ½ a tablespoon of blood)

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- These tests will be performed as described above for Visit 2:
 - Blood Pressure at Rest
 - Blood Vessel Stiffness Test
 - Endothelial Function Test

Visit 6 (about 2.5 hours if under 18; about 4.5 hours if 18 or older): The following tests will be done and are described above for visit 2:

- Physical Examination
- Blood Pressure at Rest
- Blood Draw
 - If you cannot return the University of Colorado at the 12 month time point, we will ask you to go to a locally contracted laboratory at this time for your clinical labs, and then remaining blood will be drawn at your end-of-study visit.
- Urine Sample
- Blood Vessel Stiffness Test
- Endothelial Function Test
- Saline Infusion (Only if 18 or older)
- Vitamin C Infusion (Only if 18 or older)
- Nitroglycerin (Only if 18 or older)

Visit 7 (about 1 hour):

- MRI scan: You will have an MRI scan of your kidneys to measure the kidney size.

Phone Safety Check. The coordinator will also call you after 1, 3, 6, and 9 months of taking the curcumin to check in with how you are doing and ask you some brief safety questions.

What are the possible discomforts or risks?

Discomforts you may experience while in this study include:

1. Risks of having an MRI: In this study we will take an MRI of your kidneys. The MRI machine uses powerful magnetic waves to take pictures inside the body. The waves themselves are not harmful, but they can cause metal to heat up and electronics to stop working.

You should NOT have an MRI if you have metal or electronic devices inside your body. Heart pacemakers and insulin pumps are examples of electronic devices.

The MRI machine is a small round tube. It might make you uncomfortable if you do not like tight spaces.

The most common side effect of having an MRI is flashing lights in the eyes. This is caused by the magnetic waves and is not harmful. Some people also experience warmth and reddening of the skin. This usually goes away after a few minutes.

If you are pregnant, be sure to tell the person giving you the MRI.

2. Risk of receiving curcumin or placebo: Curcumin is a dietary supplement that is the active ingredient in the Indian spice turmeric. It is designated as “generally recognized as safe” by the

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FDA. Few side-effects of curcumin have been reported, and this primarily with higher doses than will be given in this study. The primary risk is possible gastrointestinal distress (gas, constipation, diarrhea, or nausea) in a small percentage of people. In the event that you develop symptoms that are not tolerable, we will reduce your dose of curcumin.

3. Risks of Having Blood Taken: In this study we will need to collect about 1 ½ tablespoons or less of blood from you during each blood draw session. During the entire study, a total of about 2 tablespoons will be drawn if you are under 18, 7 ½ tablespoons if you are 18 or older, and an additional 1 or 2 (child/adult) tablespoons if you sign the optional consent for future research. We will get blood by putting a needle into one of your veins and letting the blood flow into a glass tube.

- Common side effects: You may feel some pain when the needle goes into your vein. A day or two later, you may have a small bruise where the needle went under the skin.
- Rare side effects: There is also a small chance that you could feel lightheaded or faint during the blood draw.
- To make the blood draw easier, we may use a numbing cream on your skin before drawing blood.
 - Common side effects: The cream may cause temporary paleness, redness, or swelling to the skin where it is applied
 - Rare side effects: There is an uncommon chance of mild burning, itching, or warmth of the skin. Rarely, an allergic reaction may occur.

Please let the investigator know if you have ever had a reaction to a skin numbing medicine.

4. Risk of Endothelial Function Test:

- Common side effects: Inflating the blood pressure cuff just below your elbow during this test may cause a moderate intensity pain “pins and needles” or numbing sensation that goes away as soon as the cuff is deflated.

5. Risk of receiving nitroglycerin under the tongue (Only done if 18 or older): Nitroglycerin is a drug used medically to treat chest pain.

- Common side effects: The most common reaction to this medication is a headache, which develops in approximately 60% of patients.
- Less common side effects: It can also cause a decrease in blood pressure, dizziness or lightheadedness. Placing the pill under your tongue may cause irritation in that area of your mouth.
- Rare side effects: In rare instances (1 in 1000) it may lower the heart rate, which could cause fainting.

We will monitor your blood pressure and heart rate every 2 minutes during administration of nitroglycerin. In addition, you will have an IV in place so fluids can be given if your blood pressure falls or fainting occurs.

6. Risk of Having an IV Inserted in Your Vein (Only done if 18 or older): In this study, we will insert a needle, connected to a plastic tube, into a vein in your hand. We will use the tube to give you fluids (hand).

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- Common side effects: You will feel some pain when we first insert the tube into your vein. You may have some redness, swelling or bruising where the tube goes under your skin.
- Rare side effects: There is a small chance that you could feel lightheaded or faint during the IV insertion. In some cases, this type of tube can cause an infection where it goes under the skin, but the risk of infection is less than 1 in 1000. In rare cases, it can cause a blood clot in the vein. You will have the tube inserted in your hand for about 2 hours.

7. Risk of Vitamin C Infusion (Only done if 18 or older) :

- Rare side effects: There is a chance the vitamin C may irritate your skin on your hand where it is being infused, but this uncommon because we dilute (water-down) the vitamin C in saline (water with salt).

8. Risks if pregnant or become pregnant: If you become pregnant, the particular treatment or procedures involved in the study may involve risks to the embryo or fetus which are currently unclear. You may not be in the study if you are breastfeeding, pregnant, or plan to become pregnant during the study. If you are a female who is old enough to potentially become pregnant, you will need to take a pregnancy test prior to receiving the study medication and monthly while in the study. If you become pregnant during the course of the study, you must stop taking your study medication right away, and contact your doctor or study staff.

There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it cannot be guaranteed.

The study may include risks that are unknown at this time.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about the effects of curcumin on blood vessel function and kidney growth in children and young adults with ADPKD. However, there is no guarantee that your health will improve if you join this study. Also, there could be risks to being in this study. If there are risks, these are described in the section describing the discomforts or risks.

Are there alternative treatments?

There may be other ways of treating ADPKD. These other ways include lowering blood pressure if it is elevated. These treatments will be continued throughout the period of the study if you are already receiving them, and may be started at the beginning of the study period if you are not.

You should talk to your doctor about your choices. Make sure you understand all of your choices before you decide to take part in this study. You may leave this study and still have these other choices available to you.

Who is paying for this study?

The research is being paid for by the National Institutes of Health.

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Will I be paid for being in the study?

You will not be paid to be in the study. Travel and hotel reimbursement may be offered if you do not live in the greater Denver metropolitan area.

Will I have to pay for anything?

It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If you decide to leave the study early, you will be asked to make one final visit so that you can complete the testing planned for the final visit.

If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

Can I be removed from this study?

You may be taken out of the study if the study doctor thinks it is not safe for you to be in the study. You can be taken out of the study even if you do not want to leave the study. Also, the sponsor can decide to stop the study at any time.

What happens if I am injured or hurt during the study?

If you have an injury while you are in this study, you should call Dr. Nowak immediately. Her phone number is 303-724-4842. We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

Who do I call if I have questions?

The researcher carrying out this study is Dr. Kristen Nowak. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Nowak at 303-724-4842. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Dr. Nowak with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

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.

Optional Consent for Blood and Urine Banking for Future Research

Dr. Kristen Nowak would like to keep some of the blood and urine that are taken during the study but is not used for other tests. If you agree, we will keep some of the blood and urine already taken in the study and also take an additional tablespoon of blood if you are 18 or older and less than half a tablespoon of additional blood if you are under 18. If you agree, the blood

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and urine will be kept and may be used in future research to learn more about chronic kidney disease and autosomal dominant polycystic kidney disease. The research that is done with your blood and urine is not designed to specifically help you. It might help people who have chronic kidney disease and autosomal dominant polycystic kidney disease and other diseases in the future. Reports about research done with your blood and urine will not be given to you or your doctor. These reports will not be put in your health records. The research using your blood and urine will not affect your care.

The choice to let Dr. Kristen Nowak keep the blood and urine for future research is up to you. No matter what you decide to do, it will not affect the care that you will receive as part of the study. If you decide now that your blood and urine can be kept for research, you can change your mind at any time and contact your study doctor to let him or her know that you do not want Dr. Kristen Nowak to use your blood and urine any longer, and they will no longer be used for research. Otherwise, they may be kept until they are used up, or until Dr. Kristen Nowak decides to destroy them.

When your blood and urine are given to other researchers in the future Dr. Kristen Nowak will not give them your name, address, phone number or any other information that will let the researchers know who you are.

Sometimes blood and urine are used for genetic research (about diseases that are passed on in families). Even if your blood and urine are used for this kind of research, the results will not be told to you and will not be put in your health records. Your blood and urine will only be used for research and will not be sold. The research done with your blood and urine may help to develop new products in the future, but there is no plan for you to be paid.

The possible benefits of research from your blood and urine include learning more about what causes chronic kidney disease, autosomal dominant polycystic kidney disease, and other diseases, how to prevent them and how to treat them. The greatest risk to you is the release of your private information. Dr. Kristen Nowak will protect your records so that your name, address and phone number will be kept private. The chance that this information will be given to someone else is very small. There will be no cost to you for any data or sample collection and storage by Dr. Kristen Nowak.

Please read each sentence below and think about your choice. After reading each sentence, circle "yes" or "no." If you have questions, please talk to your doctor or nurse. Remember, no matter what you decide to do about the storage and future use of your blood and urine, you may still take part in the study.

I give my permission for my blood and urine to be stored in a central tissue bank at the University of Colorado for future use by the study investigators:

1. I give my permissions for my blood and urine to be kept by Dr. Kristen Nowak for use in future research to learn more about how to prevent, detect, or treat autosomal dominant polycystic kidney disease.

Yes No _____ Initials

2. I give my permissions for my blood and urine to be used for research about other health problems (for example: causes of heart disease, osteoporosis, diabetes).

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Yes No _____Initials

3. I give my permission for the University of Colorado Division of Renal Diseases and Hypertension to contact me in the future to ask me to take part in more research.

Yes No _____Initials

Who will see my research information?

The University of Colorado Denver (UCD) and its affiliated hospital(s) have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

- University of Colorado Denver
- Children's Hospital Colorado (CHCO)
- University of Colorado Hospital

CHCO shares a medical record system with the Barbara Davis Center and PedsConnect; therefore it is also possible that your information could be viewed by healthcare professionals at these organizations.

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the UCD and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Dr. Kristen Nowak
Division of Renal Diseases and Hypertension
12700 East 19th Avenue, C281
Aurora, CO 80045
303-724-4842

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

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- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- The National Institutes of Health, who is the company paying for this research study.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator. To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study is completed.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)
- Portions of my previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory studies, radiology studies, procedure results
- Research Visit and Research Test records

What happens to Data, Blood and Specimens that are collected in this study?

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find the causes and cures of disease. The data, blood and specimens collected from you during this study are important to this study and to future research. If you join this study:

- The data, tissue, blood, or other specimens given by you to the investigators for this research no longer belong to you.
- Both the investigators and any sponsor of this research may study your data, blood, or other specimens collected from you.
- If data, blood, or other specimens are in a form that identifies you, UCD or the hospitals involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

HIPAA Authorization for Optional Additional Study Procedures

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In this form, you were given the option to agree to additional, optional research procedures. You must also give us your permission, under HIPAA rules, to use and disclose the information collected from these optional procedures, as described above.

If you decline to give us permission to use and disclose your information, you cannot take part in these optional procedures, but you can still participate in the main study. Please initial next to your choice:

_____ I give permission for my information, from the optional procedures I have agreed to above, to be used and disclosed as described in this section.

_____ I **do not** give permission for my information for any optional procedures to be used and disclosed; I understand that I will not participate in any optional procedures.

Certificate of Confidentiality

This study has been issued a Certificate of Confidentiality from the federal government to help protect your privacy. The Certificate prohibits the researchers from disclosing your name, or any identifiable information, document or biospecimen from the research, with the exceptions listed below. A certificate provides protections against disclosing research information in federal, state, or local civil, criminal, administrative, legislative or other proceedings.

These protections apply only to your research records. The protections do not apply to your medical records.

The researchers may disclose your name or identifiable information, document or biospecimen, under the following circumstances:

- To those connected with the research,
- If required by Federal, State or local laws,
- If necessary for your medical treatment, with your consent,
- For other scientific research conducted in compliance with Federal regulations,
- To comply with mandated reporting, such as a possible threat to harm yourself or others, reports of child abuse, and required communicable disease reporting, or
- Under other circumstances with your consent.

A Certificate of Confidentiality does not protect information you or a member of your family voluntarily release.

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Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature: _____ Date _____

Print Name: _____

Signature: _____ Date _____

Print Name: _____

_____ Date _____

Child (13-17 year olds)

Witness Signature _____ Date _____

Print Name: _____

Witness of Signature

Witness of consent process

Consent form explained by: _____ Date _____

Print Name _____