**University of North Carolina at Chapel Hill
Assent to Participate in a Research Study
Minor Subjects (7-14 yrs)**

**Consent Form Version Date:** 2/11/2015
**IRB Study #** 15-0226
**Title of Study**: ALL YOU NEED IS LOVE: Adherence and Longitudinal Life skills for Youth, Under a Nurturing Educational Environment on Disease-Intelligent Self-management: Lasting Outcomes, Visionary Empowerment
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**Funding Source and/or Sponsor:** Renal Research Institute (RRI)

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The people named above are doing a research study.

**These are some things we want you to know about research studies:**
Your parent needs to give permission for you to be in this study. You do not have to be in this study if you don’t want to, even if your parent has already given permission.

You may stop being in the study at any time. If you decide to stop, no one will be angry or upset with you.

Sometimes good things happen to people who take part in studies, and sometimes things happen that they may not like. We will tell you more about these things below.

**Why are they doing this research study?**
The reason for doing this research is to find out how we can help you learn how to self-manage your medical condition. This is important to learn because when you grow older, you will start to see an adult doctor. We will see if the materials in the study kit can help you do this. Half of the people in this study will get a study kit that has information about self-management and about kidney disease. The other half of the people in this study will get the same information, plus some more information about “Mindfulness”, which is a way to relax and get rid of stress.

**Why are you being asked to be in this research study?**
You are being asked to be in the study because the self-management and/or Mindfulness training program may help you.

**How many people will take part in this study?**
If you decide to be in this study, you will be one of about 100people in this research study.

**What will happen during this study?**
The study is in 3 parts:

1. Part 1:
	1. When you sign this consent form, we will give you your study kit and talk you through what is in it.
	2. You will answer some questions during your clinic appointment. These questions will help us learn about how you self-manage your condition
2. Part 2:
	1. You will take your study kit home with you.
	2. Every week for 6 weeks, you will do a 15-25 minute lesson using the materials in your study kit.
	3. A research team member will call you every two weeks. They will ask you some questions, and you can ask them questions if you are confused about anything
3. Part 3:
	1. About three months after your pre-test, you will answer some more questions during your clinic appointment.

You will randomly be assigned (by chance, like flipping a coin) to receive either a self-management kit or a self-management + Mindfulness kit. If you get the self-management + Mindfulness, your lessons take a little extra time. You and your parent will also sign something called a HIPPA form. This will give us the ability to look at your medical record, specifically your basic demographic information like gender and birth date and your diagnosis, the medications your take and your doctor’s name. The only individuals who will have access to the records are the researchers involved in this study.

**Who will be told the things we learn about you in this study?**
We will not tell anyone what you tell us without your permission unless there is something that could be dangerous to you or someone else.

**What are the good things that might happen?**
Research is designed to benefit society by gaining new knowledge.  You will not benefit personally from being in this research study.

**What are the bad things that might happen?**
Sometimes things happen to people in research studies that may make them feel bad. These are called “risks.” There are no known risks of participating in this study.

Things may happen that the researchers don’t know about. You should report any problems to the researcher.

**Will you get any money or gifts for being in this research study?**
You will get either an MP3 player or a gift card when you start. Both are worth $20, and you will get one or the other. You will also get a $20 gift card every time you complete 3 of the lessons from your kit. Once you answer the last set of questions at your clinic appointment, you will get another $20 gift card. That means that you will receive a total of either $60 in gift cards plus an MP3 player or $80 in gift cards (depending on which random group you are placed into) by the time the study is done.

**Who should you ask if you have any questions?**
If you have questions you should ask the people listed on the first page of this form. If you have other questions, complaints or concerns about your rights while you are in this research study you may contact the Institutional Review Board at 919-966-3113 or by email to IRB\_subjects@unc.edu.

If you sign your name below, it means that you agree to take part in this research study.

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