**University of North Carolina at Chapel Hill
Assent to Participate in a Research Study
Adolescent Participants age 15-17**

**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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**What are some general things you should know about research studies?**
You are being asked to take part in a research study.  To join the study is voluntary.
You may refuse to join, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future.   You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below.  It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form.  You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

**What is the purpose of this study?**
Adolescents with chronic kidney disease (CKD) or end-stage renal disease (ESRD) go through several changes that could be challenging. For adolescents with CKD/ESRD, self-managing their disease to prepare themselves to transfer from pediatric to adult care is important.

This study will examine if a mindfulness-based program focused on CKD addition to traditional self-management education may ultimately help patients. Mindfulness trains you in self-acceptance and coping, which can reduce the stress resulting from having a chronic health condition. Mindfulness integrates openness, acceptance and present-moment awareness. It decreases anxiety and depression and increases motivation for lifestyle change (diet, physical activity). This can help facilitate the right attitudes/behaviors for treatment adherence.

The purpose of this research study is to learn about the benefits of a comprehensive self-management program that combines traditional CKD/ESRD self-management with Mindfulness training. We intend to evaluate the added benefits of a 6-week mindfulness-based self-management program over traditional CKD/ESRD self-management, in a randomized intervention for 100 youth.

You are being asked to be in the study because you may benefit from a self-management and/or Mindfulness training program focused on CKD/ESRD.

**Are there any reasons you should not be in this study?**
You should not be in this study if you are cannot or do not want to provide consent.

**How many people will take part in this study?**
There will be approximately 100 people in this research study.

**How long will your part in this study last?**
You are being asked to participate in this study for a total of three months.

**What will happen if you take part in the study?**
The study is in 3 parts:

1. Pre-testing: When you sign this consent form, we will give you your study kit and talk you through what is in it. You will complete a pre-test survey during your clinic appointment. This pre-test will help us learn where you are in your self-management preparation.
2. Training: You will take your study kit home with you. Each week for 6 weeks, you will complete a 15-25 minute education session using the materials in your study kit. A research team member will call you every two weeks to get an update on your progress and to answer any questions you have.
3. Post-testing: Approximately three months after your pre-test, you will complete a post-test survey during your clinic appointment.

You will randomly be assigned (by chance, like flipping a coin) to receive either a self-management education kit or a self-management education + mindfulness education kit. The self-management education + mindfulness weekly education sessions take about 10 minutes more than the self-management education sessions. You will also sign a HIPPA form giving us permission to look at your medical record. The only information that will be reviewed or used for study purposes from the medical record will be your basic demographic information (gender, birth date, etc.), diagnosis, medications and doctor’s name and the only individuals who will have access to the record are the PI and study researchers directly involved in this study.

**What are the possible benefits from being in this study?**
Research is designed to benefit society by gaining new knowledge.  You may not benefit personally from being in this research study. You may benefit from the educational sessions.

**What are the possible risks or discomforts involved from being in this study?**
There are no known risks of participating in this study. There may be uncommon or previously unknown risks. You should report any problems to the researcher.

**How will information about you be protected?**
We will protect your privacy. You will be assigned a unique study ID number, and this number will be used to store your answers. Your name and any other information will never be linked with your answers. All data is secured in password-protected electronic files on a secure computer, and physical files are in a locked cabinet in a secure building. Only the research team will have access to the data.

Participants will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information.  This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information.  In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

**What if you want to stop before your part in the study is complete?**
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped

**Will you receive anything for being in this study?**
You will initially get compensation worth $20 (in the form of either an MP3 player or gift card, depending on your group) for participating in this study. You will then get a $20 gift card every time you complete 3 intervention modules from your kit. Once you complete post-intervention assessments, you will receive another $20 gift card. The total incentive that you will receive for participating in the study in either of the conditions will be $80 (either $60 in gift card format plus an MP3 player valued at $20 or $80 in gift cards total).

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

**Who is sponsoring this study?**
This research is funded by the Renal Research Institute.  This means that the research team is being paid by the sponsor for doing the study.  The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

**What if you have questions about this study?**
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form**.**

**What if you have questions about your rights as a research participant?**
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB\_subjects@unc.edu.

**Participant’s Agreement**:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

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