**University of North Carolina at Chapel Hill
Parental Permission for a Minor Child to Participate in a Research Study**

**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 and you child should know about research studies?**
You are being asked to allow your child to take part in a research study. To join the study is voluntary.

You may refuse to give permission, or you may withdraw your permission for your child to be in the study, for any reason, without penalty. Even if you give your permission, your child can decide not to be in the study or to leave the study early.

Research studies are designed to obtain new knowledge. This new information may help people in the future. Your child 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 and your child understand this information so that you and your child can make an informed choice about being in this research study.
You will be given a copy of this consent form. You and your child 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) experience several changes that could be psychosocially challenging. For adolescents with CKD/ESRD, assuming self-management of 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 interventions may ultimately improve patient outcomes. Mindfulness provides training in self-acceptance and coping, buffering stress resulting from having a chronic health condition as it integrates openness, acceptance and present-moment awareness. It decreases anxiety and depression and increases motivation for lifestyle change (diet, physical activity), facilitating the right attitudes/behaviors for treatment adherence.

The purpose of this research study is to examine the benefits of a comprehensive self-management program that integrates 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.

Your child is being asked to be in the study because they have chronic kidney disease or end-stage renal disease, and may benefit from a self-management and/or mindfulness training program.

**Are there any reasons your child should not be in this study?**
Your child should not be in this study if you or your child is unable or unwilling 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 child’s part in this study last?**
Your child is being asked to participate in this study for a total of three months.

**What will happen if your child takes part in the study?**
The study is in 3 parts:

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

Your child 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 and your child will also sign a HIPPA form granting access to your child’s medical record. The only information that will be reviewed or used for study purposes from the medical record will be your child’s 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.  Your child will not benefit personally from being in this research study. Your child 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.

**What if we learn about new findings or information during the study?**
You and your child will be given any new information gained during the course of the study that might affect your willingness to continue your child’s participation in the study.

**How will information about your child be protected?**
We will take all necessary measures to protect your child’s privacy. Your child will be assigned a unique study ID number, and this number will be used to store their answers. None of your child’s identifying information (your name and any other information) will be linked with their 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 or your child wants to stop before your child’s part in the study is complete?**
You can withdraw your child from this study at any time, without penalty. The investigators also have the right to stop your child’s participation at any time. This could be because your child has failed to follow instructions, or because the entire study has been stopped.

**Will your child receive anything for being in this study?**
Your child will initially receive compensation worth $20 (in the form of either an MP3 player or gift card, depending on your group) for taking part in this study. Your child will then receive a $20 gift card every time he/she completes 3 intervention modules. Upon completing post-intervention assessments, your child will receive a final incentive of a $20 gift card. The total incentive that your child 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 for your child to be in this study?**
It will not cost 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 or your child has questions about this study?**
You and your child have the right to ask, and have answered, any questions you may have about this research. If there are questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, contact the researchers listed on the first page of this form**.**

**What if there are questions about your child’s rights as a research participant?**
All research on human volunteers is reviewed by a committee that works to protect your child’s rights and welfare. If there are questions or concerns about your child’s 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.

**Parent’s Agreement:**

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily give permission to allow my child to participate in this research study.

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