General Information

1. General Information

1. Project Title

   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

2. **Brief Summary**. Provide a **brief non-technical description** of the study, which will be used in IRB documentation as a description of the study. Typical summaries are 50-100 words. Please reply to each item below, retaining the subheading labels already in place, so that reviewers can readily identify the content. PLEASE NOTE: THIS SECTION MAY BE EDITED BY THE IRB FOR CLARITY OR LENGTH.

   Purpose: We propose to examine the benefits of a comprehensive self-management program that integrates traditional CKD/ESRD self-management with Mindfulness training.

   Participants:100 youth with CKD/ESRD

   Procedures (methods): 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.

3. Is this new study similar or related to an application already approved by a UNC-Chapel Hill IRB? Knowing this will help the IRB in reviewing your new study.

   No

2. Project Personnel

1. Will this project be led by a STUDENT (undergraduate, graduate) or TRAINEE (resident, fellow, postdoc), working in fulfillment of requirements for a University course, program or fellowship?

   No

2. List all project personnel beginning with principal investigator, followed by faculty advisor, co-investigators, study coordinators, and anyone else who has contact with subjects or identifiable data from subjects.

   - List ONLY those personnel for whom this IRB will be responsible; do NOT include collaborators who will remain under the oversight of another IRB **for this study**.
   - If this is Community Based Participatory Research (CBPR) or you are otherwise working with community partners (who are not functioning as researchers), you may not be required to list them here as project personnel; consult with your IRB.
   - If your extended research team includes multiple individuals with limited roles, you may not be required to list them here as project personnel; consult with your IRB.

   The table below will access campus directory information; if you do not find your name, your directory listing may need to be updated.

Last Name	First Name	Department Name	Role	Detail
Ferris	Maria	Medicine-Nephrology	Principal Investigator	view
Cuttance	Jessica	UNC Kidney Center	Project Manager or Study Coordinator	view
Cohen	Sarah	Allied Health Sciences	Project Manager or Study Coordinator	view
Phillips	Alex	Medicine-Nephrology	Research Assistant	view

Nazareth	Meaghan	Statistics and Operations Research	Research Assistant	view
Javalkar	Karina	Medicine-Nephrology	Research Assistant	view

NOTE: The IRB database will link automatically to UNC Human Research Ethics Training database and the UNC Conflict of Interest (COI) database. Once the study is certified by the PI, all personnel listed (for whom we have email addresses) will receive separate instructions about COI disclosures. The IRB will communicate with the personnel listed above or the PI if further documentation is required.

3. If this research is based in a center, institute, or department (Administering Department) other than the one listed above for the PI, select here. Be aware that if you do not enter anything here, the PI's home department will be AUTOMATICALLY inserted when you save this page.

Department	Medicine-Nephrology

3. Funding Sources

1. Is this project funded (or proposed to be funded) by a contract or grant from an organization EXTERNAL to UNC-Chapel Hill?

   Yes

Funding Source(s) and/or Sponsor(s)

Sponsor Name	UNC Ramses Number	Sponsor Type	Prime Sponsor Name	Prime Sponsor Type	Sponsor/Grant Number	Detail
Renal Research Institute (RRI)	15-1379	Foundation				view

2. Is this study funded by UNC-CH (e.g., department funds, internal pilot grants, trust accounts)?

   No

3. Is this research classified (e.g. requires governmental security clearance)?

   No

4. Is there a master protocol, grant application, or other proposal supporting this submission (check all that apply)?

- ✔ Grant Application
- ✘ Industry/Federal Sponsor Master Protocol
- ✘ Student Dissertation or Thesis Proposal
- ✘ Investigator Initiated Master Protocol
- ✘ Other Study Protocol

4. Screening Questions

The following questions will help you determine if your project will require IRB review and approval.

The first question is whether this is RESEARCH

1. Does your project involve a systematic investigation, including research development, testing and evaluation, which is designed to develop or contribute to generalizable knowledge? PLEASE NOTE: You should only answer yes if your activity meets all the above.

   Yes

The next questions will determine if there are HUMAN SUBJECTS

2. Will you be obtaining information about a living individual through direct intervention or interaction with that individual? This would include any contact with people using questionnaires/surveys, interviews, focus groups, observations, treatment interventions, etc. PLEASE NOTE: Merely obtaining information FROM an individual does not mean you should answer 'Yes,' unless the information is also ABOUT them.

   Yes

3. Will you be obtaining identifiable private information about a living individual collected through means other than direct interaction? This would include data, records or biological specimens that are currently existing or will be collected in the future for purposes other than this proposed research (e.g., medical records, ongoing collection of specimens for a tissue repository).

   Yes

The following questions will help build the remainder of your application.

4. Will subjects be studied in the Clinical and Translational Research Center (CTRC, previously known as the GCRC) or is the CTRC involved in any other way with the study? (If yes, this application will be reviewed by the CTRC and additional data will be collected.)

   No

5. Does this study directly recruit participants through the UNC Health Care clinical settings for cancer patients **or** does this study have a focus on cancer or a focus on a risk factor for cancer (e.g. increased physical activity to reduce colon cancer incidence) **or** does this study receive funding from a cancer agency, foundation, or other cancer related group? (If yes, this application may require additional review by the Oncology Protocol Review Committee.)

   No

6. Are any personnel, organizations, entities, facilities or locations in addition to UNC-Chapel Hill involved in this research (e.g., is this a multi-site study or does it otherwise involve locations outside UNC-CH, including foreign locations)? You should also click "Yes" if you are requesting reliance on an external IRB, or that UNC's IRB cover another site or individual. See guidance.

   No

Exemptions

Request Exemption

Some research involving human subjects may be eligible for an exemption which would result in fewer application and review requirements. This would not apply in a study that involves drugs or devices, involves greater than minimal risk, or involves medical procedures or deception or minors, except in limited circumstances.

Additional guidance is available at the OHRE website. Exemptions can be confusing; if you have not completed this page before, please review this table with definitions and examples before you begin.

1. Would you like your application evaluated for a possible exemption?

   No

Part A. Questions Common to All Studies

A.1. Background and Rationale

A.1.1. Provide a summary of the background and rationale for this study (i.e., why is the study needed?). If a complete background and literature review are in an accompanying grant application or other type of proposal, only provide a brief summary here. If there is no proposal, provide a more extensive background and literature review, including references.

UPDATE 2/26/15:
The self-mangement education modules we have created are applicable to ages 12 to 29 and are currently not modified for different age groups. The rationale is that the sessions contain the baseline amount of information that an individual needs to begin succesfully managing and understanding chronic kidney disease. With the exception of some necesarry and important medical terminology, the session content will be delivered at a 4th grade reading level in a simple clear format. Various activities, learning modalities and deliverly formats (multiple choice questions, guided audio, charts, graphs, pictures, case stories, reflection questions, etc) will be used throughought the education modules to ensure appropriateness and applicability to ages 12-29 inclusive.

The mindfulness portion of the protocol is an additional 10 minutes per week of mindfulness education and practice. It is not currently modified for different ages and is one protocol applicable to ages 12-29. The rational is based on research on mindfulness with adults, young adults, adolescents and children (1, 2, 3, 4, 5). Studies suggest that for a single formal practice (as in the weekly sessions we are asking our participants to do in the present grant submission), a general rule of thumb is that children usually can practice one minute per their age in years (1). So, a five year old can do a formal guided practice for about five minutes, a 12 year old can do a formal practice for 12 minutes, etc. Our guided practices will never exceed 10 minutes and our youngest participant will be 12 years old. A foundational principle of the intervention is that mindfulness is universal. After practice, most children and adolescents understand midfulness, however to ensure that each participant understands (especially the younger portion of the cohort) we have built into the recruitment portion of the study either a face to face or telephone-based introduction to mindfulness and a mindfulness practice with each participant. Finally, the ideal format for mindfulness sessions that are applicable to all ages is to complete a mindfulness practice, offer a moment for reflection or questions to consider about the practice and then close with another mindfulness practice (1). As such, this is how our intervention is structured. The mindfulness recordings used in the mindfulness condition are adapted to our intervention from the program used in reference 1 below which is applicable to ages 10 and up. This is based on their experience with delivering mindfulness to children and young adults showing that most children ages ten and up can practice applying minfulness in daily life much the same way adults do and receive it in the same way. They can practice mindfulness, become aware of their thoughts, feelings and physical sensations and then choose to respond rather than react to life events. When creating the program, we took note of the optimal age range for each course element and ensured that it would be appicable to ages 12-29 (for example, the word 'feelings' is used instead of 'emotions', mindfulness activities associated with everyday life events and behaviors such as mindful eating are used towards the beginning to help participants associate mindfulness more easily to everyday life and increase understanding early on in the intervention, etc.)

Note: To accomplish ensuring a 4th grade reading level of material delivery, we are using a computer program that allows us to copy and paste content and receive informationon regarding the reading level of that content.

References:

1. Saltzman, A. & Santorelli, S. (2014). *A still quiet place: a mindfulness program for teaching children and adolescents to ease stress and difficult emotions.* Oakland California: New Harbinger Publications
2. Beauchemin, J., Hutchins, T. L., & Patterson, F., (2008). Mindfulness meditation may lessen anxiety, promote social skills, and improve academic performance among adolescents with learning disabilities. *Complementary Health Practice Review, 13(1)*, 34-45. doi:10/1177/1533210107311624

3. Saltzman, A., & Goldin, P. (2008). Mindfulness-based stress reduction for school-age children. IN S.C. Hayes & L.A. Greco (Eds.), *Acceptance and Mindfulness Treatments for Children, Adolescents, and Families.* Oakland, CA: Context Press/New Harbinger Publications.
4. Meiklejohn, J., Phillips, C., Freedman, M. L., Griffin, M. L., Biegel, G., Roach, A., et al. (2010). Integrating mindfulness training into K-12 education: Fosterign resilience of teachers and students. *Mindfulness,* 3(4), 291-307.
5. McCown, D., Reibel, D., & Micozzi, M. (2010). *Teaching Mindfulness: A practical guide for clinicians and educators.* New York: Springer

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Chronic kidney disease (CKD) is a complex condition typically managed by adherence to strict medication and dietary regimens, blood pressure monitoring, complicated medical procedures, and specific daily care tasks, especially with patients who develop end-stage kidney disease (ESKD) [i],[ii]The parents of adolescents/young adults (youth) with CKD/ESRD primarily perform the daily care tasks, but with the onset of adolescence they gradually become the responsibility of the youth. Another challenge of adolescence is the transition from pediatric to adult providers. These two major transitions for youth with CKD/ESRD may cause significant distress.

Adolescence is characterized by dramatic physical and emotional growth, but it is also a tumultuous period of development when risk-taking behaviors, vulnerability, lack of emotional regulation and poor behavior control are prevalent. These normative changes may counteract the self-management process. For an adolescent with CKD/ESRD these challenges are amplified by the disease-specific transitions they are facing, particularly if they are on dialysis or transplant care. To optimize outcomes, traditional self-management education should incorporate interventions that address emotional challenges and risky adolescent behaviors.

Self-advocacy is the patients' willingness to make decisions, negotiate with providers, assume control over self-care and pursue behaviors to promote own health (e.g. getting second opinions or partnering with providers to identify best treatments). Self-advocacy is important for managing CKD/ESRD, and can help improve adherence, but patients with kidney disease fail to utilize it [iii]. Patient portals represent a tangible way to observe patient's self-directed activities for disease management. Currently the institution-wide patient portal (MyChart) use at the University of North Carolina Chapel Hill is only 25%.

Youth with CKD/ESRD are at higher risk for complications, as a result of poor self-management and poor health[iv]. We have described that in the USA, adolescents receiving their first renal transplant between ages 14 and 16 have the highest risk of graft loss and worse outcomes at 1, 3, 5, and 10 year follow-ups post-transplant[v]. Youth with CKD/ESRD also engage in more risk behaviors and demonstrate worse adherence than any other age group[vi]. Several disease specific, individual and systemic factors may interfere with effective self-management and transition to adult-focused care in youth with CKD/ESKD: denial, depression, poor coping, low literacy, low cognition, poor patient education, prolonged dependence on parents or significant others, complex medical regimen with a high burden of care and a lack of integrated health systems/electronic health records [vii]. In CKD/ESRD, self-management includes 4 main areas: nutrition, blood pressure, blood test results, and medication management[viii]. Self-management interventions need to include all of these domains at a minimum, and be individualized to reduce hospitalizations and improve overall health[ix]. Existing self-management interventions are effective with adults, but pose several challenges with adolescents due to their age-specific vulnerabilities (i.e., risk taking behaviors, heightened response to stress, multiple transitions, puberty and hormonal changes). Thus, alternative interventions must be tested and integrated into traditional self-management protocols.

With previous Renal Research Institute funding, our team has made significant advancements in understanding healthcare transition in youth with CKD/ESRD. With this knowledge, we developed the *$STAR_X$ (Self-management, Transition and Adherence to Rx=treatment)* program which delivers individualized, comprehensive, developmentally and

culturally appropriate patient education on self-management. However, we have limited age-appropriate and literacy-congruent tools to effectively teach adolescents to self-manage their condition while learning to cope with it. Due to the complexity of CKD/ESRD care, implementing self-management programs may require extensive resources and be limited to the clinical setting. Mindfulness is a skill that can be practiced and completed anytime and anywhere, with little to no external resources. Teaching acceptance and mindfulness skills could serve as a great addition to traditional self-management interventions, and can equip youth with greater coping skills. With these capabilities, mindfulness interventions could significantly improve traditional self-management protocols.

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[i] So TY, Layton JB, Bozik K, Farrington E, Gipson PE, Gibson K, Primack W, Conley W III, Gipson DS and Ferris M. (2011) Cognitive pharmacy services at a pediatric nephrology and hypertension clinic. *Renal Failure*. *33(1):* 19-25. doi: 10.3109/0886022X.2010.536291.

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[iv] Koshy SM, Herbert D, Lam K, Stukel TA, Guttmann A. Renal allograft loss during transition to adult healthcare services among pediatric renal transplant patients. Transplantation. 2009*;*87:1733-36.

[v] Andreoni A, Forbes R, Andreoni A, Phillips G, Stewart H, Ferris ME. Age-related kidney Transplant Outcomes: Health Disparities Amplified in Adolescence . JAMA Intern Med. 2013, 173(16):1524-32

[vi] Curtin RB, Walters BA, Schatell D, Pennell P, Wise M, Klicko K. Self-efficacy and self management behaviors in patients with chronic kidney disease. Adv Chronic Kidney Dis. 2008;15:191-205.

[vii] Callahan, S. Todd, Rebecca Feinstein Winitzer, and Peter Keenan. "Transition from pediatric to adult-oriented health care: a challenge for patients with chronic disease." *Current opinion in pediatrics*. 2001;310-316.

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to support patients with chronic kidney disease (CKD): a CKD clinic self-care model. *Semin Dial*. 2013; 26: 195-202.

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[xi] Robinson, P. J. (2008). Integrating acceptance and commitment therapy into pediatric primary care. In L. A. Greco & S. C. Hayes (Eds.),*Acceptance and mindfulness treatments for children and adolescents* (pp. 237–262). Oakland, CA: New Harbinger.

[xii] Rogers, L. J., Murrell, A. R., Adams, C. H., & Wilson, K. G. (2008). The role of the behavioral consultant in promoting acceptance in schools. In L. A. Greco & S. C. Hayes (Eds.), *Acceptance and mindfulness treatments for children and adolescents*(pp. 263–286). Oakland, CA: New Harbinger.

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[xiv] Thompson M, Gauntlett-Gilbert J. Mindfulness with children and adolescents: effective clinical application. *Clinical Child Psychology and Psychiatry*, 2008; 13(3), 395-407.

[xv] Greco, L. A., & Hayes, S. C. (2008). Acceptance and mindfulness interventions for children adolescents and families. Oakland, CA: Context Press/New Harbinger.

[xvi] Thompson M, Gauntlett-Gilbert J. Mindfulness with children and adolescents: effective clinical application. *Clinical Child Psychology and Psychiatry*, 2008; 13(3), 395-407.

[xvii] Allen, N. B. (2006). Progress report to the beyondblue Victorian centre of excellence in depression and related disorders. Parkville: ORYGEN with the University of Melbourne.

A.1.2. State the research question(s) (i.e., specific study aims and/or hypotheses).

Specific Aims

1. To help adolescents develop effective CKD/ESRD self-management behaviors.

Hypothesis 1: Higher mindfulness skills will be associated with more effective self-management behaviors.

Hypothesis 2: Better self-management will be associated with higher transition readiness, better knowledge of CKD/ESRD *and better adherence/self-advocacy.*

2. To determine if a mindfulness-based self-management program has added benefits over a CKD/ESRD self-management only program.

Hypothesis 1: Mindfulness-based self-management will be more effective than a traditional CKD/ESRD *self-management program only.*

Hypothesis 2: Youth in the mindfulness-based self-management program will develop more self-advocacy and will demonstrate higher levels of self-awareness/coping skills than youth who only received traditional self-management education.

Hypothesis 3: Youth with improved mindfulness skills will be more successful in adapting to the demands of CKD/ESRD.

3. To increase interest and utilization of the patient portal "My Chart" in the electronic health record.

Hypothesis 1: As a result of our intervention, enrollment and use of the patient portal "My Chart" will increase by at least 25% among study participants.

A.2. Subjects

A.2.1. Total number of subjects proposed across all sites by all investigators (provide exact number; if unlimited, enter 9999):

100

A.2.2. Total number of subjects to be studied by the UNC-CH investigator(s) (provide exact number; if unlimited, enter 9999):

100

A.2.3. If the above numbers include multiple groups, cohorts, or ranges or are dependent on unknown factors, or need any explanation, describe here:

We plan to enroll a total of 100 adolescents (50 for the intervention and 50 for the control condition). The intervention group will receive both mindfulness and self-management education, while the control condition will receive only the self-management education.

A.2.4. Do you have specific plans to enroll subjects from these vulnerable or select populations:
Do not check if status in that group is purely coincidental and has no bearing on the research. For example, do not check 'UNC-CH Employees' for a cancer treatment study or survey of the general public that is not aimed at employees.

✔ Children (under the age of majority for their location)

Note that you will be asked to provide age ranges for children in the Consent Process section.

✖ Non-English-speaking

✖ Prisoners, others involuntarily detained or incarcerated (this includes parolees held in treatment centers as a condition of their parole)

✖ Decisionally impaired

✖ Pregnant women

✖ HIV positive individuals

✖ UNC-CH Students

Some research involving students may be eligible for waiver of parental permission (e.g., using departmental participant pools). See SOP 32.9.1

✖ UNC-CH Employees

✖ UNC-CH Student athletes, athletic teams, or coaches

✖ People, including children, who are likely to be involved in abusive relationships, either as perpetrator or victim.
This would include studies that might uncover or expose child, elder or domestic abuse/neglect. (See SOP Appendix H)

A.2.5. If any of the above populations are checked, describe how you plan to confirm status in one or more of those groups (e.g., pregnancy, psychological or HIV testing)

We plan to verify the participant's age prior to enrollment to confirm their status in the population group checked above during the study enrollment phone calls. This will determine which consent form they will need to sign and if their parent will also need to sign one. We will subsequently verify participant's age via medical records after participant signs HIPPA and consent forms and prior to beginning week 1 of the study material to confirm age provided during telephone interview.

A.2.6. If any of the above populations are checked, please describe your plans to provide additional protections for these subjects

To provide additional protections for these subjects, we will not be using any personal information and instead using predetermined randomized codes to represent each child in our secure computer system. We are ensuring that the study is fully explained to all parents and/or guardians of children participating in the study prior to coming into clinic so that they have an opportunity understand the study, what it entails and what they/their child is being asked to do each week to make an informed decision regarding participation. The child participant will also receive the same information prior to clinic visit. Any and all questions will be answered over the phone. Consent forms will be fully explained, including risks and potential reasons that they should not or may not want to participate in the study, which are minimal. Additionally, two research assistants are completing check-in phone calls with each participant (and their parent, if necessary) throughout the study to discuss progression of the weekly modules and to answer any questions or address concerns. These are protective plans built into the study to provide additional protection to these subjects.

A.2.7. Age range of subjects:

Minimum age of subject enrolled	12
	years
Maximum age of subject enrolled	29

» If no maximum age limit, indicate 99	
	years

A.3. Inclusion/exclusion criteria

A.3.1. List required characteristics of potential subjects (i.e., inclusion and exclusion criteria). If not covered, list also characteristics that would preclude their involvement.

UNC Kidney Center patients ages 12-29 in both the pediatric and adult-focused nephrology clinics that have CKD stage ≥ 3 (including dialysis and transplant), will be eligible for participation.

A.3.2. Justify any exclusion based on race, gender or ethnicity

We will exclude patients who do not speak English, as the educational interventions will be administered in English.

A.3.3. Will pregnant women or women who become pregnant be excluded?

No

A.4. Study design, methods and procedures

Your response to the next question will help determine what further questions you will be asked in the following sections.

A.4.1. Will you be using any **methods or procedures commonly used in biomedical or clinical research** (this would include but not be limited to drawing blood, performing lab tests or biological monitoring, conducting physical exams, administering drugs, or conducting a clinical trial)?

No

A.4.2. Describe the study design. List and describe study procedures, including a sequential description of what subjects will be asked to do, when relevant.

UPDATE 2/26/15:

Again, thank you for this consideration. Participants who are within the age range of 12-17, or other older participants who demonstrate the need, will not have parents directly involved in the study, however they will be made aware of what the study entails so they understand exactly what their child will be asked to do, the incentives they will receive and how the study could benefit them. They will be present at clinic during the child's in-clinic introduction to the study, kit and the idea of self-management (or self-management and mindfulness). We will work with both the parent and the child in these cases to talk about the upcoming 6 weeks, their child's schedule and barriers to them being able to complete the weekly sessions (this information will be collected via a participant interview over the phone as well as reiterated in clnic during the child's enrollment visit when a schedule of session completion is set-up). Additionally, research assistants will make bi-weekly study phone calls and updates or concerns from the parents can be acquired to better assure qualtiy of study data, although this is not currently built into the study protocol (i.e. the opportunity for parent communication of concerns or issues will be highly available). The parents will thus play a role in the study in this and similar ways throughout.

Recruitment

Enrollment will be staggered. Clinic registry will be examined to generate a list of potential participants. All eligible adolescents and their parent will receive a phone call from a research assistant explaining the study, answering any questions and asking if they would like to participate.

If the participant agrees to participate, further description of what will occur on the day of their clinic appointment. The adolescents and their parents are then randomized into either, the self-management (control) or self-management plus mindfulness (intervention) group and will receive the appropriate Study Kit at the time of clinic visit. The Kit contains all necessary study materials.

Study Design

A study will be conducted to evaluate the added benefits of mindfulness training over a traditional self-management intervention protocol. One hundred youth will be randomly assigned to either a traditional CKD/ESRD self-management training protocol, or a self-guided mindfulness-based CKD/ESRD self-management intervention. Both groups will participate in 6 weekly sessions and will be compensated at enrollment, after completion of every 3rd session as well as after completion of the final round of assessments and measurements. Trained graduate assistants will call participants to assess progress and ensure that they are completing the activities as scheduled. A standardized script of questions will be made for each phone call. Payments will be mailed following the phone call.

· Control condition: Self-management intervention ONLY group

At the time of the clinic visit consents will be acquired, self-directed CKD/ESRD management materials will be distributed, and a baseline testing and orientation will be provided. Adolescents will receive the self-management study kit (containing self-management materials and resources). A trained research assistant will engage in health self-management and transition education with the adolescents. The adolescent will be sent home with a self-management manual and asked to complete self-management related health activities structured in 6 educational modules. All participants will receive biweekly phone calls from a study team member asking them about progress and ensuring they are completing the activities as scheduled. One follow-up assessment will be completed 3 months post-intervention.

· Intervention condition: Mindfulness-based training + traditional CKD self-management intervention

At the time of the clinic visit consents will be acquired, the mindfulness based self-directed CKD/ESRD management materials will be distributed, and a baseline testing and orientation will be provided. During their appointment, participants will be oriented to mindfulness and complete two basic mindfulness activities with research assistants (we will select activities to ensure that they are developmentally appropriate). In addition, the research assistant will engage in health self-management and transition education with the adolescents. The adolescents will be sent home with the mindfulness program and self-management manual and asked to complete the mindfulness and self-management related healthcare activities structured in 6 educational modules recorded in an MP3 platform. The 6 sessions will carefully integrate mindfulness and self-management activities. Participants in the experimental group will spend about 10 minutes more due to the extra mindfulness-training component, but the traditional self-management of CKD/ESRD protocol will be completely identical with content provided to the controls. These group participants will also receive biweekly phone calls from a study team member asking them about their mindfulness practice and ensuring they are completing the activities as scheduled. One follow-up assessment will be completed 3 months post-intervention.

The educational modules for the control group will be 15 minutes in length, and for the experimental group 25 minutes in length (See table above). In addition to baseline or pre- and post-intervention testing we will also completed at 3-months follow-up in person or by phone with

all participants. At follow-up, a subset of the measures used in pre- and post-test will be administered, and participants will also complete a semi-structured interview to assess long-term effect of the intervention.

A.4.3. If subjects are assigned or randomized to study "arms" or groups, describe how they are assigned.

- *Describe the methods of computing the randomization schedule (if any) and maintaining blinding (if any).*
- *Who will perform these computations?*
- *How will you verify each subject's eligibility prior to randomization?*

Participants will be randomly assigned to either a traditional self-management training protocol or to a mindfulness-based self-management training protocol. Every other participant consecutively enrolled will receive one intervention or the other.

A.4.4. Describe any follow up procedures.

All participants will receive biweekly phone calls from a study team member asking them about progress and ensuring they are completing the activities as scheduled. One follow-up assessment will be completed 3 months post-intervention.

A.4.5. Once this study has been approved by the IRB, for how many months or years will this study be active (you are collecting data or have access to identifiers)?

12 months

A.4.6. Will this study use any of the following methods?

✗	Audiotaping
✗	Videotaping or filming
✗	Behavioral observation - (e.g., Participant, naturalistic, experimental, and other observational methods typically used in social science research)
✗	Pencil and paper questionnaires or surveys
✓	Electronic questionnaires or surveys
✓	Telephone questionnaires or surveys
✗	Interview questionnaires or surveys
✗	Other questionnaires or surveys
✗	Focus groups
✗	Diaries or journals
✗	Photovoice
✗	Still photography

A.4.7. If there are procedures or methods that require specialized training, describe who (role/qualifications) will be involved and how they will be trained.

No Answer Provided

A.4.8. Are there cultural issues, concerns or implications for the methods to be used with this study population?

No

A.5. Benefits to subjects and/or society

A.5.1. Describe how this study will contribute to generalizable knowledge that will benefit society.

We will study the effectiveness of mindfulness-based techniques to improve self-management in young adults with CKD/ESRD. Due to the complexity of CKD/ESRD care, implementing self-management programs may require extensive resources and be limited to the clinical setting. Mindfulness is a skill that can be practiced and completed anytime and anywhere, with little to no external resources. Teaching acceptance and mindfulness skills could serve as a great addition to traditional self-management interventions, and can equip youth with greater coping skills. With these capabilities, mindfulness interventions could significantly improve traditional self-management protocols.

A.5.2. Does this study have the potential for direct benefit to individual subjects in this study?

No

Consider the nature, magnitude, and likelihood of any direct benefit to subjects. If there is no direct benefit to the individual subject, say so here and in the consent form, if there is a consent form. Do not cite monetary payment or other compensation as a benefit.

Explain

We anticipate that subjects will directly benefit from the transition interventions and education provided.

A.5.3. Are there plans to communicate the results of the research back to the subjects?

No

A.6. Risks and measures to minimize risks

For each of the following categories of risk you will be asked to describe any items checked and what will be done to minimize the risks.

A.6.1. Psychological

- ✗ Emotional distress
- ✓ Embarrassment
- ✗ Consequences of breach of confidentiality (Check and describe only once on this page)
- ✗ Other

A.6.2. Describe any items checked above and what will be done to minimize these risks

The likelihood of a participant experiencing any significant amount of embarrassment is rare. There are 4 questions on the TRxANSITION Scale that refer to reproductive issues as related to their health. To minimize the risk of embarrassment, these questions may be asked in private. Participants are also told that the do not have to answer any questions that make them uncomfortable.

A.6.3. Social

- ✗ Loss of reputation or standing within the community

- ✘ Harms to a larger group or community beyond the subjects of the study (e.g., stigmatization)
- ✘ Consequences of breach of confidentiality (Check and describe only once on this page)
- ✘ Other

A.6.4. Describe any items checked above and what will be done to minimize these risks

No Answer Provided

A.6.5. Economic

- ✘ Loss of income
- ✘ Loss of employment or insurability
- ✘ Loss of professional standing or reputation
- ✘ Loss of standing within the community
- ✘ Consequences of breach of confidentiality (Check and describe only once on this page)
- ✘ Other

A.6.6. Describe any items checked above and what will be done to minimize these risks.

No Answer Provided

A.6.7. Legal

- ✘ Disclosure of illegal activity
- ✘ Disclosure of negligence
- ✘ Consequences of breach of confidentiality (Check and describe only once on this page)
- ✘ Other

A.6.8. Describe any items checked above and what will be done to minimize these risks

No Answer Provided

A.6.9. Physical

- ✘ Medication side effects
- ✘ Pain
- ✘ Discomfort
- ✘ Injury
- ✘ To a nursing child or a fetus (either through mother or father)

A.6.10. Describe any items checked above, including the category of likelihood and what will be done to minimize these risks. Where possible, describe the likelihood of the risks occurring, using the following terms:

- Very Common (approximate incidence > 50%)
- Common (approximate incidence > 25%)
- Likely (approximate incidence of 10-25%)
- Infrequent (approximate incidence of 1-10%)
- Rare (approximate incidence < 1%)

No Answer Provided

A.6.11. Unless already addressed above, describe procedures for referring subjects who are found, during the course of this study, to be in need of medical follow-up or psychological counseling

When patients are found to be in need of referral to alternate providers (i.e., psychologist, adolescent specialist, etc), the following procedure will be adhered to: the researcher who identifies an issue will consult with the patient's specialist regarding the need for a referral; if a referral is deemed appropriate, the researcher will contact an alternate provider via Epic, telephone, and/or email to complete the referral; the researcher will follow-up with the provider and/or patient via Epic, telephone, and/or email to ensure the referral was successful.

A.6.12. Are there plans to withdraw or follow subjects (or partners of subjects) who become pregnant while enrolled in this study?

No

A.7. Data and safety monitoring

A.7.1. When appropriate, describe the plan for monitoring the data to ensure the safety of participants. These plans could range from the investigator monitoring subject data for any safety concerns to a sponsor-based data and safety monitoring board or committee (DSMB, DSMC, DMC), depending on the study. For studies that do not raise obvious safety concerns, you may still describe your plans for monitoring the study as it progresses.

Participation in this study will be completely voluntary and participants may withdraw from the study at any time for any reason they wish. All efforts will be taken to ensure the safety of participants in the study, and all data will be stored in a secure UNC School of Medicine drive and in password-protected files.

This study does not raise safety concerns; however, if there are any responses to the tools/surveys/questionnaires that cause concern, the researcher will alert the participant's provider. Responses to the surveys completed online are emailed to the study coordinator every month. The study coordinator reviews them for data analysis purposes and to monitor data collection progress.

A.7.2. If not already addressed above, describe the plans for aggregate review of unanticipated problems (including but not limited to adverse events) across all sites, in order to monitor subject safety.

No Answer Provided

A.7.3. What are the criteria that will be used to withdraw an INDIVIDUAL SUBJECT from this study or halt the research intervention (e.g., abnormal lab tests, allergic reactions, failure or inability to comply with study procedures, etc.)?

There are no criteria that would be used to withdraw an individual subject from this study or halt research intervention.

A.7.4. Are there criteria that will be used to stop the ENTIRE STUDY prematurely (e.g., safety, efficacy, unexpected adverse events, inability to recruit sufficient number of subjects, etc.)?

No

A.7.5. Will this study involve a data and safety monitoring board or committee?

No

A.8. Data analysis

A.8.1. Describe the analytical methods to be used (qualitative or quantitative)

Statistical Analysis and Sample Size

We will perform significance tests on baseline descriptors (chi-square and t-tests). Information on baseline descriptors will be summarized as means and standard deviations for continuous variables and as frequencies and percentages for categorical variables. Next we will proceed with examining treatment effects between the experimental (mindfulness-based self-management intervention) and control group (traditional self-management training), and within subgroups of subjects (different racial groups, different SES groups, different age groups, or subjects with different baseline disease severities). To determine differences between the mindfulness-based self-management intervention and traditional self-management training groups at the end of the intervention period, 2 (group) x 2 (time) repeated measures analyses of variance (ANOVA) or Wilcoxon matched-pairs test should be used if data is not normally distributed will be conducted on all variables of main interest (mindfulness scale, coping, health related quality of life, transition readiness, self-advocacy, disease knowledge). In examining group differences through comparison of means, we will compute effect sizes as well.

A.8.2. Explain how the sample size is sufficient to achieve the study aims. This might include a formal power calculation or an explanation of why a small sample is sufficient (e.g., qualitative research, pilot studies)

G*Power 3 (Faul, Erdfelder, Lang, & Buchner, 2007) was used to determine sample size. Our a priori power analysis suggests that a target sample size of 100 participants would be sufficient for detecting medium standardized effects at a power of .90 and type I error rate of .05.

A.9. Identifiers

A.9.1. Check which of the following identifiers you already have or will be receiving, or select "None of the above."

- ✔ Names (this would include names/signatures on consent forms)
- ✔ Telephone numbers
- ✔ Any elements of dates (other than year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death. For ages over 89: all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 and older
- ✔ Any geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code and their equivalent geocodes (e.g. GPS coordinates), except for the initial three digits of a zip code
- ✘ Fax numbers
- ✔ Electronic mail addresses
- ✘ Social Security numbers
- ✔ Medical record numbers
- ✘ Health plan beneficiary numbers
- ✘ Account numbers
- ✘ Certificate/license numbers
- ✘ Vehicle identifiers and serial numbers (VIN), including license plate numbers

- ✗ Device identifiers and serial numbers (e.g., implanted medical device)
- ✗ Web universal resource locators (URLs)
- ✗ Internet protocol (IP) address numbers
- ✗ Biometric identifiers, including finger and voice prints
- ✗ Full face photographic images and any comparable images
- ✗ Any other unique identifying number, code, or characteristic, other than dummy identifiers that are not derived from actual identifiers and for which the re-identification key is maintained by the health care provider and not disclosed to the researcher
- ✗ None of the above

A.9.2. For any identifiers checked, how will these identifiers be stored in relationship to the research data?

- ✗ with the research data (i.e., in the same data set and/or physical location)
- ✓ separate from the research data (i.e., coded with a linkage file stored in a different physical location)

Provide details about the option you selected above:
A linkage file will be stored separately from the file containing the data with only study ID's linked to it. All files will be stored in secure drives and in password-protected files.

A.9.3. Are you collecting Social Security Numbers to be used as a unique identifier for study tracking purposes for national registry or database? (Do not check yes if collecting SSN *only* for payment purposes; this will be addressed later.)

No

A.10. Confidentiality of the data

A.10.1. Describe procedures for maintaining confidentiality of the data you will collect or will receive (e.g., coding, anonymous responses, use of pseudonyms, etc.).

Each participant will receive a unique study ID number. All identifiers will be stored in a linkage file at a separate location from the data file. The study ID number will insure that all data is anonymous. All files will be stored in a secure drive in password-protected files.

A.10.2. Describe how data will be transmitted among research team (i.e., personnel listed on this application).

Data will be transmitted among the research team in the form of a password-protected data file in which data has been de-identified using unique study ID numbers for each participant. The data will be stored in a secure drive that the research team may access.

A.10.3. Are you collecting sensitive information such as sexual behavior, HIV status, recreational drug use, illegal behaviors, child/physical abuse, immigration status, etc?

No

A.10.4. Do you plan to obtain a federal Certificate of Confidentiality for this study?

No

A.10.5. If relevant, discuss the potential for deductive disclosure (i.e., directly identifying subjects from a combination of indirect IDs).

Each participant will only receive one unique study ID number.

A.10.6. Will any of the groupings or subgroupings used in analysis be small enough to allow individuals to be identified?

No

A.11. Data sharing and transmission

A.11.1. Check all of the following who will receive **identifiable data** (contains any of the 18 identifiers listed above) outside the immediate research team (i.e., not listed as personnel on this application)? *

- ✔ No one
- ✘ Coordinating Center
- ✘ Statisticians
- ✘ Consultants
- ✘ Other researchers
- ✘ Registries
- ✘ Sponsors
- ✘ External labs for additional testing
- ✘ Journals
- ✘ Publicly available dataset
- ✘ Other

A.11.2. For any recipients checked above, explain the confidentiality measures to be taken

No Answer Provided

A.12. Post-study disposition of identifiable data or human biological materials

A.12.1. Describe your plans for disposition of data or human biological specimens that are identifiable in any way (directly or via indirect codes) once the study has ended. If you plan to destroy linkage codes or identifiers, describe how and when this will be done.

We do not intend to dispose of original data elements, but plan to protect them in perpetuity. The linkage codes and identifiers will be destroyed once the study has ended so that no information can be traced to any individual participant, however the data collected will remain perpetually protected.

Part B. Direct Interaction

B.1. Methods of recruiting

B.1.1. Check all the following means/methods of subject recruitment to be used:*

- ✔ In person
- ✘ Participant pools
- ✘ Presentation to classes or other groups
- ✘ Letters
- ✘ Flyers

- ✗ Radio, TV recruitment ads
- ✗ Newspaper recruitment ads
- ✗ Website recruitment ads
- ✓ Telephone script
- ✗ Email or listserv announcements
- ✓ Follow up to initial contact (e.g., email, script, letter)
- ✗ Other

B.1.2. Describe how subjects will be identified

Subjects will be identified through the clinic lists for pediatric and adult nephrology clinics at UNC. The medical record of each patient on the clinic schedule will be viewed for the minimum eligibility requirement information. Specifically, the age and diagnosis of patients on the clinic lists will be used to determine eligibility.

B.1.3. Describe how and where subjects will be recruited and address the likelihood that you will have access to the projected number of subjects identified in A.2.

Subjects will be recruited on the phone a few days before their clinic visit. The study and consent forms will be thoroughly explained. If the potential participant expresses interest in participating in the study, consent will be obtained over the phone. Participants will be approached at their clinic visit in order to sign consent forms (as a reconfirmation of their consent in addition to the consent they have given over the phone), enroll in the study, and complete pre-testing surveys.

B.1.4. Describe how you will protect the privacy of potential subjects during recruitment

Details of potential subjects will never be recorded unless they consent to participation. Research coordinators will refer to the clinic lists in the electronic medical record while making their calls without saving any patient information until consent is obtained.

B.1.5. Describe how subjects will be contacted, if not addressed above

Subjects will be contacted by phone.

B.1.6. Describe who will do the recruiting

Two research coordinators will recruit participants over the phone. Three trained research assistants will be conducting the in-person follow ups to the phone calls in clinic.

B.1.7. Describe efforts to ensure equal access to participation among women and minorities

We will not discriminate based on sex, race or ethnicity for this study. All eligible participants will be contacted for participation.

B.2. Protected Health Information (PHI)

Protected Health Information (PHI) is any identifiable information about the subject's health that relates to their participation in this research and is obtained from sources other than the subject, such as medical records, health

care providers, insurance plans, etc. more

B.2.1. Are you requesting a limited waiver of HIPAA authorization?
If you need to access Protected Health Information (PHI) to identify potential subjects who will then be contacted, you will need a limited waiver of HIPAA authorization (see SOP 29.3). This does not apply to situations where you will never contact subjects directly (e.g., retrospective chart review), in which case you should request a full waiver under section D.

No

B.2.2. Will you need ongoing access to PHI (e.g., medical records) to conduct the study, beyond the identification of potential subjects as addressed above? In this case you will need to obtain a signed HIPAA Authorization from each subject.

Yes

In order to access patient records you are required to provide a copy of the IRB approval letter and copies of signed HIPAA authorization forms for each patient whose record you will access, to Healthcare Information Management (HIM).

B.3. Subject Contact, Duration and Privacy

B.3.1. Number of contacts per subject

9

B.3.2. Duration of each contact. If multiple contacts, provide the range or average time for each contact.

1. Initial phone call for recruitment (1 contact): 15 minutes 2. Participant enrollment in clinic and pre-test surveys (1 contact): 30 minutes 3. Biweekly phone calls for 3 months (6 contacts): 10 minutes each 4. Follow up evaluation and post-test surveys (1 contact): 30 minutes In addition, participants will be completing one 15-25 minute educational module per week.

B.3.3. Total duration of individual subject's participation, including follow up evaluation, if applicable

225-285 minutes

B.3.4. Where are you studying subjects or obtaining their data?

Non-healthcare setting,Healthcare setting

Please check all that apply:

- ✔ UNC Medical Center (N.C. Memorial Hospital, N.C. Children's Hospital, N.C. Womens' Hospital, N.C. Cancer Hospital, N.C. Neurosciences Hospital, Ambulalory Care Center (ACC))
- ✘ Rex Healthcare
- ✘ Chatham Hospital
- ✘ Johnston Memorial
- ✘ Pardee Hospital
- ✘ High Point Regional Health
- ✘ Caldwell Memorial Hospital
- ✘ UNC Physician Network - affiliated site(s)
- ✘ Other

B.3.5. Provide more information about the location(s) where research will be conducted (e.g., if UNC Medical Center is checked in #4 above and study visits will be conducted in the CTRC, enter “CTRC” here.)

All participant enrollment, pre-testing and post-testing will be conducted at the pediatric or adult nephrology outpatient clinics at UNC Medical Center.

Participants will be completing weekly educational modules at their homes.

B.3.6. Describe procedures that will ensure privacy of the subjects in this study. Examples include the setting for interviews, phone conversations, or physical examinations; communication methods or mailed materials (e.g., mailings should not indicate disease status or focus of study on the envelope)

All participant data will be deidentified using unique study ID numbers and stored in a password-protected file in a secure drive. All physical documents (such as consent forms) will be stored in a locked (badge access all hours) storage area in a secure (badge access after hours) building at the UNC Medical Center (Burnett-Womack Building). Communication will be conducted by telephone and in-person during clinic visits. Materials to be mailed (participation incentives) will not include any disease-related information on them. Voicemails will not be left for participants.

B.4. Incentives for participation

B.4.1. Are there incentives (monetary or non-monetary) for subjects to participate or are you reimbursing subjects for study-related costs (e.g., travel, parking, hotel accommodations or childcare)?

Yes

A. Please describe any incentives and/or reimbursements for study-related costs separately below.

Participants will receive incentives in the form of gift-cards based on their time commitment to the intervention. Participants in the mindfulness+ self-management intervention group will be given an MP3 player (cost is $20) as an initial incentive following the completion of consent and assessments. Participants in the self-management only group will receive $20 The MP3 player is necessary to listen to intervention audio recordings and participants may keep it for their personal use.

They will then receive a $20 incentive every time 3 intervention modules are completed. There are a total of 6 intervention modules. Upon completing post-intervention assessments, the participant will then receive a final incentive of $20 for a total of $80 per participant.

B. Specify the schedule for incentives and if/how this will be prorated if the subject withdraws (or is withdrawn) from the study prior to completing it.

If a participant withdraws from the study prior to completing it, they will keep all prior incentives they have received, but they will not receive any more incentives following withdrawal.

C. For compensation in foreign currency, provide a US dollar equivalent.

N/A

D. Discuss the potential for coercion, given factors like the amount of the incentive, the age of the subjects, the purchasing power in foreign countries, the time involved and complexity of procedures, etc.

There is little potential for coercion, as participants will be above 12 years of age (no young children) and the time commitment on part of the participants is equivalent to the amount of hours they complete throughout the study. The incentives are thus equivalent to the amount of time they are spending for each portion of the intervention.

E. If the subjects are children who will receive the compensation, i.e., the child, the parents or both?

Compensation (other than the MP3 player) will be mailed to the household of the participant. The compensation is intended for the participant (the child).

B.4.2. Are you collecting Social Security numbers for payment and/or tax-related purposes?

No

B.5. Costs to be borne by subjects

B.5.1. Will there be any costs that subjects will incur related to participation in the study? Do not include costs for standard care for which patients would be billed if they were not in this study. Also do not include the time spent participating in the study.

No

Part C. Existing Data, Records, Specimens

C.1. Data Sources

C.1.1. What existing records, data or human biological specimens will you be using? (Indicate all that apply or select 'None of the above'): *

✗ Data already collected from another research study

Were the investigators for the current application involved in the original collection? --

✗ Patient specimens (tissues, blood, serum, surgical discards, etc.)

Has the clinical purpose for which they were collected been met before removal of any excess? --

✗ Data already collected for administrative purposes

✗ Student records (You will need to satisfy FERPA requirements: see SOP 24.6.2 for guidance)

✓ UNC Health Care System Medical records in any format.

Electronic medical records using Epic or WebCIS

If you access the records of fewer than 50 patients under a full or limited waiver of HIPAA, submit a copy of your IRB approval letter and a completed Research Disclosure Form to Health Information Management (HIM). Do not submit this information to the IRB. For additional information about this process, you should contact HIM directly at 919-595-5691 or 919-966-1255.

✗ UNC Dental Records

✗ Data coming directly from a health plan, health care clearinghouse, or health care provider?

✓ Publicly available data

✗ Other

✗ None of the above

For EACH data source checked above, provide a description of the data, proposed use, how data were collected (including consent procedures), and where data currently reside.

Electronic medical records will be used for obtaining demographic information, information about medicines and disease severity/burden, and lab values collected by the physicians at each visit. US Census Bureau publicly available data may be used to characterize participants' zip codes.

C.1.2. Describe your plans for obtaining permission from the custodians of the data, records or specimens (e.g., pathology dept, tissue bank, original researcher):

All research team members have completed HIPAA and CITI training, have undergone Epic Research Coordinator training, and have access to Epic.

C.1.3. Do the custodians of the data, records or specimens require a data use agreement?

No

C.2. Coding and Data Use Agreements

C.2.1. When you receive these data, records or human biological specimens will they be coded? Coded means identifying information that would enable the research team to readily ascertain the individual's identity has been replaced with a number, letter, symbol, or combination thereof (i.e., a code). If you will not be using existing materials, check "No."

No

Part D. The Consent Process

D.1. Obtaining informed consent from subjects

The standard consent process is for all subjects to sign a document containing all the elements of informed consent, as specified in the federal regulations. Some or all of the elements of consent, including signatures, may be altered or waived under certain circumstances. If you will be requesting a waiver answer "not applicable" for any of the following questions that will not pertain to this study. You will be asked to provide relevant information in the section below on waivers.

D.1.1. Will children under the age of majority in their locale (18 years in NC) be enrolled?

Yes

Please explain the process for obtaining parental permission (unless waiver of permission will be requested later)

Parental consent will be obtained from all participants under the age of 18.

Check the characteristics of children to be enrolled: *

- ✗ 0 - 6 years
- ✓ 7 - 14 years
- ✓ 15 - 17 years

Explain the process for obtaining the assent of the child (unless waiver of assent will be requested, in which case you should provide justification here).

The study and consent forms will be thoroughly explained to the parent and the child simultaneously, and children will be asked to sign an assent form while the parents are asked to sign a consent form. Unless both of these consents are obtained, we will not enroll participants in the study. We will assure participants that participation is voluntary and that their decision will have no bearing on the care that they receive at UNC.

D.1.2. Will adult subjects be enrolled in your study?

Yes

Explain the process for obtaining consent from the subject or the subject's legally authorized representative, if relevant

The study and consent forms will be thoroughly explained to the adult, and the adult will be asked to sign a consent form. Unless consent is obtained, we will not enroll participants in the study. We will assure participants that participation is voluntary and that their decision will have no bearing on the care that they receive at UNC.

D.1.3. Will decisionally-impaired subjects be enrolled in your study? (includes unconscious patients, some psychiatric disorders, others who lack the capacity to give consent)

No

D.1.4. Are you planning to obtain consent from any Non-English speaking subjects?

No

D.1.5. Describe who (by role) will be obtaining consent or parental permission.

Research coordinators and trained research assistants will obtain consent or parental permission. All personnel have research experience and have obtained consent from children and parents for previous studies conducted in this group.

D.1.6. Discuss the potential for influencing the subject's decision to participate. Describe steps that will be taken to minimize undue influence during the consent process. These might include a waiting period between the initial consent discussion and obtaining consent, or obtaining consent by someone other than a person with perceived authority (e.g., professor, employer, treating physician).

We will reassure participants at every stage of the recruitment and enrollment process that participation is voluntary and that their decision to participate or not will have no bearing on the care that they receive at UNC. We will not emphasize the compensation during the consent process.

We will obtain consent in a two-step process. The initial consent discussion will occur over the phone a few days before the clinic visit, and participants will have that time to think about their decision. Consent will be obtained again when participants are approached in their clinic visit. If participants decline participation over the phone, they will not be approached in clinic.

Consent will never be obtained by the faculty advisor, a physician. Consent will always be obtained by a research coordinator or research assistant whose only role in relation to the patient is in the realm of research.

D.1.7. Has the sponsor of this study provided a model consent form?

No

D.2. Waiver of written documentation of informed consent

The default is for subjects to sign a written document that contains all the elements of informed consent. Under limited circumstances, the requirement for a signed consent form may be waived by the IRB. For example, this might occur for phone or internet surveys, when a signed consent form is either impractical or unnecessary, or in circumstances where a signed consent form creates a risk for the subject.

D.2.1. Are you requesting a waiver of any aspect of written (signed) documentation?

No

D.3. Full or partial waiver of consent

The default is for subjects to give informed consent. A waiver might be requested for research involving only existing data or human biological specimens. More rarely, it might be requested when the research design requires withholding some study details at the outset (e.g., behavioral research involving deception). In limited circumstances, parental permission may be waived. This section should also be completed for a waiver of HIPAA

authorization if research involves Protected Health Information (PHI) subject to HIPAA regulation, such as patient records.

D.3.1. Are you requesting any of the following:

- ✖ a waiver of informed consent in its entirety
- ✖ a waiver or alteration of some of the elements of informed consent
- ✖ a waiver of HIPAA authorization (If you are accessing patient records for this research, you must also request a waiver of HIPAA authorization)

D.3.2. If your request for a waiver applies to some but not all of your subject groups and/or consent forms, please describe and justify

No Answer Provided

D.3.3. Does this request for waiver support a study design that involves deception or withholding of information?

No Answer Provided

Consent Forms

This submission requires the following consent forms

Template Type
Adult Consent Form
Assent Form Ages 15-17
Assent Form Ages 7-14
HIPAA Authorization
Parental Permission Form

This submission includes the following consent forms

File Name	Document Type
template_for_Adult_Consent_Form_updated.docx	Adult Consent Form
template_for_Assent_Form_Ages_15-17_updated.docx	Assent Form Ages 15-17
template_for_Assent_Form_Ages_7-14_updated.docx	Assent Form Ages 7-14
template_for_HIPAA_Authorization.docx	HIPAA Authorization
template_for_Parental_Permission_Form_updated.docx	Parental Permission Form

view consent forms

Attachments

This submission requires the following attachments

Document Type
Grant Application
Electronic Questionnaire Survey
Telephone Questionnaire Survey
Telephone Script for Recruitment
Recruitment Follow Up

This submission includes the following attachments

File Name	Document Type

RRI Grant_2015_UNC.docx	Grant Application
follow-up recruitment telephone script guide.docx	Recruitment Follow Up
Phone Recruitment Script.docx	Telephone Script for Recruitment
Study Questionnaires.docx	Electronic Questionnaire Survey
Check-in phone calls script guidelines .docx	Telephone Questionnaire Survey

view attachments

Addenda

Data Security Requirements

view addenda

By certifying below, the Principal Investigator affirms the following:

I will personally conduct or supervise this research study. I will ensure that this study is performed in compliance with all applicable laws, regulations and University policies regarding human subjects research. I will obtain IRB approval before making any changes or additions to the project. I will notify the IRB of any other changes in the information provided in this application. I will provide progress reports to the IRB at least annually, or as requested. I will report promptly to the IRB all unanticipated problems or serious adverse events involving risk to human subjects. I will follow the IRB approved consent process for all subjects. I will ensure that all collaborators, students and employees assisting in this research study are informed about these obligations. All information given in this form is accurate and complete.

This study proposes research that has been determined to include Security Level 3 data security requirements. I agree to accept responsibility for managing these risks appropriately in consultation with departmental and/or campus security personnel. The Data Security Requirements addendum can be reviewed here.

If PI is a Student or Trainee Investigator, the Faculty Advisor also certifies the following:

I accept ultimate responsibility for ensuring that this study complies with all the obligations listed above for the PI.

Certifying Signatures:

Signature: Electronic Signature Received **Date:** 2/12/2015 12:30:03 AM
Maria Ferris

The expectation is that this approval is being given on behalf of the head of the Department, Division, or Center. If the chair or director is an investigator on this project or otherwise conflicted in approving it, the Vice-Chair or Chair's designee should review it. By approving, you are certifying the following on behalf of your department, division or center:

- This research is appropriate for this Investigator and our department
- The investigator(s) are qualified to conduct the research
- There are adequate resources (including financial, support and facilities) available
- For units that have a local review committee for pre-IRB review, this requirement has been satisfied
- I support this application, and hereby submit it for further review

This study proposes research that has been determined to include Security Level 3 data security requirements. I agree to accept responsibility for managing these risks appropriately in consultation with departmental and/or campus security personnel. The Data Security Requirements addendum can be reviewed here.

If you are approving for other purposes (e.g., CTRC, DSMB, IBC, PRC, RSC, or other review committees), you affirm the following:

- The proposed submission is approved and may be forwarded for IRB review.

This study proposes research that has been determined to include Security Level 3 data security requirements. I agree to accept responsibility for managing these risks appropriately in consultation with departmental and/or campus security personnel. The Data Security Requirements addendum can be reviewed here.

Department Approval Signatures:

By signing in the appropriate space, the Department Chairperson(s) is indicating only that he/she has seen and reviewed this submission

Department: Medicine-Nephrology
Signature: Electronic Signature Received **Date:** 2/12/2015 01:56:24 PM
Name & Title: Lee Berkowitz, Vice Department Chair, Eunice Bernhard Distinguished Professor