Post Approval Submissions

Renewal Action Requested

ALERT: Modifications proposed as part of this renewal must be accomplished by editing the individual answers to the questions and data elements that make up the application. The modifications cannot be processed until the actual changes have been made throughout the application.

1. Renewal action requested by Principal Investigator (choose only one):

Study has always involved only analysis of data or specimens; there has never been any direct interaction or contact with subjects:
✔ Continue study as approved.
Study involves (or involved) direct interaction/intervention/contact with subjects:
✘ Continue study as approved, including enrollment of new subjects.
✘ Enrollment of new subjects closed; interaction/intervention with previously enrolled subjects continues.
✘ Subjects have completed all research-related interactions/interventions, but study remains open for longterm monitoring or follow-up.
✘ All research-related interaction with subjects is complete, including any contact or follow-up. Renewal is requested for data analysis.

Progress Report

1. Number of Subjects involved through direct contact or use of their data (for multi-site studies, include only subjects covered by this IRB) (Note: **b+d** should not be larger than **a**)

A. Total projected number as approved by IRB:	200
B. Total number of subjects included/enrolled to date (do NOT include 'screen failures')	150
C. Number of subjects included/enrolled since last renewal:	0
D. Number to be included/enrolled in upcoming year	50

2. Have any subjects withdrawn voluntarily or been withdrawn from the study?

   No

3. Have there been any complaints about the research from subjects or others?

   No

4. Have there been any findings (e.g., publications, new information, study results) that alter the risk/benefit ratio or otherwise impact the study?

   No

5. Have there been any relevant multi-site reports?

   No

6. If this study has a Data and Safety Monitoring Committee (DSMC or DSMB), is there a report that has not been previously submitted to the IRB?

   No

7. Have there been any deviations since the last renewal?

   No

8. Have there been any unanticipated problems (including but not limited to adverse events and adverse subject outcomes) since the last renewal?

   No

9. Are you requesting any modifications to the study application, the consent documents, or any related documents at the time of this renewal?

   No

10. Has this study been audited by a sponsor or monitor since approved or last renewed?

    No

11. Will you be obtaining consent (initial or re-consent) from subjects in the upcoming approval period?

    Yes

Reminder: Please confirm consent forms are up to date.

Continuing with Renewals

Click the "save and continue" button to access your existing application. Your application should reflect your study as it is currently being conducted, including any proposed modifications. In addition, please only include supporting documents currently in use (delete any no longer being used); and replace any outdated document with the most recent version.

General Information

1. General Information

1. Project Title

   CKD Parent-Youth Project

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:To characterize the level of knowledge about CKD and its management among parents of youth with CKD and its relationship to their child's health outcomes. To characterize youth with CKD and their parent's preferred platform to learn about this condition. To correlate the parenting styles of parents of youth with CKD to their child's self-management skills.

   Participants: 100 parent-child dyads

   Procedures (methods): Focused interviews will be conducted with parents. Survey data will be obtained for the children and the parents.

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?

   Yes

This study will require the identification of a single faculty advisor, who should be added in Project Personnel on this page. This should be the faculty member who will mentor this research, who may or may not be your academic faculty advisor.

The faculty advisor will be required to co-certify with the student/trainee PI. You should also make sure this person has a chance to review and edit the submission before you submit.

Choose the status of the student/trainee:

graduate or professional

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
Annaim	Ali	Medical Education	Principal Investigator	view
Ferris	Maria	Department of Medicine	Faculty Advisor	view
Bickford	Kristi	UNC Kidney Center	Project Manager or Study Coordinator	view
Cohen	Sarah	Allied Health Sciences	Co-investigator	view
Javalkar	Karina	Department of Medicine	Research Assistant	view
Phillips	Alex	Department of Medicine	Research Assistant	view
Ryan	Jessica	UNC Kidney Center	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	Medical Education

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)	14-0783	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 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

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.

The relationship that children with chronic kidney disease (CKD) have with their parents may influence the long-term outcome of a child's condition. Yet, parenting a child with advanced CKD can be difficult , as the burden of care for this condition (medications and/or home dialysis) is directly related to the CKD severity. Furthermore, while parents are responsible for the management of their child's condition when the child is young, they need to learn to take a supporting role as their child ages. This transfer of responsibility from parent-directed care to disease self-management, if not well planned, can result in poor outcomes such as kidney transplant loss.

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

Aims:

1. To characterize the level of knowledge about CKD and its management among parents of youth with CKD and its relationship to their child's health outcomes. *Hypothesis:* Parents whose child with CKD was diagnosed at a younger age will have greater knowledge about this condition/management and their child will have better health outcomes (e.g. less emergency room use and greater prescription refill rates).

2. To characterize youth with CKD and their parent's preferred platform to learn about this condition. *Hypothesis:* Younger participants will prefer electronic-related learning platforms

3. To correlate the parenting styles of parents of youth with CKD to their child's self-management skills. *Hypothesis:* Youths raised by an authoritative parenting style have greater self-management skills.

A.2. Subjects

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

200

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

200

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:

Children age 8-21 years old.

Parents

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)

Medical records will identify the children as those between the ages of 8 to 21 years old.

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

Children will be recruited along with their parents. Children will have their assent done and their parents will also consent to be in the study.

A.2.7. Age range of subjects:

Minimum age of subject enrolled	8

	years
Maximum age of subject enrolled	99
» 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.

Inclusion/Exclusion Criteria: Consecutive youth with CKD ≥ 2, ages 8 to 21 and their parents will be included, as long as the patients were diagnosed > 3 months prior to our study. Hispanic study candidates will be eligible for enrollment as long as they are able to read English. Patients with developmental delays as deemed by the provider will not be eligible for recruitment.

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

Patients with developmental delays as deemed by the provider will not be eligible for recruitment.

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.

Both the parents and their child will be asked series of focused interview questions. The parent will complete the following surveys in addition to the interview:

1. **REALM (Rapid Estimate of Adult/Adolescent Literacy in Medicine):** Parents will asked to read a list of common medical words and lay terms for body parts and illnesses aloud. This measure health literacy.
2. **The TR$_X$ANSITION Scale (parent version)**: A 32 questions related to the child's health condition knowledge and disease management skills to find out what they know and don't know. A researcher will ask the questions out loud.
3. **Kidney Knowledge (KiKs) survey:** A 19 question survey to measure knowledge of kidney disease. A researcher will ask the questions out loud.
4. **Parental Authority Questionnaire for parent** : There are two sets of questions, each 30 questions long, that will assess parenting style. One set of questions is designed for children, and the other set is designed for parents. A researcher will ask the questions out loud.
5. **Learning Preference:** A 5 question survey to learn how the parent gathers information about their child's condition. This is an online survey.

The children (8-21 years old) will be asked to complete the following.

1. **REALM (Rapid Estimate of Adult/Adolescent Literacy in Medicine):** The child will

asked to read a list of common medical words and lay terms for body parts and illnesses aloud. This measure health literacy.

2. **The TR$_X$ANSITION Scale (parent version)**: A 32 questions related to your health condition knowledge and disease management skills to find out what you know and don't know. A researcher will ask the questions out loud.
3. **Kidney Knowledge (KiKs) survey:** A 19 question survey to measure knowledge of kidney disease. A researcher will ask the questions out loud.
4. **Parental Authority Questionnaire for child**: A 30 question survey that will assess parenting style. A researcher will ask the questions out loud.
5. **Learning Preference:** A 5 question survey to learn how the child gathers information about their condition. This is an online survey.

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?*

Subjects will not randomized.

A.4.4. Describe any follow up procedures.

We are only sending participants with giftcards.

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)?

The study will run from March 15, 2014 until December 2014

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.

None.

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.

The knowledge base of parents who have children with CKD has to be expansive, ranging from making appointments to weighing the options of renal replacement therapy, in order to properly manage their child's CKD. The ways that parents can obtain and incorporate information can include reading up on information from books, booklets or the Internet. The use of web-based programs for parent diabetic education has shown encouraging result. By identifying education platforms that are preferred by parents, the allocation of resources for education in the clinical setting can be more efficient.

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

Yes

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

No Answer 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.

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

If there is a breach of confidentiality then participants may feel a sense of stigmatization since they will be identified as someone who participated in a research study. This may cause them to feel isolated from their peers.

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

No Answer Provided

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.

Investigators will monitory subject data for any safety concerns. 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.

Any unanticipated problems will be addressed through a conference to be held by the all the investigators in the study.

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. This is not a clinical study, but rather a study to collect quantitative and qualitative data that will be used to develop assessment, education, and intervention tools for children with chronic kidney disease and their parents.

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)

. For quantitative analysis, we will perform descriptive statistics as median (25th–75th percentile) for continuous variables or frequency and percentage for categorical variables. Stage of CKD will be determined by estimated GFR based on the Schwartz formula from the medical record. We will measure differences in participant characteristics with Kruskal-Wallis test and Pearson's chi-square (or Fisher's exact tests as needed) in continuous or categorical variables. Bivariate associations with overall kidney disease knowledge scores will be calculated with linear regression for the patient characteristics. To account for confounding, we will measure the variables described in this model. Additional exploratory analyses will be performed for age, sex, and race. We will report beta coefficients for both unadjusted and adjusted analyses. The adjusted model we will use includes ordinary least squares regression and we will retain variables that have significant associations in bivariate analyses.

For qualitative analysis, we will perform thematic analysis of the topics and ideas that are presented during the focused interviews. Recurring themes or concepts will be grouped together into larger super groups with examples given by study participants. These super groups will be compared to the results of the statistical tests that we will perform to identify any factors that relate between the quantitative and qualitative responses.

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)

: Power analysis was calculated in a multiple linear regression framework. According to power calculations using SAS 9.1 software, a sample size of 100 dyads (200 people) should be sufficient to obtain power of .90 for the current model, assuming an alpha of .05 and an effect size (i.e., partial correlation) of .45. Thus, there is a 95% chance of detecting an effect if it actually exists, provided at least 14.25% of the variance is accounted for by the test predictors.

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:
All the identifiers will be stored a password protected folder in a drive folder that is provided by the Nephrology department. There is only one folder that has all the identifiers on it, and it is password protected.

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.).

The MRN's and names will be linked to a transition ID that will be stored in a password protected folder. The remainder of the data will be linked to a transition ID.

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

The information will be transmitted as transition ID.

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).

No potential for deductive disclosure.

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

n/a

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.

The linked list will be destroyed 2 years following the completion of this study. This date is chosen so that any secondary analyses on the data can be run for future publications. Additionally this will allow us to respond to any data analysis questions that may be asked by journal editors.

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

Participants will be drawn from a pool consented persons in the linked study.

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.

1. Participants have already agreed to participate in the linked study. They will be recruited from this pool of individuals. The likelihood of accessing the projected number of subjects will be high since the pool of participants in the linked study is over 800 persons. Subjects will be recruited in clinic lobbies, while they are waiting for their scheduled appointment, OR in clinic exam rooms, either before or after they have been seen by their health care provider. Subjects will be approached by a researcher and given a brief overview of the study. A fact sheet will also be provided for review. If the potential participant expresses interest in study enrollment, they will be given the study consent/assent forms. The researcher conducting recruitment will allow the potential participant time to review the consent/assent forms alone. Then, the researcher will ask if the potential participant has any questions regarding the study and/or consent/assent forms. All questions will be answered before obtaining signatures.

Additionally participants will be recruited via telephone. The contact information for these potential participants will be obtained from our linked study. These participants will be called and asked to see if they are interested. For those who agree, the consent forms will be mailed to them with a return, addressed envelope. Once the returned consent forms are obtained, the participants will be called again to conduct the focused interview and the TRANSITION survey. The remaining surveys will be emailed to participants.

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

Since researchers are specifically assigned to work in the various pediatric subspecialty clinics, knowledge of their health condition is already assumed (i.e., diabetes clinic - it is assumed that all returning patients have a diagnosis of diabetes).

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

N/A

B.1.6. Describe who will do the recruiting

Recruitment will be accomplished by the co-investigators and research assistants.

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

Since eligibility criteria does not exclude potential subjects because of race or sex, anyone who meets the age and diagnosis criteria will be approached for enrollment.

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.

Yes

Will you access the records of 50 or more patients under this limited waiver?

No

*If you access the records of fewer than 50 patients under this waiver, 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 595-5691 or 966-1255.*

Please provide a response to each of the following questions:

Under this limited waiver, you are allowed to access and use only the minimum amount of PHI necessary to review eligibility criteria and contact potential subjects. Describe the information you are planning to collect for this purpose

Date of birth and diagnosis

Describe how confidentiality/privacy will be protected prior to ascertaining the patient's willingness to participate

We will not retain any data on any patients who are not appropriate for recruitment in the study. Data on patients who may be appropriate will be protected until we obtain consent/assent.

Describe when and how you will destroy the contact information if an individual declines participation

Our aim is to recruit patients while they are physically present in clinic. If a potential participant declines to be in the study, we will mark them as declined in our database. This will prevent us from contacting them in the future regarding this study.

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

2 contacts per subject

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

2. For the first contact it should take approximately 10 mintues. The second contact may take up to one hour to complete the questionnaire and focused interview.

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

Total time of participation for a subject will be 1.2 hours

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

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.)

Participants will be studied in pediatric nephrology clinic here at UNC.

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)

The interviews will be conducted in private patient rooms. Parents will be interviewed in the same rooms as their child, and the parent will be present when the child is interviewed. The child will complete a series of surveys, and they will be interviewed by one of the research assistants. There is a focused question guide (see attached documents) will be used to guide the interviews. Additionally the survey tools that we will use have been attached to this application.

B.4. Incentives for participation

B.4.1. Are there incentives (monetary or non-monetary) for subjects to participate?

Yes

A. Please describe

We will pay for their parking on the day of their clinic visit. We will also provide them with a small fee for pay for the time spent doing the focused interview. The amount will be $20.

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.

The fee will be paid following the focused interview. This will not have to be prorated for those who withdrawal from the study since the fee will be given upon completion of the single data collection interaction.

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 limited potential for coercion since the fee is small for the time spent providing the data. The coverage of parking has limited potential for coercion

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

The parents will the ones who receive the compensation.

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?	Yes
✘ 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.

Medical records: Demographic information such as patient age, number of visits to the nephrology clinic, and laboratory results will be collected. This information will be used in our analysis to look for any potential confounders that may help to explain the results that will be obtained.

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):

We are the custodians of the other data source.

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."

Yes

Will any of the personnel involved in this study (this includes collaborators providing data or specimens, personnel listed on grants, co-authors, and faculty advisors) have access to a key that deciphers the code, enabling linkage of identifying information to private information or samples?

Yes

Please identify the mechanism which precludes your access to the codes and include a copy of any agreements or documents that explain these protections:

Data use agreement with custodian of data (agreement prohibiting the release of the key to decipher the code to the applicant under any circumstances)?	No
Data are publicly available?	No
Honest broker (centralized custodian who controls data and will not release codes or IDs)?	Yes
Other	--

Do ALL of these data, records or specimens exist at the time of this application?

Yes

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)

Parents will be present at the time of the visit, and they will provide consent for the child to participant in the study. Additionally there will be an assent form for the children to sign.

Check the characteristics of children to be enrolled: *

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

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

Parents will sign a consent form to participant in this study.

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.

Ali Annaim, Karina Javalkar, Alex Phillips, and Sarah Cohen will be obtaining consent and parent permission.

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).

1. The persons who will be obtaining consent will minimize any perceived authority that they may have. The principal investigator is a medical student who is on a leave of absence. He will minimize his involvement in the care of any of the study participants while the study is ongoing. He will not see any of the participants with their physicians if they are in clinic.

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

Adult_Consent_Form_1.doc	Adult Consent Form
Child_assent_form_15-17yo_1.doc	Assent Form Ages 15-17
Child_assent_form_7-14yo_2.doc	Assent Form Ages 7-14
HIPAA_Authorization.docx	HIPAA Authorization
Parental_permission_form_1.doc	Parental Permission Form
Parental_permission_form_1.doc	Parental Permission Form

view consent forms

Attachments

This submission requires the following attachments

Document Type
Grant Application
Electronic Questionnaire Survey
Interview Questionnaire Survey
Telephone Script for Recruitment

This submission includes the following attachments

File Name	Document Type
Ferris et al PARENTyouth grant Final 8 31 2013 (2).docx	Grant Application
Telephone_Script1.docx	Telephone Script for Recruitment
Victory Junction questions.docx	Electronic Questionnaire Survey
Focus interview questions.docx	Interview Questionnaire Survey
Focus interview questions_child.docx	Interview Questionnaire Survey
KiKs Kidney Knowledge Survey.docx	Other Questionnaire Survey
Parental Authority Questionnaire for child.docx	Other Questionnaire Survey
Parental Authority Questionnaire for parent.docx	Other Questionnaire Survey
REALM_Adolescent.pdf	Other Questionnaire Survey
REALM_Adult.pdf	Other Questionnaire Survey
UNC TRxANSITION Scale for Parents.docx	Other 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:** 1/11/2015 11:35:16 AM
Ali Annaim

Signature: Electronic Signature Received **Date:** 1/11/2015 02:43:47 PM
Maria Ferris