General Information

1. General Information

1. Project Title

The FHLY (Food quality and Health Literacy among Youth with Chronic Conditions) Study

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: The present research project seeks to gain further knowledge about how AYA patients w chronic conditions and their caregivers' health literacy and level of medication adherence correla their knowledge of disease-specific dietary restrictions and nutritional behaviors (food choice).

Participants: We will invite adolescents and young adults 12 years of age and older who have bee diagnosed with essential HTN or CKD including transplant and their parents. Both English and S speaking patients may participate. Demographic information of age, sex, and race will be collecte the participants.

Procedures (methods):

We will invite 100 participants (dyads of patients ≥12 years of age with CKD or essential HTN ar their caregivers). Both members of the AYA-caregiver dyads will receive the Newest Vital Sign and patients only will receive the Morisky Medication Adherence Scale (MMAS-8). We will then administer a short survey assessing each patient and their parent's understanding of the dietary restrictions of the AYA's chronic condition. They will then be asked to photograph their refrigerat freezer, and grocery bill and send the picture by email to us. The AYA and parent's survey, refrig grocery bill photograph will be individually compared to their Newest Vital Sign and Medication Adherence scores.

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.

Yes

If yes, provide IRB study number here (and explain in the COVER MEMO why this is relevant to the current study and why it would be useful for the IRB to know).

13-4567

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

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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.

Full Name	Role	Department Name	IRB Training	COI WebID	COI Number	Initial COI Disclosure	Potential Conflict	COI Review Status	COI Management Plan	Detail
Nikita Patel	Principal Investigator	Medicine Administration	Current on: 05/15/2015	105897	15-12464	✔		No Conflict		
Maria Ferris	Faculty Advisor	Medicine-Nephrology	Current on: 05/15/2015	105896	15-12467	✔		No Conflict		

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 Administration

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)	13-3005	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.

Health literacy is defined as the degree to which individuals obtain, process, and understand basic health information and services to make informed health decisions. Health literacy is a stronger predictor of health than age, income, employment, education, and race. Health literacy has been explored in the past, however most health literacy research does not explicitly focus on food or nutritional behavior. Specifically, nutritional literacy in adolescent and young adults with chronic conditions has not been explored greatly. Although comprehensive reviews have linked low health literacy with poor health outcomes, few reviews have looked at health literacy with a nutritional focus and in the context of nutritional behaviors . It is crucial that adolescents and young adults understand the nutritional management of their disease as they transition into adulthood and self-care.

Health literacy tools have yet to be explored in the context of nutrition when one has a chronic condition, specifically essential hypertension or hypertension in childhood-onset chronic kidney disease (CKD). Hypertension in young adults can lead to cardiovascular disease risk. Similarly, hypertension in adolescent patients with CKD can contribute to cardiovascular disease as adults and serious future cardiac events. Despite this, numerous studies have demonstrated that hypertension is common and is frequently misunderstood by patients in this population. Greater efforts are needed to effectively target these vulnerable patients to reduce the future burden of adult cardiovascular disease, including on a nutritional level.

Understanding the interplay between patients' and their caregivers' nutritionally-focused health literacy, disease-specific nutrition knowledge, and their home environment could provide personalized interventions to promote better nutritional choices and reduced negative health outcomes in adolescent and young adult patients with chronic conditions.

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

Research Question 1: Does a patient's health literacy and medication adherence level relate to his/her caregiver's health literacy level?

I hypothesize that the health literacy and adherence scores of pediatric patients' (AYA with HTN and CKD) will be positively correlated with their caregivers' health literacy scores.

Research Question 2: Is the health literacy and adherence of pediatric patients and the health literacy of parents related to their knowledge of dietary restrictions related to the AYA's chronic condition?

I hypothesize that there will be a significant positive correlation between health literacy of the AYA-caregiver dyads with the dyad's knowledge of the AYA's dietary restrictions.

Research Question 3: Does health literacy of an AYA-caregiver dyad predict nutritional behaviors, specifically related to the type of food items in their home refrigerator and grocery bill?

I hypothesize that there will be a significant positive correlation between health literacy of AYA-caregiver dyads and positive home food choice behaviors.

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:

We will invite 100 adolescents 10-29 years of age who have been diagnosed with essential HTN or CKD including transplant and their parents. Each adolescent in the study will include the patients' caregiver. This totals to 200 participants.

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. Any minor subject who attains the age of majority during the course of the research study must provide consent as an adult, unless consent has been waived, which is requested in section D.3.1.

✔ 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)

Participants of the current study will be recruited while visiting the UNC Kidney Center or in-patient at the NC Children's Hospital. As such, participants and their conditions will be verified as children and patients by their age and chronic condition listed in medical records. The caregiver's will also be asked to confirm the status of the pediatric patient.

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

Confidentiality will be maintained throughout the duration of the study. Participants are also able to decline participation. A thorough informed consent process will occur prior to initiating any study procedures.

A.2.7. Age range of subjects:

Minimum age of subject enrolled	10 years
Maximum age of subject enrolled » If no maximum age limit, indicate 99	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.

We will invite 100 adolescents 12 years of age or older who have been diagnosed with CKD or essential HTN and their caregivers. Caregivers must be the legal guardians of the patients . Patients and parents must be present at the time of participation to ensure accurate matching of data for analysis. English and Spanish speaking participants only will be invited to participate in the study. Individuals unable to provide consent will not be included.

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

Participants will not be excluded based on race, gender, or ethnicity.

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.

Measures:

Health Literacy. Health literacy will be measured with the Newest Vital Sign. The Newest Vital Sign is a six-item questionnaire that measures literacy and numeracy skills. An individual's score on the Newest Vital Sign (NVS) tool will be calculated by summing the correct number of responses. The lowest possible score is 0, while the maximum possible score is 6. Scores from 0-1 indicate a high likelihood of limited literacy; scores 2-3 indicate possible limited literacy; and scores 4-6 indicate adequate literacy. The Newest Vital Sign will be administered to both the patient as well as his or her caregiver.

Treatment Adherence. The Morisky Medication Adherence Scale is an 8-item questionnaire that is simple to use in clinical settings to identify patients with adherence problems and help monitor adherence over the course of a treatment. A score of 0 indicates high adherence, a score between 1-2 indicates medium adherence, while a score of 3-8 indicates low adherence.

Procedure/Data Collection:

The NVS tool will be administered to patients and their caregivers, and the MMAS-8 will be

administered to patients only.

An online, single survey administration will be used to collect data for all of the research questions. The survey, termed the FHLY survey (Appendix C), will be administered through the UNC Qualtrics platform. Questions asked will be tailored to assessing each patient's nutritional understanding of their dietary restrictions of their specific chronic condition. Questions in the FHLY survey are pulled from the Knowledge Assessment Game of an ongoing larger interventional trial funded by the Centers for Disease Control.

A standardized picture will be used for the patient and their caregiver to identify certain foods they should avoid according to their dietary restriction.

The patient and caregiver will be asked to photograph a picture of the contents of their home refrigerator, freezer, and grocery bill to be sent by email to us.

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 not be assigned or randomized to study "arms" or groups.

A.4.4. Describe any follow up procedures.

The majority of the study will be conducted during one visit in clinic. This first visit will collect the measures of Newest Vital Sign, Morisky Medication Adherence Scale, 24-hr dietary recall, picture identification activity, and the FHLY survey. The last part of the study requires the patient-caregiver dyad to submit via email a picture of their home refrigerator, freezer, and grocery bill to be sent by email to us after returning home.

Dietary restrictions will be noted as recommended by providers in the patient's EHR. Adherence to medication will be measured via the Morisky Medication Adherence scale while Literacy will be measured via the Newest Vital Sign scale. The dietary recall will be patient-reported during the first clinical visit as well. Both activities, FHLY study as well as the Picture identification activity, will be done during the first clinical visit as well.

Dietary restrictions and medication adherence will be measured based on what medications and dietary restrictions/recommendations they had prior to their visit. If they are not on any medication, this part of the study will be skipped for that patient, but will not exclude them from the other parts of the study. Even if they are not under any specific dietary recommendations or restrictions, but they are diagnosed with a condition that has specific dietary needs, they can still be included in the study during their first visit.

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)?

This study will begin once IRB has approved of the study. The majority of study data collection will occur between June 1st, 2015 through July 31st, 2015. The study will officially end by December 31st, 2015.

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.

The student (private investigator) will conduct all study procedures. These study procedures include administration of the informed consent process and administration of the study measures and survey. Training will occur prior to any study procedures. The training will include standardized survey techniques.

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 current study seeks to gain further understanding of how health literacy levels and medication adherence can indicate disease specific knowledge of nutrition and food choice behaviors. Simultaneously, the project will contribute to understanding health literacy levels of the chronic kidney disease and essential hypertension population and how health literacy of young adult patients with these chronic conditions relates to that of their caregivers. These components of the study will help in providing adequate healthcare and improving the health of society.

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

The direct benefit to the patient-caregiver dyad is low, and will be indicated in the consent form. However, the implications of this study could provide targeted interventions to health literacy levels and disease-specific nutrition knowledge that can be applied to this specific (young adult) population.

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

A foreseeable risk is that a patient-caregiver dyad may feel embarrassed when assessed on their health literacy level or disease-specific nutrition knowledge. The risk of embarassment will be minimized by reminding patients that answers and participation are confidential. Patients will also be assured that the study is voluntary, and they may opt to remove themselves at any time. Lastly, participants will be reminded that the participation in the study will have no effect on the care provided to them.

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

The study does not include detailed medical analysis of patients.

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.

The present study does not raise safety concerns. The prinicipal investigator will monitor the data collected on a weekly basis. The data will be kept private and confidential and unlinked to the patient-caregiver dyad. Identifiers will be kept private and confidential.

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.)?

The study posses minimal risk to participants. There are no criteria to withdraw individual subjects from participation as the study procedures entail a one time questionnaire and picture.

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)

Data analysis will be conducted using IBM SPSS Statistics Version 20. Basic demographic information

will be analyzed with descriptive statistics.

Research Question 1: I will be examining the univariate associations between health literacy in patients, adherence in patients, and health literacy in parents/caregivers. Correlations between patient literacy, patient adherence, and parent health literacy will be evaluated with all of them considered continuous variables.

Research Question 2: I will construct a linear regression model including parent health literacy, patient health literacy, and patient adherence as predictors to assess the degree to which these three factors predict dietary restriction knowledge in AYA-patients dyads.

Research Question 3: The images of the home refrigerator/freezer content will be analyzed adapting qualitative methodology by determining the most common food items (themes) after data collection is completed. A scale will be developed giving food items (e.g. prepackaged food, dark colas, or ice cream) a numeric value (5= excellent/very healthy food choices, 4= good food choices, 3=neither health/nor unhealthy choices, 2=poor choices, 1=very poor choices). We will examine associations between these categories with literacy level (patient and parent), patient adherence and dietary restriction knowledge (with chi square tests or ANOVA tests). This is a tentative outline, pending on the number of categories for nutritional behavior (food choices) that will result from the qualitative data analysis.

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)

The present study is a pilot study, thus requiring a smaller sample size of 200. This number will allow the investigators to observe any potential trends and inform future studies and interventions aimed at improving health literacy and patient knowledge and compliance.

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:
The data will be collected via an online survey method (UNC qualtrics). One aspect of the data requires e-mailing a picture of a refrigerator, freezer, and grocery bill. Everything else will be done in clinic. The personal identifiers (e-mail and geographic location) will be collected in order to compensate with a gift card upon completion of the study. Responses to the questionnaire will be on an electronic, password protected dataset. These responses will have a study identification number. The medical record number and consent forms will be stored in a locked space, only accessible to study personnel. The private investigator only will receive emails from the participants with the picture portion of the project. After receiving the picture and adding it to the participants' study number and file, their email will be deleted. After compensation with a gift card via email or mail, this identifier will also be deleted.

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.).

Participants will be given a study identification numbers prior to completion of the study procedures. Pediatric patients and their caregivers will be matched for their study identification numbers. For example, the first participant to enroll in the study will have a study identification number of 101 for the pediatric patient, while the caregiver will be given an identification number 201. Participants will only be referred by study identification number.

The email for the photograph portion of the study will be received to a password protected email only known to study personnel. After receiving their email with their photograph, the picture will be added to their respective study number and file. After sending compensation with a gift card, all email and mail addresses will be deleted.

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

All data will be on password protected spreadsheets. Data will be transmitted through these password protected files.

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).

There is no potential for deductive disclosure since the unique IDs assigned do not contain any combination of social security or medical record number, DOB, address, or name. Participants are randomly assigned numbers.

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.

Original data elements will not be destroyed. They will be protected in perpetuity.

The identifier of name will be deleted immediately and replaced with a study participant number. Date of birth will continue to be listed but only associated with a study participant number. Contact information, specifically the participant's or parent's email address, will be deleted from study files after the gift card has been sent.

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

We will invite 100 adolescents 12 years of age or older who have been diagnosed with chronic kidney disease or essential hypertension. They, along with their caregivers, will be approached in clinic outpatient or as an inpatient at the NC Children's Hospital. Caregivers must be the legal guardians of the patients. Patients and caregivers must be present at the time of participation to ensure accurate matching of data for analysis.

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.

All participants will be recruited from NC Children's Hospital and the UNC Kidney Center Clinic. Participants will be recruited inpatient and outpatient. Participants will be approached by a researcher and given a brief overview of the study. If the potential participant expresses interest in study enrollment, they will be given the study fact sheet and consent forms. The researcher conducting recruitment will allow the potential participant time to review the consent forms alone. Then, the researcher will ask if the potential participant has any questions regarding the study and/or consent forms. All questions will be answered before obtaining signatures. There is a 100% likelihood of having access to all 100 participants at UNC Kidney Center.

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

Potential participants will be approached in a private hospital room. No identifiers will be gathered prior to signing consent forms.

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

Potential participants will only be contacted in person at the in-patient or out-patient setting of their hospital stay. They will be also be sent a gift card if they choose to receive one.

B.1.6. Describe who will do the recruiting

The principal investigator and research assistants will recruit potential participants.

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

All participants meeting requirements will be approached for the study. Strict adherence to the inclusion and exclusion criteria will ensure equal access to participation. Participants will not be excluded based

on age, race, or sex.

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

2

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

First contact will be approximately 20-30 minutes for each participant and will be in clinic. This encounter will consist of measures and 24-hr dietary recall, picture identification, and survey administration. The second encounter will be via email, as the participant will send the picture through this method.

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

30 minutes

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 the clinic at UNC Kidney Center.

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)

Participants will complete the survey in a private space. Additionally, data analysis will be kept in a password protected database. All subjects will be assigned unique study identification numbers that will be used in lieu of any personal identifiers. Other than this on-site encounter, they will send an email to a password protected private email.

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.

Caregiver-patient dyads who complete all study procedures will be given a $10.00 gift card.

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.

After the receipt of their photograph, they will receive an email with a gift card.

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

$10 gift card in US currency.

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.

This study is completely voluntary and participants can choose which portions of the study they would like to complete. Potential participants will be approached as usual and informed of the study with potential for incentive. They may accept or deny participation without being penalized. Participants who complete all of the study procedures will be given a $10.00 gift card.

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

The pair will receive the gift card, but the gift card will be given to the caregiver.

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'):

✔ Medical records in any format.

Electronic medical records using Epic, WebCIS or other electronic system

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.

✖ 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 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.

We will be conducting medical record chart reviews to obtain diagnosis information.

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):

EHR will be accessed with permission from the UNC Kidney Center providers.

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?
(Note: Any minor subject who attains the age of majority during the course of the research study must provide consent as an adult, unless consent has been waived, which is requested in section D.3.1.)

Yes

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

Parents will be given a brief introduction of the study, along with a fact sheet about the study. They will be able to review the consent and assent forms with their child in private and ask any questions prior to signing any forms.

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).

Potential participants will be approached by a researcher and given a brief introduction to the study. If they express interest in learning more, a fact sheet and consent form will be given to them, which they will be given time to review in private before making a decision to participate.

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

Potential participants will be approached by a researcher and given a brief introduction to the study. If they express interest in learning more, a fact sheet and consent form will be given to them, which they will be given time to review in private before making a decision to participate.

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?

Yes

Click here to obtain the Translation Verification form, which should be completed and uploaded with Attachments at the end of the application.

If you will be obtaining consent in Spanish, consent form templates are provided on the OHRE website. If you will be obtaining consent in other languages, you will need to upload translations of the English consent form(s) once approved by the IRB.

Describe how consent in the native language will be obtained. Address both written translation of the consent and the availability of oral interpretation. It is expected that the information in the consent document(s) will be communicated to participants or their legally authorized representative (LAR).

All consent and assent forms will be provided in Spanish. There will be a research assistant who is bilingual and a faculty co-investigator who is fluent in Spanish. If necessary, access to Spanish interprepters in the hospital will be used.

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

The principal investigator and research assistant will be obtaining informed consent from all participants prior to study participation.

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).

Consent will be obtained by the researchers named on this application. They do not have any authority and will not be perceived as having such (e.g., will not wear a white lab coat, dressed in lay person's clothing). To minimize coercion or undue influence, the researchers will permit the potential subjects to review the consent/assent forms in private to allow discussion between the patient and parent/caretaker. It will be stressed that participation is completely voluntary and will in no way affect the health care they receive.

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

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 English Consent to Research Study.docx	Adult Consent Form

Assent form Ages 15-17.docx	Assent Fo Ages 15-1
Assent form ages 7-14.docx	Assent Fo Ages 7-14
Adult Spanish Consent to research study.doc	Foreign Language Consent Form
Biomedical-Parental-Permission-for-a-Minor-Child-to-Participate-in-a-Research-Study-Spanish.doc	Foreign Language Consent Form
SPANISH Consent form for 15 to 17 year olds.doc	Foreign Language Consent Form
SPANISH Consent form for 7to14 year olds.doc	Foreign Language Consent Form
HIPAA Authorization.docx	HIPAA Authoriza
HIPAA Authorization Spanish.doc	Other Consent Materials
Parental Permission Form.docx	Parental Permissio Form

view consent forms

Attachments

This submission requires the following attachments

Document Type
Grant Application
Pencil and Paper Questionnaire Survey
Electronic Questionnaire Survey
Translation Verification **This attachment not provided because:** Not Yet Available / Not Applicable

This submission includes the following attachments

File Name	Document Type
Nikita_Patel_Proposal_2015_CMSRP.pdf	Grant Application
translation verification.pdf	Translation Verification
Questionnaires - IRB.docx	Electronic Questionnaire Survey
Questionnaires - IRB.docx	Pencil and Paper 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:** 4/13/2015 05:15:35 PM

Nikita Patel

Signature: Electronic Signature Received **Date:** 4/19/2015 05:57:27 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 Administration		
Signature:	Electronic Signature Received	**Date:**	4/20/2015 09:14:50 AM
Name & Title:	Sherry Whitaker, Asst Director Sponsored Programs		
Department:	Medicine-Nephrology		
Signature:	Electronic Signature Received	**Date:**	4/20/2015 09:54:53 AM
Name & Title:	Lee Berkowitz, Vice Department Chair, Eunice Bernhard Distinguished Professor		