Post Approval Submissions

Modification Information

To modify an approved study, edit the individual answers that make up the application. The questions below are intended solely for the IRB to have a summary statement of your requested action. The modifications cannot be processed until the actual changes have been made throughout the application.

1. Provide a brief non-technical summary of any changes you will be making to the study. The text you enter here will be reproduced in the IRB approval document, and should contain the details that you and/or your sponsor find relevant (e.g., master protocol/amendment version number and date). Typical summaries are 50-100 words. Include a list of any documents that have been modified or added. PLEASE NOTE: THIS SECTION MAY BE EDITED BY THE IRB FOR CLARITY OR LENGTH.

   I will be adding 1 personnel: Yi Zhong, Research Assistant.

2. Is this modification being submitted in response to an unanticipated problem/adverse event or new findings?

   No

3. Do any of the proposed changes increase risk?

   No

Please explain:

No increase in risk

4. Does this modification involve new information that requires reconsent of CURRENT subjects?

   No

5. Is this study permanently closed to enrollment of subjects, all interventions and follow-up complete, and open for DATA ANALYSIS ONLY?

   No

Continuing with Modifications

Click the "save and continue" button to access your existing application.
You may make any changes to the application that you are requesting at this time.

General Information

1. General Information

1. Project Title

   Successful Transition to Adulthood with Therapeutics (STARx)

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.

   The purpose of STARx is to develop valid, reliable, evidence-based transition tools for children and adolescents with a chronic health condition, their families, and their health care providers. Development and implementation of these tools will be used to guide transition intervention and education efforts. Participants will be child, adolescent, and young adult patients diagnosed with a pediatric onset chronic health condition. The parents/caregivers of these patients may also be asked to

participate to provide information that will contribute to the parental view of the transition process. This study will incorporate in person interviews, online surveys/questionnaires, medical record reviews, and contact with outside providers (i.e., schools, pharmacies, hospitals, etc).

2. Project Personnel

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

   No

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

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

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

Full Name	Role	Department Name	IRB Training	COI WebID	COI Number	Initial COI Disclosure	Potential Conflict	COI Review Status	COI Management Plan	Detail
Yi Zhong	Research Assistant	Economics	Current on: 05/21/2015		n/a	n/a	n/a	n/a		
Jessica Ryan	Research Assistant	UNC Kidney Center	Current on: 05/21/2015		n/a	n/a	n/a	n/a		
Eniko Rak	Co-investigator	Allied Health Sciences	Current on: 05/21/2015							
Alex Phillips	Research Assistant	Biology	Current on: 05/21/2015		n/a	n/a	n/a	n/a		
Niki Patel	Research Assistant	Medicine Administration	Current on: 05/21/2015		n/a	n/a	n/a	n/a		
Meaghan Nazareth	Research Assistant	Statistics and Operations Research	Current on: 05/21/2015		n/a	n/a	n/a	n/a		
Mia Lassiter	Research Assistant	Department of Medicine	Current on: 05/21/2015		n/a	n/a	n/a	n/a		
Meredith Johnson	Research Assistant	Medicine Administration	Current on: 05/21/2015		n/a	n/a	n/a	n/a		
Karina Javalkar	Research Assistant	Psychology	Current on: 05/21/2015		n/a	n/a	n/a	n/a		
Yichun Hu	Other	Department of Medicine	Current on: 05/21/2015		n/a	n/a	n/a	n/a		
Maria Ferris	Principal Investigator	UNC Kidney Center	Current on: 05/21/2015							
Sarah Cohen	Research Assistant	Psychology	Current on: 05/21/2015		n/a	n/a	n/a	n/a		
Kristen Bickford	Study Coordinator	UNC Kidney Center	Current on: 05/21/2015							
Ali Annaim	Research Assistant	Medical Education	Current on: 05/21/2015		n/a	n/a	n/a	n/a		

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	UNC Kidney Center

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						view
Renal Research Institute (RRI)	Currently Not Available	Other				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.

One of the great triumphs of pediatric medicine is that most children with serious chronic disease now

survive into adulthood; in fact, by some estimates, more than 90% of these children now survive past their twentieth birthdays (White 1999). For example, kidney transplant recipients can now expect a 10-year survival rate of 85.6%, whereas patients on dialysis have a 10-year survival rate of 66.9% (Ferris et al. 2001).

Such survival usually does not come without potential harm to normal cognitive, physiological, emotional, and maturational development. Many of the side effects of serious pediatric chronic diseases and the therapies used to treat them are particularly challenging in the context of adolescent development.

Paradoxically, quality of life may dramatically improve in the first year after diagnosis, as treatment of a serious condition relieves pain or illness and improves outlook (Otley et al. 2006) but, in general, young people who have survived into adulthood with chronic disease have "achieved significantly fewer milestones, or at older age than their peers, in all course-of-life domains" (Stam et al. 2006).

As pediatric chronic disease patients move toward adulthood and, in most cases, from pediatric to adult medicine, they may not have the skills or capacities they need to manage their conditions. They are increasingly expected to manage more of their care, despite the challenges they face. Hence, adherence to and self-management of necessary, life-prolonging, but difficult therapeutic regimens is an urgent problem as adolescent patients advance toward adulthood (Rapoff 2006).

Adolescents with special health care needs, chronic illnesses, or physical or developmental disabilities, may also find the transition from pediatric to adult health care difficult because of the challenge of finding an adult health provider who is comfortable caring for these patients. Furthermore, young people may not feel emotionally or cognitively prepared to take over the role of being adult health care consumers and their families may have trouble letting go of the child who has required such great care.

Evidence-based literature on the transition to adulthood is sparse (Miller et al. 2005) and largely from the providers' standpoint. The community of stakeholders caring for pediatric chronic disease patients has been well aware of the need for transition tools, programs, and measures (Rosen et al. 2003; AAP 2002), but development of such tools and plans has lagged far behind the assessment that we need them.

Thus, patients and their providers presently lack patient-centered or family-centered evidence to guide provision of care and development of best practices to assist adolescent patients as they transition to adulthood. The purpose of this proposal is to create an evidence-based program that fosters and measures successful transitions to adulthood with a chronic illness.

References

American Academy of Pediatrics (AAP). A consensus statement on health care transition for young adults with special health care needs. Pediatrics 2002; 110:1304–6.

Ferris ME, Gipson D, Kimmel P, Eggers P. Survival of Adolescents Initiating End-Stage Renal Disease Care in the United States. J Am Soc Nephrol, 2001; 12:327A.

Miller MR, Gergen P, Honour M, Zhan C. Burden of illness for children and where we stand in measuring the quality of this health care. Ambulatory Pediatrics 2005; 5(5):268-278.

Otley AR, Griffiths AM, Hale S, Kugathasan S, Pfefferkorn M, Mezoff A, Rosh J, Tolia V, Markowitz J, Mack D, Olivia-Hemker M, Wyllie R, Rothbaum R, Bousvaros A, Del Rosario JF, Evans J, Blanchard W, Hyams J for the Pediatric IBD Collaborative Research Group. Health-related quality of life in the first year after a diagnosis of pediatric inflammatory bowel disease. Inflamm Bowel Dis 2006; 12(8):684-691.

Rapoff MA. Management of adherence and chronic rheumatic disease in children and adolescents. Best Practice & Research Clinical Rheumatology 2006; 20(2):301-314.

Rosen DS, Blum RW, Britto M, Sawyer SM, Siegel DM. Transition to adult health care for adolescents and young adults with chronic conditions: position paper of the Society for Adolescent Medicine. J Adolesc Health 2003; 33(4):309-11.

Stam H, Hartman EE, Deurloo JA, Groothoff J, Grootenhuis M. Young adult patients with a history of pediatric disease; Impact on course of life and transition into adulthood. Journal of Adolescent Health 2006; 39:4-13.

White PH. Transition to Adulthood. Current Opinion in Rheumatology 1999; 11:408-411.

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

We aim to develop easy-to-administer transition tools that give patients, their parents, and their health care providers an accurate indication of the readiness for transition to adulthood, and adult medicine, of any given patient with a pediatric-onset chronic illness. The STARx studies will triangulate methods, including questionnaire development and medical record review, to develop valid, reliable, evidence-based transition tools for patients, their families, and their health care providers. Our specific study aims are:

Specific Aim 1. To test the feasibility and utility of a medical passport to improve disease self-management and medication knowledge among patients with pediatric onset chronic health conditions.

Hypothesis: The Medical Passport is a useful tool to improve patient education and self-knowledge in patients with chronic health conditions.

Specific Aim 2. To test the utility of the STARx Transition Readiness Survey as a self-reporting tool about issues of transition among patients with pediatric onset chronic health conditions.

Hypothesis: The STARx Transition Readiness Survey is an effective tool that allows patients with pediatric onset chronic health conditions to self-identify and rate their own personal transition skills.

Specific Aim 3. To test the utility of the TRxANSITION Scale™ as a tool to diagnose and monitor the process of transition over time for patients with pediatric onsent chronic health conditions.

Hypothesis: The TRxANSITION Scale™ is an effective method to diagnose transition skills that require attention to achieve improvement in patients with pediatric onsent chronic health conditions..

Specific Aim 4. To test the literacy level of patients with pediatric onsent chronic health conditions and their parents.

Hypothesis: Parental and adolescent lower literacy levels are correlated with worse health outcomes for patients with pediatric onset chronic health conditions.

We will also be exploring additional factors that may influence the process of transition. These factors may include, but are not limited to, disease burden, medication/treatment adherence, psychosocial and demographic characteristics. These factors will contribute qualitative and quantitative data to the specific aims.

A.2. Subjects

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

1000

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

1000

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:

No Answer Provided

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)

No Answer Provided

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

No Answer Provided

A.2.7. Age range of subjects:

Minimum age of subject enrolled	1 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.

Inclusion criteria for **patient participants**:

- any patient with a minimum age of 1 who has been diagnosed with a chronic health condition of pediatric onset

Inclusion criteria for **parent participants**:

- any parents, grandparents, legal guardians, or caregivers of patients with a chronic health condition of pediatric onset.

Exclusion criteria for **patients and parents** include:

- inability to provide assent or consent
- inability to complete a component of a sub-project due to physical, mental, and/or cognitive disabilities

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.

This study is designed to collect information and data from patients with chronic health conditions and their families that will aid in the assessment and tracking of participants' transition readiness status. The info and data collected will be used to develop education and intervention protocols, in addition to guiding future exploratory studies on the transition from pediatric to adult health care.

All participants will be enrolled through informed consent/assent. The following is a comprehensive, descriptive list of the tools/questionnaires that may be used to collect data/information from patients and parents/caretakers. This data/info will help define the needs and outcomes of the transition process. Not every patient will have to complete every item below. Instruments administered will depend on the patient's disease, subspecialty provider, time, and willingness to complete.

1. **REALM:** The Rapid Estimate of Adult/Adolescent Literacy in Medicine (REALM) is a screening instrument to assess a patient's ability to read common medical words and lay terms for body parts and illnesses. It is designed to assist medical professionals in estimating a patient's literacy level so that the appropriate level of patient education materials or oral instructions may be used. The test takes two to three minutes to administer and score. The REALM has been correlated with other standardized tests

(Family Medicine, 1993: 25:391-5).

2. **Parent survey on Transition:** We will collect socio-demographic and burden of care information via parental self-report at baseline.

3. **Measures of Health-Related Quality of Life (HRQL)**: HRQL will be assessed yearly for all patients with the PedsQL 4.0 SF15 for patients <18yo, the PedsQL 4.0 Young Adult Report for patients 18-25yo, and the PedsQL 4.0 Parent version for patients <18yo (Varni). The PedsQL 4.0 is a one page survey where items can be reverse scored and linearly transformed to a 0-100 scale, so that higher scores indicate better HRQOL. These are well-validated global instruments that contain individual subscales representing physical, emotional, and social well being.

4. **The $TR_XANSITION$ Scale (patient and parent version)**: The TR_XANSITION Scale is a 32 question instrument divided into 10 knowledge and skill domains. It takes an average of 7.5mins to conduct. The data collected here will also be used for further validation of the instrument. A guide has been included to assist with tool implementation and scoring. This survey is web-based and can be located at http://domint.med.unc.edu/starx/questionaire/index.cfm.

5. **Mood Face Scale:** A brief, pictorial tool to help assess a patient's mood. The scale is comprised of 9 faces which depict varying degrees of mood, from extremely happy to extremely sad.

6. **Medical Passport:** A brief, portable health record that is the size of credit card and individualized to reflect each patient's personal health information. This document includes the following patient information: name, DOB, insurance provider, emergency contact number for hospital, diagnosis(es), allergies, health provider contact numbers, personal emergency contact numbers provided by patient, and medication name, dosage, and purpose. The patient's picture is also included on the medical passport unless they choose to have something else in its place (i.e., picture of a butterfly or Spiderman). The patient is asked to carry his/her medical passport in their wallet, purse, book bag, etc at all times. The purpose of this document is to enhance communication of a patient's medical needs between providers, encourage responsibility for one's health, and also serve as a quick resource if a health emergency were to arise.

7. **STARx Transition Readiness Survey:** This survey is a web-based, self-administered tool developed to assess a patient's readiness to transition from their own point of view. There is also a version for those patients who have already transitioned. Patients complete this survey at baseline, 6mos, 12mos, and then every 12mos thereafter on their own, either at home or while they are in clinic. It is comprised of 18 questions and includes self-reported knowledge of (1) disease diagnosis, (2) medications/treatment, (3) health insurance, (4) ability to make medical appointments, (5) ability to use health resources and (6) disease self-management. The survey takes no more than 8mins to complete. This survey is web-based and can be located at http://domint.med.unc.edu/starx/questionaire/index.cfm.

8. **The Family Relationship Index:** For patients <18yo, this self-administered, evidence-based questionnaire is a shorter version of the Family Environment Scale (FES) comprising 27 items in three of the 10 FES domains: conflict, cohesion, and expressiveness. In addition to the subscales, an overall score on the family environment can be calculated. This subset of scales from the FES and their composite score have been used with families of children who have asthma, diabetes, juvenile rheumatoid arthritis, recurrent abdominal pain, sickle cell disease, and those undergoing bone marrow transplant, and the psychometric properties are strong (Holahan & Moos, 1983; Moos & Moos, 1994).

9. **CES-D :** A brief, easily completed measure of depression that consists of 31 items and is used in patients who are >18yo.

10. **SELENA SLEDAI (SLE Disease Activity Index):** Used to measure disease activity in patients who have SLE (systemic lupus erythematosus).

11. **Medical Passport Usage Survey:** For us to learn how, why, when, and if the medical passport is being used, patients who have a medical passport will be asked to complete this questionnaire. Patients

will be asked to answer questions about where they use their medical passport, what purpose it serves for them, and what they think about it.

12. **Patient/Parent Satisfaction Survey:** A brief set of questions to assess the quality of services provided by medical staff as perceived by patients and their parents/caretakers.

13. **Morisky 8 item Medication Adherence Scale:** A self-report measure of medication taking behavior.

14. **Social Support Questionnaire SSQSR (Short Form-Revised):** A brief survey that measures a person's perceived emotional and instrumental support.

15. **Kidney Transplant Knowledge Questions:** 10 questions that assess a patient's knowledge regarding kidney transplantation preparation and procedures.

16. **Adult ADHD Self-Report Scale (ASRS v1.1) Symptom Checklist:** An 18 question screening scale that helps diagnose adult ADHD through self-report of symptoms. We will be administering the 6 question version.

17. **The Newest Vital Sign:** The Newest Vital Sign: A a nutrition label that is accompanied by 6 questions and requires 3 minutes for administration. It is reliable (Cronbach >0.76 in English and 0.69 in Spanish) and correlates with the TOFHLA. Area under the ROC curve is 0.88 for English and 0.72 for Spanish versions. Patients with more than 4 correct responses are unlikely to have low literacy, whereas fewer than 4 correct answers indicate the possibility of limited literacy.

18. **Severity of Illness Scale** (Young-Salem & Prevatt, 2001). This six question scale asks the doctor to report on a number of different disease characteristics, so that an overall disease severity estimate can be obtained. The responses range from 1-7 with 1 representing lower disease severity and 7 representing higher disease severity.

19. **The Diabetes Social Support Questionnaire-Friend Version** (DSSQ-Friends; Bearman & La Greca, 2002) is a self-administered questionnaire that assesses adolescent's perceived peer support for taking their medications. The scale includes four questions about emotional support. Similar to the DDSQ-Family, when completing the measure, participants are first asked the frequency with which each behavior occurs ("How often does a friend.....?") from 0-5 (0= never and 5= at least once a day). Next, participants are asked to provide a rating of the perceived supportiveness of the behavior ("How does this make you feel?") from -1- 3 (-1= not supportive and 3= very supportive).

20. **The Adolescent Medication Barriers Scale** (AMBS; Simons & Blount, 2007). The AMBS is a self-report measure designed to assess adolescent-perceived barriers to medication adherence.The AMBS consists of 17 items with a maximum score of 85. The sample mean for the scale is 38.1 (SD = 10.7). The Cronbach's alpha of the total scale was .86 indicating strong internal consistency. There are three subscales: disease frustration/adolescent issues ($\alpha = .84$), ingestion issues ($\alpha = .70$), and regimen adaptation/cognitive issues ($\alpha = .76$; Simons & Blount).

21. **The Diabetes Social Support Questionnaire-Family Version** (DSSQ-family; La Grecca & Bearman, 2002) is a self-administered 13 item scale with high internal consistency ($\alpha = .91$). When completing the measure, participants are first asked the frequency with which each behavior occurs ("How often does a family member.....?") from 0 to 5 (where 0 = never and 5 = at least once a day). Next, participants are asked to provide a rating of the perceived supportiveness of the behavior ("How does this make you feel?") from -1 to 3 (-1 = not supportive and 3 = very supportive).

22. **The Marlow-Crown Social Desirability Scale**, Short-Form (Reynolds, 1982) is a13 item self-report scale that examines a person's level of social desirability. For example, participants answer true or false to multiple statements such as, "I sometimes feel resentful when I don't get my way." The item to total score correlations range from .32 - .47, and the scale is highly correlated with the Marlow-Crown standard form (.93). The total mean is 5.31 (SD = 2.90). All items have a factor loading of .4 or above (Ballard, 1992).

23. **The Brief Measure of Diabetes Self-Efficacy** (Iannotti et al., 2006). This 10 item short scale was created for participants with Diabetes; therefore, the questions were slightly modified to reflect IBD and CKD. Specifically in each question, the words your diabetes was replaced with your illness. For example, all questions begin with, "How sure are you that you can do each of the following, almost all the time?" The original survey next stated, "Identify things that could get in the way of managing your diabetes." In the version used for this study, the questions read "Identify things that could get in the way of managing your illness." Participants respond on a 10-point scale ranging from, "not sure at all" to "a lot". Cronbach's alpha for this scale is high (.90), and the test-retest intraclass correlation coefficient for the measure is .89. The mean for the scale is 7.52 (SD =1.58). Additionally, a scree plot indicates that all items have a factor loading of at least .53 (Iannotti et al.).

24. **Prescription Drug Label** (based on the US department of Health and Human Services) will be used to assess patient and parents' ability to read, understand, and interpret a drug label. This assessment asks participants to identify the pharmacy name and address, the number of refills left, name and strength of drug, and the prescription refill date, among other questions.

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?*

Most of the patients we enroll will receive transition related surveys (Tscale, STARx). Given that not all the clinics that participate in our study have the staff or time to provide all reserach tools, we will comply with each clinic's requests. For example, rheumatology is interested only in transition as it relates to disease severity but not interested in literacy measurement. Therefore, these patients will only recieve transition related scales (STARx, Tscale) and disease severity surveys. This is an observational longitudinal cohort w/ assessments completed every 6 to 12mos, depending on the clinic needs and staff availability.

Due to the limited number of tools that have been translated into Spanish, those participants who are Spanish speaking will only be eligible to receive the TRxANSITION Scale, STARx Transition Readiness Survey, and medical passport. Those are tools we have created and are therefore able to translate into Spanish.

A.4.4. Describe any follow up procedures.

1. **REALM:** implemented one time at baseline.

2. **Parent survey on Transition**: completed one time.

3. **Measures of Health-Related Quality of Life (HRQL)**: completed at baseline and then every 12mos thereafter (if deemed appropriate).

4. **The TR$_x$ANSITION Scale (patient and parent version)**: administered at baseline, 6mos, 12mos, and then every 12mos thereafter.

5. **Mood Face Scale:** administered in coordination w/ STARx Transition Readiness survey (or whenever deemed necessary).

6. **Medical Passport:** updated as needed to reflect any changes.

7. **STARx Transition Readiness Survey:** administered at baseline, 6mos, 12mos, and then every 12mos thereafter.

8. **The Family Relationship Index:** completed one time.
9. **CES-D** : completed one time (or whenever deemed necessary).
10. **SELENA SLEDAI (SLE Disease Activity Index):** completed one time.
11. **Medical Passport Usage Survey:** completed one time.
12. **Patient/Parent Satisfaction Survey:** completed every 12mos.
13. **Morisky 8 item Medication Adherence Scale:** completed one time.
14. **Social Support Questionnaire SSQSR (Short Form-Revised):** completed one time.
15. **Kidney Transplant Knowledge Questions:** completed one time.
16. **Adult ADHD Self-Report Scale (ASRS v1.1) Symptom Checklist:** completed one time.
17. **The Newest Vital Sign:** completed two times (baseline and then follow-up post education intervention)
18. **Prescription Drug Label:** completed two times (baseline and then follow-up post education intervention)

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

This study is ongoing and data is collected longitudinally. There are no specific start or stop dates for participation. Participation is completely voluntary and participants can choose to stop at any point in time.

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

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

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

No Answer Provided

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

No

A.5. Benefits to subjects and/or society

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

Collecting data in one databank is expected to help researchers learn more about how to prepare adolescents for their transition to adult life with a chronic condition. Practitioners may use such information to improve adherence with medical appointments and medical regimens, which would thus improve outcomes.

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

We anticipate that subjects will directly benefit from the transition interventions and education provided. They will have access to one-on-one time with the transition coordinator during clinic visits if deemed necessary, will be provided with resource information as needed, and may receive individual medical passports.

Those subjects who choose not to complete the TRxANSITION Scale and STARx Transition Readiness Survey are not anticipated to benefit from participation since they will only be asked to answer questions and will not be provided education or intervention.

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

Yes

If yes, describe

Results of TRxANSITION Scales will be shared with each participant through a printed report. This report will show participants in what areas they need to improve their knowledge and skills.

A.6. Risks and measures to minimize risks

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

A.6.1. Psychological

- ✗ Emotional distress
- ✓ Embarrassment

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

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

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

A.6.3. Social

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

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

There is a rare likelihood of breach of confidentiality if a patient loses their medical passport. Medical passports are given to the patient for their own personal use. We are not responsible for what they choose to do with them.

A.6.5. Economic

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

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

No Answer Provided

A.6.7. Legal

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

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

No Answer Provided

A.6.9. Physical

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

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

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

No Answer Provided

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

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

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

No

A.7. Data and safety monitoring

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

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

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

No Answer Provided

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

There are no criteria that would be used to withdraw an individual subject from this study or halt research intervention. 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 the purpose of monitoring and tracking the process of transition.

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)

The analytical method is quantitative. We will be using all the validated scales to capture each construct we are interested in.

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 power analysis was calculated in a multiple linear regression framework. According to power calculations using SAS 9.1 software, a minimum sample of 100 would produce a power of .80 for the current model, assuming an alpha of .05 and an effect size (i.e., partial correlation) of .45. Thus, there is an 80% chance of detecting an effect if it actually exists, provided at least 20.25% of the variance in transition knowledge is accounted for.

A.9. Identifiers

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

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

✗ Certificate/license numbers

✗ Vehicle identifiers and serial numbers (VIN), including license plate numbers

✗ Device identifiers and serial numbers (e.g., implanted medical device)

✗ Web universal resource locators (URLs)

✗ Internet protocol (IP) address numbers

✗ Biometric identifiers, including finger and voice prints

✓ Full face photographic images and any comparable images

✗ Any other unique identifying number, code, or characteristic, other than dummy identifiers that are not derived from actual identifiers and for which the re-identification key is maintained by the health care provider and not disclosed to the researcher

✗ None of the above

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

✓ with the research data (i.e., in the same data set and/or physical location)

✗ separate from the research data (i.e., coded with a linkage file stored in a different physical location)

Provide details about the option you selected above:
--

A.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.).

All participants are assigned a unique study ID. All data collected will be coded using their ID.

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

Data will be transmitted via password protected spreadsheets stripped of any identifiers.

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. They 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.

We do not intend to dispose of original data elements, but plan to protect them in perpetuity.

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

The principal investigator, study coordinator, research assistant(s), and/or UNC health providers will identify potential subjects through the subspecialty clinic registries. Clinic schedules will be reviewed and potential participants will be identified by eligibility criteria.

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

Subjects will be recruited 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 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.

In some cases, when we are unable to be present in a specific clinic, we may recruit participants through mail and phone contact. These participants will be identified by their health provider and referred to our study. We will send a letter, fact sheet, and consent form to the potential participant, informing them that their health provider thought this study may be of interest or benefit to them. Contact information will be provided if the potential participant has any questions/concerns for the researchers regarding the study. These potential participants will be followed up with in clinic at their next regularly scheduled appointment.

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

Health providers will help to identify potential subjects in each of their specific clinics. It will be encouraged that they provide their patient with a brief introduction about the study. The health providers will then inform the researcher who will be completing recruitment/enrollment of the potential subject. 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

Subjects will be contacted in person during their clinic appointment. If a health provider would like to refer a patient for participation in our study and that subject is not in clinic at that time, a study introduction letter will be sent to that patient (who's contact information will be received from the health provider) along with a study fact sheet and consent forms.

B.1.6. Describe who will do the recruiting

The researchers named on this application will be responsible for recruitment.

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?

Yes

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 we are not able to do so, and their health provider refers them to our study for potential enrollment, the contact information we receive (i.e., name, address, phone numbers) will be disposed of immediately, either through file deletion or shredding.

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

At least one.

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

The duration of each contact will depend on what components of the study will be administered. Below are estimates of how long each survey/questionnaire may take: 1. REALM: no more than 3mins

2. Parent survey on Transition: no more than 10mins 3. Measures of Health-Related Quality of Life (HRQL): no more than 5mins 4. The TRxANSITION Scale (patient and parent version): no more than 8mins 5. Mood Face Scale:no more than 1min 6. Medical Passport: completed by a researcher; requires no time of the patient other than that to take a photo. 7. STARx Transition Readiness Survey: no more than 5mins 8. The Family Relationship Index: no more than 7mins 9. CES-D: no more than 5mins 10. SELENA SLEDAI (SLE Disease Activity Index): completed by the researcher and/or health provider; no additional time required of the patient. 11. Medical Passport Usage Survey: no more than 8mins 12. Patient/Parent Satisfaction Survey: no more than 8mins 13. Morisky 8 item Medication Adherence Scale: no more than 2mins 14. Social Support Questionnaire SSQSR (Short Form-Revised): no more than 5mins 15. Kidney Transplant Knowledge Questions: no more than 5mins 16. Adult ADHD Self-Report Scale (ASRS v1.1) Symptom Checklist: no more than 3mins 17. The Newest Vital Sign: no more than 3mins 18. Prescription Drug Label: nor more than 3mins

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

A subject will remain an active participant until they are deceased or request to be withdrawn from the study.

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.)

UNC Children's Hospital - subspecialty clinics, inpatient

Ambulatory Care Clinics

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)

Interview sessions will be held in private rooms and will be voluntary in nature. If any participant opposes being recorded, the digital recorder will not be used during that session. Hard copy data will be stored in a filing room that is locked and only accessible by an ID card that has been granted access permission. Data analysis will be kept in a password protected database. All subjects will be assigned unique study IDs that will be used in lieu of any personal identifiers.

Phone conversations will take place in private rooms and will not be recorded.

All mail correspondence will be sent in plain, Department of Medicine envelopes with only the

participant's mailing address.

The data from semi-annual chart review will be entered into a password-protected program and stripped of identifiers to ensure confidentiality. Names will be kept in a separate secure database. The security of the database will be maintained using password-restricted access to computers and files.

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.

For 2013, our funding sponsor (RRI) has provided $10,000 in incentives for participants who complete this year's study aim (health literacy). Only participants who complete this part of our study will be eligible to receive this incentive. Participants who are already enrolled may be eligible to receive the incentive if they agree to complete the health literacy components of this year's study aim (the newest vital sign and the prescription drug label). We may also enroll new participants not previously enrolled in our study for this study aim. The other aspects of our study continue as is. The $10,000 is allocated for 250 participants (new or currently enrolled, who have not completed the health literacy assessments - newest vital sign and prescription drug lable). Participants would be eligible to receive a $20 gift card for their completion of baseline assessments and another $20 gift card for a one time f/u assessment.

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.

Participants who choose to complete the literacy portion of this study will receive a $20 gift card for completion of baseline assessments. They will receive an additional $20 gift card for completion of the f/u assessment.

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

Not applicable.

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 w/out being penalized. Participants (patients and their parents) who choose to complete the literacy portion of this study will be given a $20 gift card upon completion of baseline assessments. They will then receive a $20 gift card upon completion of follow-up assessments. If they do not complete the f/u assessments, they do not recieve the second $20 gift card.

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

Participating patients and their parents are eligible to 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'):

✔ 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.

✘ 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 socio-demographic, diagnosis, medication, and treatment information. We will also be contacting patient pharmacies to obtain refill rate information to assess medication adherence and medication possession ratio.

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):

For medical record access through WebCIS, form HD-974 has been completed by all researchers named on this application. Pharmacies and outside providers may require consent to relase patient information on their own forms, therefore patients will be responsible for completing this and providing their consent.

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, provided with a fact sheet, and permitted to review the consent/assent forms with their child in private.

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

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).

Consent/assent forms have been translated into Spanish by a native spanish speaker. We have 2 research assistants who are bilingual and able to communicate with this population. We also have access to Spanish interpreters in the clinic if necessary.

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

The research assistants and study coordinator named on this application will be obtaining consent and parental 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).

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 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_1.30.2015.doc	Adult Consent Form
Child assent form_15-17yo_1.30.2015.doc	Assent Form Ages 15-17
Child assent form_7-14yo_1.30.2015.doc	Assent Form Ages 7-14
HIPAA Authorization.docx	HIPAA Authorization
Parental permission form_1.30.2015.doc	Parental Permission Form

view consent forms

Attachments

This submission requires the following attachments

Document Type
Pencil and Paper Questionnaire Survey
Electronic Questionnaire Survey
Interview Questionnaire Survey
Other Questionnaire Survey
Letter for Recruitment
Translation Verification **This attachment not provided because:** Not Yet Available / Not Applicable

This submission includes the following attachments

File Name	Document Type
Recruitment letter_parent.doc	Letter for Recruitment
Recruitment letter_patient18+.doc	Letter for Recruitment
STARx Study Fact Sheet.doc	Other Materials for Recruitment
Adult ADHD screening scale.doc	Electronic Questionnaire Survey
CES-Depression Scale.doc	Electronic Questionnaire Survey
Face scale_2009.doc	Electronic Questionnaire Survey
Family Relationship Index.doc	Electronic Questionnaire Survey
Kidney Transplant Knowledge.doc	Electronic Questionnaire Survey
MWPNC Medical Passport Survey.docx	Electronic Questionnaire Survey
MWPNC Parent Satisfaction Survey.docx	Electronic Questionnaire Survey
MWPNC Parent Survey on Transition for Kidney Kids.docx	Electronic Questionnaire Survey
MWPNC Patient Satisfaction Survey.docx	Electronic Questionnaire Survey
MWPNC PedsQL Parent of 8-18yo.docx	Electronic Questionnaire Survey
MWPNC PedsQoL 13-18 Teen.docx	Electronic Questionnaire Survey
MWPNC PedsQoL Young Adult.docx	Electronic Questionnaire Survey
Morisky Med Adherence Scale.pdf	Electronic Questionnaire Survey
STARxTRS_Transitioned YA.doc	Electronic Questionnaire Survey
Social Support SSQSR (short-form revised).doc	Electronic Questionnaire Survey
adolescent medication barriers scale.PNG	Electronic Questionnaire Survey
diabetes social support questionaire - friend version.PNG	Electronic Questionnaire Survey
marlowe crown social desirability scale.PNG	Electronic Questionnaire Survey
medication management self-efficacy.PNG	Electronic Questionnaire Survey
social support questinairre - family version.PNG	Electronic Questionnaire Survey
Adol and YA T-scale_paper version_08.01.11.doc	Interview Questionnaire Survey
Newest Vital Sign.pdf	Interview Questionnaire Survey
Parent T-scale_08.01.11.doc	Interview Questionnaire Survey
SPANISH Adol and YA T-scale.doc	Interview Questionnaire Survey
SPANISH Parent T-scale.doc	Interview Questionnaire Survey
REALM Adolescent.pdf	Other Questionnaire Survey
REALM Adult.pdf	Other Questionnaire Survey
severity of illness scale.PNG	Other Questionnaire Survey
Prescription drug label.doc	Pencil and Paper Questionnaire Survey
SELENA SLEDAI.pdf	Pencil and Paper Questionnaire Survey
Completion Report.pdf	Other
E. Schnieder CITI completion certificate.JPG	Other
Johnson_citiCompletionReport4094710.pdf	Other
M. Lassiter CITI completion report.pdf	Other
mark citi training.pdf	Other

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:** 5/12/2015 02:48:34 AM

Maria Ferris