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

**Consent Form Version Date:** 04/13/2015
**IRB Study #** 15-0663
**Title of Study:** The FHLY (Food quality and Health Literacy among Youth with Chronic Conditions) Study
**Principal Investigator:** Nikita Patel
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**Funding Source and/or Sponsor:** National Institutes of Diabetes, Digestive, and Kidney Diseases (NIDDK)
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**What are some general things you and you child should know about research studies?**
You are being asked to allow your child to take part in a research study. To join the study is voluntary.
You may refuse to give permission, or you may withdraw your permission for your child to be in the study, for any reason, without penalty. Even if you give your permission, your child can decide not to be in the study or to leave the study early.

Research studies are designed to obtain new knowledge. This new information may help people in the future. Your child may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you and your child understand this information so that you and your child can make an informed choice about being in this research study.
You will be given a copy of this consent form. You and your child should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

**What is the purpose of this study?**
 The purpose of this research study is to gain further knowledge about how young adults with chronic conditions and their caregivers’ health literacy and level of medication adherence correlate to their knowledge of their disease-specific dietary restrictions and nutritional behaviors. Health literacy is defined as the degree to which individuals obtain, process, and understand health information and services to make informed health decisions. The present study is one of the first comparing health literacy of a young adult and their caregiver to the understanding they have of their disease and consequent food choice behaviors.
 Your child is being asked to be in the study because the doctor has recommended that he or she be on certain dietary restrictions.

**How many people will take part in this study?**
There will be approximately 200 people in this research study.

**How long will your child’s part in this study last?**

Your child’s involvement will be for 20-30 minutes in the clinic. We will also ask that you send us a picture of your refrigerator, freezer, pantry, or grocery bill.

**What will happen if your child takes part in the study?**
Prior to coming into clinic, we request that you bring in a picture of your refrigerator, freezer, and pantry as well as a picture of your most recent grocery bill. In clinic, **the first part of the study will require you to fill out two simple surveys that assess health literacy and medication adherence. Following the completion of the survey, both participant and caregiver will fill out a short quiz on the chronic condition-specific dietary restriction questionnaire, as well as will be asked to do a 24-hr dietary recall. Following this, the patient and caregiver will be asked to identify foods they should avoid in a standard picture. For all of the questions on the surveys or questionnaires, you may opt to skip any question for any reason.**

**What are the possible benefits from being in this study?**
Research is designed to benefit society by gaining new knowledge.  Your child will not benefit personally from being in this research study.

**What are the possible risks or discomforts involved from being in this study?**

There are no risks to this study.

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

**How will information about your child be protected?**
Privacy and confidentiality will be maintained throughout the study duration. Records will be secured in a password-protected database only accessible to relevant research personnel. Each participant will be identified using a study ID number, and no identifiers (such as name, date of birth, or phone number) will be tied to the participant’s study ID.

Participants will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your child’s information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

**What if you or your child wants to stop before your child’s part in the study is complete?**
You can withdraw your child from this study at any time, without penalty. The investigators also have the right to stop your child’s participation at any time. This could be because your child has had an unexpected reaction, or has failed to follow instructions, or because the entire study has been stopped.

**Will your child receive anything for being in this study?**
You and your child will receive a $10 gift card for being in this study.

**Will it cost you anything for your child to be in this study?**
It will not cost anything to be in this study.

**Who is sponsoring this study?**

This research is funded by Carolina Medical Student Summer Research Program. This means that the research team is being paid by the sponsor for doing the study.  The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

**What if you or your child has questions about this study?**
You and your child have the right to ask, and have answered, any questions you may have about this research. If there are questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, contact the researchers listed on the first page of this form**.**

**What if there are questions about your child’s rights as a research participant?**
All research on human volunteers is reviewed by a committee that works to protect your child’s rights and welfare. If there are questions or concerns about your child’s rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB\_subjects@unc.edu.

**Parent’s Agreement:**

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

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