**University of North Carolina at Chapel Hill
Assent to Participate in a Research Study
Adolescent Participants age 15-17**
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**Consent Form Version Date:** 04/2015
**IRB Study #** 15-0663
**Title of Study:** The FHLY (Food quality and Health Literacy among Youth with Chronic Conditions) Study
**Principal Investigator:** Nikita Patel
**Principal Investigator Department:** Medicine Administration
**Principal Investigator Phone number:** 919-457-8433
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**Faculty Advisor Contact Information**: (919) 966-2561

**Funding Source and/or Sponsor:** National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK)

**What are some general things you should know about research studies?**
You are being asked to take part in a research study. Your parent, or guardian, needs to give permission for you to be in this study. You do not have to be in this study if you don’t want to, even if your parent has already given permission. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You 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 understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You 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. 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.

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

**How long will your part in this study last?**
The involvement will include a 20-30 minute encounter in-clinic. Also, a picture will be requested taken at home and brought in of your pantry, refrigerator, freezer, and grocery bill.

**What will happen if you take part in the study?**

**The first part of this study will request of you to bring in a photograph of your home fridge, freezer, pantry, and grocery bill. The second part of this study will require you and your caregiver to fill out two simple surveys that assess health literacy and medication adherence in-clinic. Following the completion of the survey, you and your caregiver will fill out a short quiz on your dietary restrictions. You will also be asked to try and recall what you ate in the last 24 hours. We will then do a short activity where you will identify in a picture foods that you should avoid. 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.  You 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 not risks involved with this study.

**How will information about you 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 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 want to stop before your part in the study is complete?**

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped

**Will you receive anything for being in this study?**
You will be receiving a $10 gift card for taking part in this study.

**Will it cost you anything to be in this study?**

It will not cost you anything to be in this study.

**Who is sponsoring this study?**

This research is funded by the Carolina Medical Student Summer Research Program and the National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK). 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 have questions about this study?**
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form**.**

**What if you have questions about your rights as a research participant?**
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your 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.

**Participant’s Agreement**:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

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