**University of North Carolina at Chapel Hill**
**Consent to Participate in a Research Study**
**Adult Participants**

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

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**What are some general things you should know about research studies?**
You are being asked to take part in a research study.  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. 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.

**How many people will take part in this study?**
There will be approximately 200 people in this research study, or 100 dyads of young adults and their caregivers.

**How long will your part in this study last?**

Participation in this study includes a 20-30 minute encounter in clinic to fill out three questionnaires. Before coming into clinic, you will be requested to send in a picture of your refrigerator, freezer, and pantry and most recent grocery bill by email.

**What will happen if you take 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.  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 no risks involved in 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. You may also forego any section of the study. 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 to be received if all parts of the study are completed.

**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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