

DTF1200



PATIENT INFORMATION

**Rady Children's Hospital – San Diego  
and University of California, San Diego**

**Adolescent Assent Form**  
(ages 13-17)

***¡Más Fresco! More Fresh Fruit and Vegetable Prescription Program  
for Families with Type 2 Diabetes Mellitus***

***Introduction***

Dr. Rhee and the Division of Child and Community Health at UC San Diego, in collaboration with Rady Children's Hospital/UC San Diego Division of Pediatric Endocrinology are conducting this research and asking for your consent to participate. This section provides a summary of important information. The rest of the form provides additional details.

- Research is voluntary- whether or not you join is your decision. You can discuss your decision with others (such as family, friends or your physician).
- You can say yes but change your mind later.
- If you say no, we will not hold your decision against you.
- Your decision will not affect your health care or any other benefits you may be entitled to.
- You can say no even if the person inviting you is part of your healthcare team
- Please ask questions or mention concerns before, during or after the research.

The purpose of this study is to learn how nutrition education and fruit and vegetable vouchers affect your health and dietary behaviors. Participation in the study will allow you and your family to use vouchers to buy fruits and vegetables, which may benefit you directly. Participation will also help us learn important information for future similar programs.

When you enroll in the program, your parent will receive Fruit and Vegetable vouchers that can be used to buy qualifying fresh fruits and vegetables and dried beans and legumes at participating Northgate Gonzalez Market locations.

There is minimal risk associated with participating in this study. There may be some survey questions you or your parent do not wish to answer, which you and they can choose not to answer.

Alternatives to this study are to not participate. This will not affect your regular care at the Diabetes Clinic.

Please take your time to make your decision. Discuss it with your parent or caregiver. Additional, detailed information about this research is provided below. Please feel free to ask questions before signing this assent.

## **STUDY INVESTIGATOR AND SPONSOR**

Investigator(s): Kyung Rhee, MD, MSc, MA

Sponsor: United States Department of Agriculture

## **WHY HAVE YOU BEEN ASKED TO PARTICIPATE AND HOW YOU WERE SELECTED?**

You have been asked to participate in this study because you have type 2 diabetes, are receiving Medi-Cal benefits or CalFresh benefits, and are seen at the Rady Children's Hospital Diabetes Clinic.

## **HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?**

300 children will be in this study.

## **WHAT MAKES THIS DIFFERENT FROM THE USUAL TREATMENT?**

You will be assigned to a study group, to either immediately start receiving monthly fruit and vegetable vouchers for 12 months, or to receive the monthly vouchers for 12 months, after a 6-month waiting period.

You will be assigned by chance to a study group. Your chance of being assigned to each group is 50:50. Neither you nor the researchers can choose the group to which you will be assigned.

When you get regular bloodwork for your diabetes care, we will also measure a blood level twice during the study that can be used to help assess fruit and vegetable intake. This will be done with no extra cost to you or your parent/caregiver, and will not require an extra needle stick.

## **HOW LONG WILL YOU BE IN THE STUDY?**

You will be in the study for 18 to 24 months, depending on which study group you are assigned to.

You can stop being in the study at any time. But, if you decide to stop, we encourage you to talk to the research doctor first.

## **WHAT IS INVOLVED IN THE STUDY?**

This is what will happen if you decide to participate in this study:

- You will be randomized to a study group. Either immediately or after a 6-month waiting period, your parent/caregiver will start receiving 7 monthly vouchers (total \$105 per month) for 12 months. Vouchers will be either mailed to your house or given to your parent/caregiver at your routine follow-up appointments in the Diabetes Clinic.
- Vouchers can be used to purchase eligible fruits and vegetables, including fresh, whole or cut fruits and vegetables without added sugars, fats, oils, or salt. Vouchers can also be used to purchase dried beans and legumes.
- You will continue to come to your regularly scheduled appointments in the Diabetes Clinic.
- We will also ask you and your parent/caregiver to complete a survey about food in your home and your diet every 6 months during the study.
- We will track the results of your routine bloodwork that your physician will get as part of your regular diabetes care.
- We will also check an additional lab when you get your routine bloodwork to assess your fruit and vegetable intake. This will be an additional 2-4 cc of blood that will be done three times during the study period. You or your insurance will not be charged for this test.

### **WHAT ARE THE RISKS OF THE STUDY?**

Participation in this study may involve some added risks or discomforts. In addition to the risks described at the beginning of this form,

1. There may be some survey questions you or your parent/caregiver do not wish to answer, which you or your parent/caregiver can choose not to answer.
2. There is the potential risk of loss of privacy of information.

The research team will make every effort to keep all personal identifying information confidential. (Please see the Confidentiality section below for more details on how your personal information will be protected.)

You will be assigned to a study group at random (by chance). Your assignment is based on chance rather than a medical decision made by the researchers. The study group to which you are assigned to might not be the group you would prefer to be in.

You will continue getting routine bloodwork through your provider for routine diabetes care.

Possible side effects from blood drawing include:

- faintness,
- irritation of the vein, such as swelling or redness
- pain, bruising or bleeding at the blood draw site.
- There is also a slight possibility of infection or fainting.

Using the numbing cream used for blood draws may cause skin irritation, the skin may temporarily turn red, white, or develop a rash.

For more information about these risks and side effects, ask your study doctor.

### **ARE THERE BENEFITS TO TAKING PART IN THE STUDY?**

Participants in this study will benefit by being able to purchase more fruits and vegetables and dried beans and legumes at Northgate Gonzalez Markets. Increased consumption of fruits and vegetables and dried beans and legumes may improve your health.

### **WHAT OTHER OPTIONS ARE THERE?**

The alternative to study participation is to not participate. You may opt out at any point. Your family will still be able to receive any Northgate promotions and discounts that are offered at the store to all its customers. However, your parent/caregiver will no longer receive monthly vouchers after withdrawal from the study. You will also continue to receive your regular medical care at the Diabetes Clinic at Rady Children's Hospital San Diego.

### **CAN YOU BE REMOVED FROM THE STUDY WITHOUT YOUR CONSENT?**

You can be removed from the study if you do not attend your regularly scheduled diabetes appointments.

### **WHAT ABOUT CONFIDENTIALITY?**

Every reasonable effort will be made to keep your records confidential.

All information collected will be kept confidential and stored in locked cabinets or on a secure Rady Children's Hospital computer server. You will be assigned a unique ID number to be linked to the survey and laboratory data. The list of identification numbers and names will be kept separate and stored in a locked file cabinet or electronically on a secure network server. Only study team members will be able to access this information. All data will be destroyed within 7 years of the close of the study.

While you are in this study, all related records may be made available to:

- United States Department of Agriculture
- The UCSD Institutional Review Board (for the protection of human subjects in research)
- Other regulatory agencies responsible for overseeing research, such as the federal Office for Human Research Protections

We will keep your records confidential unless we are required by law to share any information.

Personal identifiers might be removed from the information or biospecimens collected as part of the research. After such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

Biospecimens (such as blood, tissue, or saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research, and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them.

If the study results are published or presented, you will not be identified.

### **WILL YOU RECEIVE ANY RESULTS FROM PARTICIPATING IN THIS STUDY?**

Your diabetes provider will communicate the results of your routine bloodwork as usual.

### **WHAT ARE THE COSTS?**

There are no costs associated with study participation. The additional bloodwork will be done at the time of your routine blood tests for diabetes care, and will be paid by the study sponsor at no cost to you.

### **WHAT IF YOU ARE INJURED IN THE STUDY?**

If you are injured or become ill as a direct result of this research study, you will be provided with medical care.

### **WILL YOU GET COMPENSATED TO BE IN THIS STUDY?**

You and your parent/caregiver will receive a \$20 gift card to Northgate Gonzalez Market or a VISA gift card as compensation for your time and effort in completing the surveys. You will receive the gift card at each of these time points after you and your

parent/caregiver complete the surveys: baseline, 6 months, 12 months, and 18 months. Your parent will also receive vouchers for fruits and vegetables, dried beans and legumes as explained above.

**WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?**

For questions about the study or a research-related injury, please call the researcher:

Dr. Kyung Rhee  
858-534-6827

**WHAT ARE YOUR RIGHTS AS A RESEARCH SUBJECT?**

Being in this study is voluntary. You don't have to be in this study if you don't want to or you can stop being in the study at any time. Your decision will not result in any penalty or loss of benefits that you have now. If you have questions about your rights you may call:

University of California, San Diego  
Human Research Protections Program  
858-246-HRPP (858-246-4777)

You will be told about any new information that may affect your health, welfare, or willingness to stay in this study.

**AGREEMENT TO BE IN THE STUDY**

Your signature below means that you have read the above information about this research study and have had a chance to ask questions to help you understand what you will do in this study and how your information will be used.

You can change your mind later if you want to. You will be given a copy of this consent form and a copy of the Subject's Bill of Rights. By signing this consent form you are not giving up any of your legal rights.

You agree to participate in this research study.

\_\_\_\_\_  
NAME OF SUBJECT

\_\_\_\_\_  
AGE

\_\_\_\_\_  
SIGNATURE OF SUBJECT (13 YRS - 17 YRS)

\_\_\_\_\_  
DATE

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SIGNATURE OF THE PERSON CONDUCTING  
THE INFORMED ASSENT DISCUSSION

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DATE

## ADOLESCENT SUBJECT'S BILL OF RIGHTS

It is important that the purpose and procedures of the research study are fully understood and that consent is offered willingly. A subject in a research study has the right to:

1. Be told about the nature and purpose of the research.
2. Be told about all procedures to be followed and of any drug or device to be used.
3. Be given a description of any risks or discomforts, which can be reasonably, expected to happen.
4. Be told about any benefits that may be expected as a subject of this research.
5. Be told about any other appropriate options instead of this research and of their risks and discomforts.
6. Be told about any medical treatments that are available if there are complications from this research.
7. Be encouraged to and given a chance to ask any questions concerning the study or the procedures involved in this research.
8. Be told that you can stop being in this research study at any time and that the decision to stop will not affect medical care in any way.
9. Be given a copy of the signed and dated written assent form.
10. Not be pressured in any way to be in this research study or to choose not to be in this research study.

If you have any further questions or concerns about your rights as a research subject, please contact your research doctor or UCSD's Human Research Protections Program at 858-246-HRPP (858-246-4777).