



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

**Adult Informed Consent**

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

***Introduction***

Dr. Rhee and the UC San Diego Division of Child and Community Health and the Center for Community Health, in collaboration with Rady Children's/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 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 parent/caregiver to use vouchers to buy fruits and vegetables, which can benefit you directly. Participation will also help us gain new knowledge for future similar programs.

When you enroll in the program, you 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.

Here is how it works:

- Each family enrolled will receive seven vouchers worth \$15 each for a total value of \$105 per month. You will receive 7 vouchers per month for a total of 12 months. Vouchers will be either mailed to your household or given to you 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 can use up to 4 vouchers (total of \$60) at a time during any one shopping trip.
- You will also be able to participate in other discount promotions and nutrition education activities at Northgate Markets.
- You will be able to use your vouchers until your voucher funds are depleted.
- We will track how much you spend with your voucher to learn how families use their voucher dollars.
- We will also ask you and your parent/caregiver to complete a survey about food in your home every 6 months during the study.
- We will track the results of the routine lab work that your physician will obtain as part of your routine 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 obtained three times during the study period. You or your insurance will not be charged for this test.
- We will also use the medical record to check if you had any changes to your diabetes medications while in the study.
- This information will be kept private and will not be shared with anyone outside of the study team.

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

There is the potential risk of loss of privacy of information. However, the research team will make every effort to keep all personal identifying information confidential. All information collected will be kept confidential and stored in locked cabinets or on a secure Rady Children's Hospital computer 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.

Finally, there may be some pain and discomfort secondary to laboratory assessments, however participation in the study does not increase this risk as you will continue to receive regular bloodwork as part of your routine diabetes care.

Participation in this program is entirely voluntary. At any point, you may withdraw from the study.

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

## **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 subjects 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 1 in 2 (or 50:50). Neither you nor the researchers can choose the group to which you will be assigned.

When you get routine lab work for your diabetes care, we will also measure a lab value that can be used to help assess fruit and vegetable intake. This will be done with no extra cost to you and will not require an extra needle stick.

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

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

You can stop your participation at any time. However, if you decide to stop participating in the study, we encourage you to talk to the research doctor.

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

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

- You will be randomized to a study group. Either immediately or after a 6-month waiting period, you will start receiving 7 monthly vouchers (each worth \$15, for a

total of \$105 per month) for 12 months. Vouchers will be either mailed to your household or given to you at your routine follow-up appointments in the Diabetes Clinic.

- (Please see additional details above.)

### **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 do not wish to answer, which you can choose not to answer.
2. There is the potential risk of loss of privacy of information. (Please see the Confidentiality section below for more details on how we will protect your personal identifying information.)

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 redness or swelling
- pain, bruising, or bleeding at the blood draw site.
- There is also a slight possibility of infection.

If you use numbing cream for blood draws, there may be skin irritation and 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 and well-being.

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

The alternative to study participation is to not participate. You may opt out at any point. You will still be able to receive any Northgate promotions and discounts that are offered at

the store to all its customers. However, you will no longer receive monthly vouchers after withdrawal from the study. You will also continue to receive all 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

A copy of this permission form, and the HIPAA authorization form that you will sign, will be placed in your medical record. Your records and information will not be released without your permission unless required by law.

We may need to report information about known or reasonably suspected incidents of abuse or neglect of a child, dependent adult or elder including physical, sexual, emotional, and financial abuse or neglect. If any investigator has or is given such information, he or she may report such information to the appropriate authorities.

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. This additional bloodwork will be paid by the study sponsor at no cost to you.

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

If you are injured as a direct result of participation in this research, Rady Children's Hospital – San Diego or the University of California will provide any medical care needed to treat those injuries. Neither Rady Children's Hospital – San Diego nor the University will provide any other form of compensation to you if you are injured. You may call the Human Research Protections Program Office at 858-246-HRPP (858-246-4777) for more information about this, to inquire about your rights as a research subject or to report research-related problems.

### **WILL YOU BE COMPENSATED?**

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. You will also receive vouchers for fruits and vegetables, dried beans and legumes as part of this study, as explained above.

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

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

Dr. Kyung Rhee  
858-534-6827

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

Taking part in this study is voluntary. You may choose to not take part or you may choose to leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled. 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.

**SIGNATURE AND CONSENT 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 PARTICIPANT

\_\_\_\_\_  
AGE

\_\_\_\_\_  
SIGNATURE OF PARTICIPANT

\_\_\_\_\_  
DATE

\_\_\_\_\_  
SIGNATURE OF THE PERSON CONDUCTING  
THE INFORMED CONSENT DISCUSSION

\_\_\_\_\_  
DATE



## **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 or someone, who is asked to give consent on behalf of another person for such participation, has the right to the following:

1. Be informed of the nature and purpose of the research.
2. Be given an explanation of 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 result from this research study.
4. Be given an explanation of any benefits, which can be reasonably expected to the subject as a result of this research study.
5. Be informed of any appropriate alternative procedures, drugs, or devices that may be advantageous and of their relative risks and discomforts.
6. Be informed of any medical treatment, which will be made available to the subject if complications should arise from this research.
7. Be given an opportunity and encouraged to ask any questions concerning the study or the procedures involved in this research.
8. Be made aware that consent to participate in the research may be withdrawn and that participation may be discontinued at any time without affecting continuity or quality of medical care.
9. Be given a copy of the signed and dated written consent form.
10. Not be subjected to any element of force, fraud, deceit, duress, coercion, or any influence in reaching the decision to consent or to not consent to participate in the research.

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