



# CARB

Carbohydrates and Related Biomarkers  
Part of the TREC Study



# INFORMATION BOOKLET



## *Why are we doing the **CARB Study**?*

Doctors cannot always explain why one person gets cancer and another does not. Scientists at the Hutchinson Center have studied general patterns of cancer to learn about “risk factors” —things in our lives that may increase our chances (or risk) of developing cancer. Risk factors may include a person’s weight, the amount of exercise they usually get, or the type of foods they eat.

To better understand how foods relate to cancer risk, scientists at the Hutchinson Center want to study the biological markers (“biomarkers”) of foods that people eat. These biomarkers, found in blood and urine, can be levels of nutrients from foods such as glucose (sugar). They can also be products our bodies make when we eat, such as insulin.

The **CARB Study** is a feeding study. It tests how carbohydrates and other foods you eat affect biomarkers in your blood and urine. We also want to see if people’s weight affects their biomarkers.

## *What are carbs?*

Carbohydrates (carbs) are foods made of flour, starch or sugar. Carbs include

- Pasta, bread, and cake
- Grains like rice and barley
- Starchy vegetables like potatoes and corn
- Foods with natural or added sugar, like fruit and candy

When we eat carbs, our body breaks them down into glucose (sugar). This glucose then goes into the blood. Some carbs, called refined or high glycemic carbs, break down into a high amount of glucose. Other carbs, called complex or low glycemic carbs, break down into a low amount of glucose.

## The feeding study—a short explanation

We will test 88 men and women between 18 and 45 years old. About half of them will be normal weight, and the other half will be overweight. We will test:

- How your body processes high glycemic and low glycemic carbs.
- If the different types of carbs affect people’s biomarkers.
- If there is any difference in carb response between people who are normal weight and people who are overweight.

We will give you all your food to eat and drink (except water) for two 28-day feeding periods (a total of 56 days). You will eat dinner at the Hutchinson Center Monday through Friday. Each evening we will give you your breakfast, lunch and snacks for the next day. On Friday evenings we will give you the food for the weekend. There will be at least four weeks between the feeding periods when you will go back to eating your own food. This period could be longer—it will depend on your schedule. Thus, you will be part of this study for at least 12 weeks.

We will take samples of your blood after an overnight fast at the beginning and the end of each feeding period. We will ask you to collect all your urine for 24 hours at the end of each feeding period. We will also ask you to complete a number of questionnaires during each diet period. You will be asked to collect a small stool sample, in your own home, before the first feeding period, and once during each feeding period. The stool sample collection is *optional*. You can decide not to provide a stool sample and still participate in the study. There is also an *optional* 8-hour Postprandial Test (PPT) on the last day of each feeding period. If interested, see the PPT information booklet.

### You are eligible to be in the CARB Study if you are

- Between 18 and 45 years old.
- In good health.
- Nonsmoker.
- Process carbohydrates normally (we will test this).
- Fit into one of the study weight groups (we will measure this).

### You cannot do this study if you

- Are pregnant or breastfeeding.
- Take medications every day, including prescription and over-the-counter medications. This includes birth control: pill, shot, patch or IUD with hormones.
- Use tobacco products every day.
- Use any type of recreational drug.
- Drink alcohol more than four times each week. This includes beer, wine and hard liquor.

## Where does the CARB Study take place?

All study activities will take place at the Hutchinson Center’s Prevention Center. The Prevention Center includes the clinic and also the Human Nutrition Lab (HNL) dining room, where you will eat your meals and pick up your food to take home.

The Prevention Center is located on the E Level of the Robert Arnold Building (“M” on the map) on the Fred Hutchinson Cancer Research Center – Day Campus (Fairview Ave. N and Campus Drive) in Seattle. Parking is free in the Arnold Building garage, entered from Campus Drive, off Fairview Ave N., and open from 7:00 a.m. to 7:00 p.m.

Metro Bus Routes serving The Hutchinson Center are the #66 (Eastlake Ave. N and Aloha) and the #70 (Fairview Ave. N and Yale) and the South Lake Union Streetcar.

Free shuttle bus service to FHCRS is available Monday through Friday from the University of Washington Health Science Building, D wing.



## Screening

Before you can join the study, we must make sure you meet the study's eligibility rules. There are four steps.

- Step 1.** Find your height and weight range on the Body Mass Index (BMI) table—page 2 of the screening questionnaire. If your weight fits into one of the study weight groups, you may be eligible to join the study. Go on to [Step 2](#).
- Step 2.** Complete the screening questionnaire and send it back to the [CARB Study](#). The questionnaire asks about everyday habits and medical treatments that could affect the study results.

If you qualify, you will be asked to come to the Prevention Center clinic for one visit to complete the third and fourth steps.

- Step 3.** We will get an accurate measure of your height and weight. We can only include people who fit one of the study's weight groups.
- Step 4.** We will make sure you can process carbs normally by measuring the amount of glucose in your blood after a 12-hour overnight fast. This is called a Fasting Blood Glucose (FBG). If the result falls above the normal range or higher than 100 mg/dl, you will not be able to join the study. You may wish to discuss the test results with your doctor.

Within a week, you will be sent a letter with the results of the screening. If you are eligible to join the study, we will phone you to set up a time to meet to discuss the study in more detail. A separate consent form will be used for the Feeding Study.

## *The feeding study—in detail*

The feeding study consists of two 28-day feeding periods separated by a 28-day “washout” period when you eat your own food. Before the first feeding period, you must attend an information meeting, complete some at-home activities, and come in for the baseline visit.

### Feeding study information meeting

We will ask you to attend a meeting at the Prevention Center. This meeting will take about 2 hours. We will:

- Review the feeding study in detail
- Answer your questions
- Offer you samples of the study food to taste
- Review the questionnaires to be completed at home
- Instruct you to keep a 3-day food record. This will help us know how much food you usually eat.

If you agree to join the study, we will ask you to sign a consent form. We will also set up the dates and appointments for all the study activities.

### Before you begin the first feeding period

At home, you will need to complete the following activities:

- Keep a 3-day food record
- Fill out questionnaires on health, lifestyle, diet and physical activity
- Collect a small stool sample at home and bring it to your Day 1 blood draw (optional)

We will set up a Baseline Visit at the Prevention Center. This visit will take about an hour. You do not need to fast for this visit, so it can be scheduled for the morning or afternoon, whatever fits your schedule.

## Baseline Visit

At the baseline visit, we will:

- Review your completed 3-day food record and questionnaires
- Give you a body composition test (DEXA scan)
- Set up your feeding study calendar and schedule your Day 1 clinic appointment (about 2 weeks later)
- Give you supplies to take home for the first stool collection. For each stool sample collection we will provide you with a kit that makes it easy to collect the sample. It includes a large plastic container that fits your toilet, a flushable bag to line the collection container, disposable gloves, and a small, well-sealing tube for you to bring the sample to FHCRC. The stool sample collection is optional. You can decide not to provide a stool sample and still participate in the study.

## DEXA scan

A dual energy x-ray absorptiometry (DEXA) scan uses a low x-ray dose to measure how much bone and body fat you have. You will lie on your back on a padded table for about 15 minutes for the body scan. The total test takes about 30 minutes. The DEXA scan is not painful and there is little risk of radiation exposure. The x-ray dose is very low. Because exposure to even a small amount of radiation could be harmful to a fetus (baby), we will ask women to take a urine pregnancy test before the DEXA scan. At the end of the study, we will give you your DEXA results.

## Feeding study activities

Each feeding period will start on a Monday, Tuesday or Wednesday, depending on your schedule. You will eat dinner at the Human Nutrition Lab Monday through Friday nights and take home breakfast, lunch and a snack for the next day. On Friday nights you will take home all your food for the weekend and Monday breakfast and lunch. All uneaten food must be brought back to the HNL to be measured.

The “washout” period will be at least four weeks between feeding periods when you will eat your own food. The time between the two feeding periods might even be longer, depending on your schedule.

## Study activities during each feeding period

- We will draw some of your blood on the morning of the first study day (Day 1) and on the last study day (Day 29). You will need to fast for 12 hours before each blood draw. We will draw about 65 ml (4¼ tablespoons) each time, for a total of 130 ml (8½ tablespoons). We will also take your blood pressure and pulse.
- On the morning of Day 1 of the first feeding period, we will weigh you and measure your waist and hip size using a tape measure. We may ask you to put on an examination gown for these measurements. At all other clinic visits, we will weigh you in your street clothes.
- You will eat dinner at the Human Nutrition Lab Monday through Friday for two 28-day periods. The dining room is open for dinner between 4:00 and 7:00 p.m. Other times are possible by special request. Each evening we will give you your breakfast, lunch and snacks for the next day. On Friday evenings we will give you the food for the weekend and Monday breakfast and lunch.
- Every time you come in to eat dinner, we will weigh you.
- You will keep a daily physical activity record and food check-off form.
- You will complete questionnaires several times during each feeding period and once during baseline. The days you complete the questionnaires will vary.
- You will collect all your urine for 24 hours beginning the morning of Day 28 and ending on the morning of Day 29 of each feeding period.
- You will collect a stool sample: once before the first feeding period and then during the fourth week of each feeding period for a total of three collections (*optional*).
- If you are female, we will ask you to keep track of your menstrual cycle.
- If you agree, do the optional 8-hour Postprandial Test (PPT) on the last day (Day 29) of each feeding period.

### Example of a feeding period calendar

Week	WEEKDAYS		WEEKENDS
	Monday	Tuesday, Wednesday, Thursday, Friday	Saturday and Sunday
1	Feeding Period 1: Day 1 A.M. Clinic for fasting blood draw, take home B&L, eat dinner at HNL, take home B&L for next day	Days 2, 3, 4 & 5 Eat dinner at HNL, take home B&L for next day, weight check, complete questionnaires  Friday: Take home food for weekend and Mon B&L	Days 6 & 7 Eat meals at home
2	Days 8, 9, 10, 11 & 12 Eat dinner at HNL, take home B&L for next day, weight checks, complete questionnaires Friday: Take home food for weekend and Mon B&L		Days 13 & 14 Eat meals at home
3	Days 15, 16, 17, 18 & 19 Eat dinner at HNL, take home B&L for next day, weight checks, complete questionnaires. Friday: Take home food for weekend and Mon B&L		Days 20 & 21 Eat meals at home
4	Days 22, 23, 24, 25 & 26 Collect stool sample (optional) Eat dinner at HNL, take home B&L for next day, weight checks, complete questionnaires Friday: Take home food for weekend and Mon B&L		Days 27 & 28 Eat meals at home  Sunday, Day 28 Begin 24-hr urine collection Fast for next day blood draw
5	Day 29 End 24-hr urine collection A.M. Clinic for fasting blood draw, bring urine Do optional 8-hour Postprandial Test (PPT) End of Feeding Period 1 Begin washout period Eat your own food		Washout Period (eat your own food)
6	Washout period (eat your own food)		
7	Washout period (eat your own food)		

Week	WEEKDAYS		WEEKENDS
	Monday	Tuesday, Wednesday, Thursday, Friday	Saturday and Sunday
8	Washout period (eat your own food)		
9	Feeding Period 2: Day 1 A.M. Clinic for fasting blood draw, take home B&L, eat dinner at HNL, take home B&L for next day	Days 2, 3, 4 & 5 Eat dinner at HNL, take home B&L for next day, weight checks, complete questionnaires  Friday: Take home food for weekend and Mon B&L	Days 6 & 7 Eat meals at home
10	Days 8, 9, 10, 11 & 12 Eat dinner at HNL, take home B&L for next day, weight checks, complete questionnaires. Friday: Take home food for weekend and Mon B&L		Days 13 & 14 Eat meals at home
11	Days 15, 16, 17, 18 & 19 Eat dinner at HNL, take home B&L for next day, weight checks, complete questionnaires Friday: Take home food for weekend and Mon B&L		Days 20 & 21 Eat meals at home
12	Days 22, 23, 24, 25 & 26 Collect stool sample (optional) Eat dinner at HNL, take home B&L for next day, weight checks, complete questionnaires Friday: Take home food for weekend and Mon B&L		Days 27 & 28 Eat meals at home  Sunday, Day 28 Begin 24-hr urine collection Fast for next day blood draw
13	Day 29 End 24-hr urine collection. A.M. Clinic for fasting blood draw and bring urine Do optional 8-hour Postprandial Test (PPT)		
	End of study		

B=Breakfast

L= Lunch

HNL=Human Nutrition Lab

## Study diets

We will give you all your food and drink (except water) during the two feeding periods. The order of the feeding periods will be random.

In one feeding period, you will eat a high glycemic carb diet—high in food made with white flour and other refined carbs.

In the other feeding periods, you will eat a low glycemic carb diet—low in sugar and high in complex carbs such as whole grains, fruits and vegetables.

During the feeding period, **you must eat only what we give you**. You cannot eat or drink any of your own food except water, coffee, or tea. If you need sweetener or milk for your coffee or tea, we will give it to you. What you can add to coffee or tea is limited by the study rules. You may drink as much water as you want.

Each feeding period lasts 4 weeks (28 days). Between feeding periods you will go back to eating your own food. This break will last at least 4 weeks. It could be longer, depending on your schedule.

$$\begin{array}{r}
 4 \text{ weeks (first feeding period)} \\
 +4 \text{ weeks or more (your own food)} \\
 +4 \text{ weeks (second feeding period)} \\
 \hline
 = 12 \text{ weeks or more in the study}
 \end{array}$$

The food you will eat is real food, just like you buy in the grocery store. The high glycemic carb diet and the low glycemic carb diet differ in the amount and types of carbs. The high glycemic carb diet is high in sugar and starchy vegetables. It includes white bread, white rice and pasta, fruits and vegetables, cake and cookies. The low glycemic carb diet is low in sugar. It includes whole grains such as barley, beans and lentils, limited choices of fruit and vegetable, and whole grain bread.

We do not want you to gain or lose weight. The amount of calories you eat on the study will be similar to what you eat now. You will need to eat all the food we give you each day. However, if you are extra hungry or feel that you can't finish all the foods, please tell the study staff and we will adjust the portions we give you. If you are unable to eat the study diets as assigned and after we make changes, we will ask you to withdraw from the study.

## Study menus

The [CARB Study](#) menu will repeat every seven days, so you will eat each item at least four times during each feeding period (and some even more). Please look over the menus carefully before you start the study. You cannot strongly dislike any of the listed foods, as you must be prepared to eat all the offered menu items. You must not be allergic or intolerant to any food listed except milk. Low-lactose milk (Lactaid-100) can be substituted for regular milk. This menu is designed for research purposes; therefore, we cannot make any other substitutions.

Some calorie-free/low-cal foods can be added to either diet in limited amounts. These include things like sugar substitutes, diet soda and Crystal Light™, sugar-free gum and hot sauce and spices.

The days that you will eat the study diets will be assigned, but we will do our best to fit your schedule.

## Study questionnaires

During the study we will ask you to complete questionnaires about your appetite, energy level, sleep and general thoughts and feelings. We will ask you to complete these questionnaires once before you begin the study and about once a week while you are on the study diets.

## You cannot do the following while on the study

- You cannot consume alcohol.
- You cannot use any tobacco products.
- You cannot take any medications (prescription and over-the-counter like Tylenol, antibiotics, oral/patch or injection contraceptives, etc), vitamins, or herbal supplements during each feeding period.
- You must stop taking any medications or dietary/herbal supplements one week before beginning each feeding period.

If you are prescribed any medication, or if you must take an over-the-counter medication, dietary or herbal supplement during the study, please let us know. We may need to ask you to withdraw or change your study dates.

We also ask you not to start any new exercise programs while you are in the study. Please continue your usual physical activities.

If you are female, and you become pregnant or decide to try to get pregnant while you are in the study, we will ask you to withdraw from the study.

## *What are the benefits of the study?*

You will benefit from this study by receiving a nutrient analysis of your usual food intake and the results of the DEXA scan at the end of the study. You will also be helping us in our research on cancer prevention. This research may benefit society in the future by developing recommendations about diets that may prevent cancer.

## *What are the risks of the study?*

**Blood draw:** You may experience a little discomfort or have a temporary bruise from having blood drawn. Occasionally, you may feel lightheaded or feel faint when having blood drawn. If you feel faint, tell the person drawing your blood and she or he will have you lie down until the feeling goes away. Sugar-containing drinks will also be available.

**DEXA scan:** The DEXA scan involves exposure to radiation. Although it can vary from person to person, the whole-body radiation exposure from each DEXA scan will be about 5 mrem. The total exposure for the study will be about 2% of the average annual exposure a person in the United States receives from natural background radiation. The risk of harm from this amount of radiation is low and no harmful health effects are expected. However, the risk of harmful effects may increase if a person is exposed to more procedures that involve radiation.

**Diet:** You may have mild bloating or abdominal discomfort for a few days at the beginning of each diet period. This is because the study diet may be higher in fiber than your usual diet.

**Urine and stool collections:** Collecting urine and stool samples may cause you to feel uncomfortable.

## *What will we do with your samples?*

**Blood:** We will look at some substances normally made by your body, including glucose, insulin, leptin, proteins and associated components.

**Urine:** We will measure breakdown products of the diet.

**Stool:** We will look at the types of bacteria present in your stool.

## *Compensation*

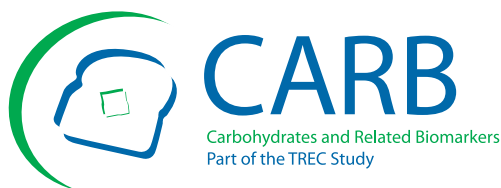
After you complete the entire study, you will receive **\$750**. Because of the study's design, you must complete both feeding periods before receiving payment. If you are unable to complete the study (due to illness, family emergency, unforeseen circumstances), but you have completed one feeding period, you will receive **\$250**. If you do not complete any feeding period, no payment can be given. You will receive an additional compensation of **\$20** for each stool sample collection and **\$200** for completing both Postprandial Tests.

## *So, what should you do now if you are interested in joining the CARB Study?*

We welcome any questions you may have now and in the future. If you have questions about the study, please feel free to contact [Yvonne Schwarz](mailto:Yvonne.Schwarz@fhcrc.org) at (206) 667-7804, [yschwarz@fhcrc.org](mailto:yschwarz@fhcrc.org) or [Dr. Marian Neuhouser](mailto:Dr.Marian.Neuhouser@fhcrc.org) at (206) 667-4797, [mneuhaus@fhcrc.org](mailto:mneuhaus@fhcrc.org).

If you are interested in joining the [CARB Study](http://www.carbstudy.org), please complete the screening questionnaire that was sent to you and return it in the self-addressed, stamped envelope we have provided. If you do not have a screening questionnaire, you can call the study line at (206) 667-2547 and request that a copy be sent to you. Please leave us your name and mailing address. The screening questionnaire can also be printed from our website at [www.carbstudy.org](http://www.carbstudy.org). Send it to:

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See our website at [www.carbstudy.org](http://www.carbstudy.org)

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**FRED HUTCHINSON  
CANCER RESEARCH CENTER**

A LIFE OF SCIENCE

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