

PATIENT INFORMATION AND INFORMED CONSENT FORM

Title: Type 2 Diabetes Outcomes Study

Sponsor: Wisconsin Dietetic Association

Investigator: Name: _____

Work Facility: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Phone Number: _____

Introduction: We invite you to take part in this research study for adults with Type 2 diabetes. The nature of this study, its risks/benefits and other important information are discussed below. Please ask the dietitian to explain any information in the form that that is unclear, and feel free to discuss any questions you have about this study with the dietetic professional you are seeing.

Purpose: The purpose of this study is to evaluate outcomes of medical nutrition therapy (MNT) provided by a registered dietetic professional in the care of adults with Type 2 diabetes. This study will examine relationships between MNT provided by a dietetic professional and health and lifestyle outcomes, including:

- control of blood sugar
- risk of long-term complications
- self-management skills
- health care costs
- quality of life

Procedures: At least 500 Type 2 diabetes patients from across the state of Wisconsin will take part in this study for up to 6 months following their initial visit for medical nutrition therapy counseling. Your treatment will not be any different from routine care and counseling provided by a dietetic professional except that certain information about your diabetes self-management will be reported to the organization sponsoring this study.

At your initial appointment with the dietitian you will be asked questions about your diabetes self-management—including those regarding food preparation practices at home, eating out, physical activity patterns, self-monitoring of blood glucose and your overall health both before and after nutrition counseling. Without your written consent, the information you provide, the results of your lab tests, and any other confidential information from your medical record, will NOT be shared with anyone not affiliated with this facility. With your informed consent, coded information (excluding your name and medical record number) will be submitted to the Wisconsin Dietetic Association for inclusion in the study.

At approximately 3 and 6 months after your initial appointment, you will be contacted and asked questions again regarding diabetes self-management as well as your perceptions regarding the medical nutrition therapy counseling you received. Diabetes-related lab values and medications will also be recorded.

Risks/Benefits: No reasonably foreseeable risks or discomforts to you are anticipated with this study. Long-term benefits of this study may include a) improvement in dietitians' current practice standards, and b) increased recognition by physicians, insurance companies and others of the value of medical nutrition therapy in the provision of cost-effective care delivered by the registered dietetic professional.

Costs: You will incur no additional costs for participating in this study. You or your insurance company will pay, as usual, for the costs of the office visits with the dietetic professional and any lab tests required/requested by your physician.

Alternative Treatments: You do not have to be in this study. If you decline, you will receive the same standard of medical nutrition therapy services from the dietetic professional.

Voluntary Participation/Withdrawal from Study: Participation in this study is your choice. You may decide not to participate, or you may withdraw from the study at any time, without penalty and without affecting your future medical care or medical nutrition therapy at this site.

Confidentiality: Information from this study will be submitted to the sponsoring organization. This signed consent form or medical records which identify you will not be submitted, and will only be available to physicians and staff involved in your care at this facility. The results of this research study may be presented at meetings or in publications; your identity, however, will not be disclosed.

Questions: The dietetic professional you are scheduled to see today will answer your questions at this time. If you have further questions or research-related concerns regarding this study, you may call:

Lynn Edwards, RD, CD
Executive Coordinator
Wisconsin Dietetic Association
1-888-232-8631

If you have questions about your rights as a research subject, you may contact the following person at this institution:

Name: _____

Phone: _____

Subject's Consent Statement

I have read and I understand this consent form. My questions have been answered satisfactorily. I understand that I may withdraw from the study at any time. I freely and voluntarily agree to participate in this study.

I understand that I will receive a copy of this consent form if requested.

Patient Signature: _____ Date: _____

Witness Signature: _____ Date: _____