Type 2 Diabetes Diet study
SUBJECT INFORMATION AND CONSENT FORM

STUDY TITLE: Effects of Intermittent Fasting and High Protein Intake on Individuals with Type 2 Diabetes.

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FUNDING:
Department of Medicine Research funds/continuous funds held by Dr. Terra Arnason
Department of Pharmacy Research funds/continuous funds held by Dr. Kerry Mansell
General CONTACT NUMBER: Please call/leave message at 306 844 1119 regarding "Diabetes Diet Study"
24-HOUR EMERGENCY CONTACT NUMBER: Dr. Terra Arnason: 306-260-7592

INTRODUCTION
You are being asked to take part in this research because you have been diagnosed with Type 2 Diabetes. Participation is voluntary and it is up to you if you wish to be enrolled in this study. If you do decide that you will take part in this study, you are still free to withdraw at any time, without giving any reasons for your decision. If you do not wish to participate, you will not lose the benefit of any medical care to which you are entitled or presently receiving.

WHO IS CONDUCTING THE STUDY?
This study is being conducted by researchers within the College of Medicine at the University of Saskatchewan. The investigators or staff will not receive any direct financial benefit from conducting this study, other than their regular salary.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to investigate the effects and health benefits of a 1 month structured diet on your diabetic control. This diet has been shown to smooth glucose levels, result in loss of body fat (as it gets used up during your fasting hours), and improve cholesterol profiles. This diet has never been tested in diabetic patients who may benefit the most.

WHAT DOES THE STUDY INVOLVE FOR THOSE WHO PARTICIPATE?
This is an **8 week commitment** involving both your standard diet and the study diet. **The study diet** is referred to as Intermittent Fasting (IF), where you eat as much as you like for 4-6 hours each afternoon/evening, but abstain from any calorie intake for the rest of the day. You are encouraged to drink unlimited coffee/tea during the fasting hours, without added sugars or creams. You will not be aiming to intentionally restrict calories but you will be required to eat a high proportion of your food as protein during the 4-6 hours. You will be required to attend a 30 minute information session at the Royal University Hospital before starting this diet to provide you with information, meal planning, food choices, and support to help you to follow the diet. You will also review the symptoms of low blood sugar and how to safely treat it. The remaining 18-20 hours are considered fasting, with limited liquids allowed. There are no exercise restrictions or changes required. **The standard diet** consists of your regular meal timing patterns. There is no calorie counting or calorie limits. You will maintain your standard diet for two weeks before and after the study diet.

You will need to **self-monitor your blood glucose** with your own glucometer for the entire 8 week duration of the study period. This is required at least 3 times a day; upon waking, before dinner, and before bed. We will be able to provide you with log books to record your blood sugars. You will also keep a **daily dietary log** recording the hours spent fasted for the entire 8 weeks of the study period. You will be asked to also complete a **photo food intake diary using your own digital camera or smartphone and fill out scales to rate your hunger, fullness, and satisfaction** during every meal period for three days in each of the study periods (**nine days in total**), and to maintain contact with the researchers via phone, text message or e-mail on those days. If possible, you will also be required to send these photos via e-mail or text message to the research staff upon request – otherwise you will be required to bring your digital camera/smartphone to each meeting where a researcher will upload the study photos onto a secure hard drive. No photos will be shared with anyone other than research staff, and after analysis all photos will be stored securely on a USB drive in Dr. Arnason's secured medical office.

Importantly, **we require your permission to draw a fasting blood sample three times during this study**: the day you begin the 1 month study diet, the final day of the study diet, and two weeks after the completion of the study diet to determine if there have been changes to your diabetic and metabolic control. We will be measuring clinical markers of health (weight, blood pressure, waist size) as well as blood measures of diabetic control (glucose, insulin and inflammation levels). The serum levels of

non-diabetic markers can be disrupted in Type 2 Diabetics, and part of the experimental question we are trying to answer is to see if they correct with the fasting diet. Blood samples will be destroyed at the end of the study. **Your medical care will not be delayed or enhanced in any way regarding your usual diabetic management.**

We would also like to request medical records at 3, 6 and 12 months post study from your regular family doctor for results from your regularly scheduled diabetes-related blood tests and physical measurements (body weight, waist circumference) taken during that time. Our primary interest is glycated hemoglobin (HbA1c), as we are not able to capture it in our brief study period. We will also use these medical records in order to observe changes in fasting glucose, CRP, creatinine, body weight, and waist circumference if the family physician captures these biomarkers in routine care.

WHAT ARE THE RISKS AND BENEFITS OF PARTICIPATING IN THIS STUDY?

During the fasting part of the study diet, there is a small risk of **low blood sugar**. Part of the Information session is to review signs and symptoms of low blood sugar and how to treat it. If your blood sugars measures below 4 mmol on your glucometer and you have symptoms of hypoglycemia, **you should break your fast and eat.** Please contact the investigators by phone to review if the fasting should continue.

Your medication will be reviewed to ensure they do not put you at risk of low blood sugars while fasting. While the study diet has not been tested in Type 2 diabetics, many diabetics follow the religious fasting of Ramadan, where nothing is taken by mouth during daylight hours. The incidence of low blood sugars during Ramadan has been very low (only 3 per 100 individuals per month), and our careful review of your medications will minimize this risk. Lastly, standard blood draw procedures will be followed, so there will a chance of slight bruising and soreness at the blood draw site, and in very rare instances there is a possibility for infection at the site. If any of these risks occur, or if there is a research-related injury, you are instructed to contact the primary investigator – Dr. Terra Arnason at the 24 hour emergency contact number.

RESEARCH RELATED INJURY

In the case of a medical emergency related to the study, you should seek immediate care and, as soon as possible, notify the study doctor. Inform the medical staff you are participating in a clinical study. Necessary medical treatment will be made available at no cost to you. By signing this document, you do not waive any of your legal rights against the sponsor, investigators or anyone else.

WHAT HAPPENS IF I DECIDE TO WITHDRAW?

Your participation in this research is voluntary and you have the right to withdraw at any time. All data collected about you during your enrolment will be retained for analysis.

WHAT WILL THE STUDY COST ME?

You will not be charged for any research-related procedures. You will not be paid for participating in this study. You will not receive any compensation, or financial benefits for being in this study, or as a result of data obtained from research conducted under this study. You will be expected to use your own glucometer and your own test strips in most instances although a small supply will be available for selected glucometer types. *You will be expected to purchase your own food for the study*. You will be expected to use your own smartphone, otherwise you will not be required to complete the photo food diary portion of the study.

HOW DO I FIND OUT ABOUT MY RESULTS?

Upon completion of the study, when all data has been analyzed and results have been obtained, we will provide you with your individual results as well as a summary of the overall study in a letter at the conclusion of the study.

WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

In Saskatchewan, *the Health Information Protection Act (HIPA)* protects the privacy of your personal health information. No information that discloses your identity will be released or published without your specific consent to the disclosure. Our study files will be securely stored with limited access. Research records and medical records identifying you may be inspected in the presence of the Investigator and the University of Saskatchewan Research Ethics Board for the purpose of monitoring the research. However, no records, which identify you by name or initials, will be attached to any information. The pooled results of this study may be presented in a scientific meeting or published, but your identity will not be disclosed.

WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?

If you have any questions or desire further information about this study before or during participation, you can contact anyone of the researchers: Dr. T. Arnason, Lead Investigator, Division of Endocrinology, Royal University Hospital (306) 966-7911, Dr. Kerry Mansell, Co-Lead, College of Pharmacy (306) 966-5235, or student researcher Matthew Bowen (306) 717-7661.

If you have any concerns about your rights as a research subject and/or your experiences while participating in this study, contact the Chair of the Biomedical Research Ethics Board (Bio-REB) of the University of Saskatchewan, at 306-966-4053. The Research Ethics Board is a group of individuals (scientists, physicians, ethicists, lawyers and members of the community) that provide an independent review of human research studies. This study has been reviewed and approved on ethical grounds by the Biomedical Research Ethics Board (Bio-REB) of the University of Saskatchewan.

please retain the previous pages for future reference. Please sign and detach this page for return to the study investigators.

CONSENT TO PARTICIPATE

- I have read (or someone has read to me) the information in this consent form.
- I understand the purpose and procedures and the possible risks and benefits of the study.
- I was given sufficient time to think about it.
- I had the opportunity to ask questions and have received satisfactory answers.
- I am free to withdraw from this study at any time for any reason and the decision to stop taking part will not affect my future medical care.
- I have been informed there is no guarantee that this study will provide any benefits to me.
- I give permission for the use and disclosure of my de-identified personal health information collected for the research purposes described in this form.
- I understand that by signing this document I do not waive any of my legal rights.
- I will be given a signed and dated copy of this consent form

- My family physician will be informed about my participation in this study, and, if required, consulted regarding my health and treatment.
  - ❑ Yes, you may contact my primary care physician
  - ❑ No, please do not contact my primary care physician
  - ❑ I do not have a primary care physician.

- I grant the Saskatchewan Ministry of Health permission to disclose my health care information to the study researchers ❑ Yes ❑ No

I agree to participate in this study:

Printed name of participant: Signature Date

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Printed name of person obtaining consent: Signature Date

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