Consent and Authorization Document

STUDY SUMMARY

The purpose of this study is to compare individual versus couple-based lifestyle intervention to prevent type 2 diabetes. If you agree to participate, you will be asked to complete a series of assessments over the course of approximately 14 months, including: (1) wearing an activity monitor for 7 days at the beginning and end of the study; (2) completing questionnaires about yourself, your relationship, and your health; (3) blood draws at a University of Utah Hospital research center at the beginning and end of the study; (4) a joint interview together with your partner. You and your partner will also be randomly assigned to either the CDC National Diabetes Prevention Program's (NDPP) *Prevent T2* curriculum or a couple-based adaptation our research team developed together with community partners, *Prevent T2 Together*. Both are lifestyle intervention programs that focus on healthy eating and physical activity to help reduce risk of developing type 2 diabetes. Participation in this study is voluntary.

RISKS

The risks of this study are minimal. There is a small chance you may experience discomfort at the site or an infection due to the blood draws. Further, it is possible that you may feel upset thinking or talking about life experiences or behaviors, or with the lifestyle intervention classes and interview being audio-recorded. These risks are similar to those experienced when discussing personal information with others. If you feel upset from these experiences, you can tell the researcher, and she will tell you about resources available to help. There is minimal risk of loss of privacy or confidentiality.

BENEFITS

There are no direct benefits for taking part in this study, although you may experience improvements in health behaviors, health outcomes, and relationship functioning as a result of the lifestyle intervention. However, we hope the information we get from this study will inform future research on couple-based lifestyle intervention that has the potential to advance the field of diabetes prevention.

STUDY PROCEDURE

This study will occur over the span of approximately 14 months. If you decide to participate, the procedures we will ask you to complete are detailed below.

STUDY PHASE	Consent	Pre Lab Assessment & Questionnaire	Baseline 7-Day Assessment	Monthly Questionnaire (during Lifestyle Intervention)	Post A1c Assessment	Post Questionnaire	Follow-Up 7-Day Assessment	Interview
LOCATION	Online	U of U Hospital	At home	At home	UU DPP Classroom or At home	At Home	At home	U of U
COMPENSATION (for each partner)	-	$150	$35	$25 gift card per questionnaire	$25	$50	$35	$50
LENGTH	30-60 min.	3 hrs.	7 days	Up to 1 hr./month	1 hrs.	1 hr.	7 days	2 hrs.
PURPOSE	Informed consent	Blood draw, online questionnaire	Activity monitor, daily questionnaire	Online questionnaire monthly during intervention	Point-of-care A1c	Online Questionnaire	Activity monitor, daily questionnaire	Joint couple interview
	1 month			12 months				

Pre Lab Assessments. You will complete a 3-hour visit to Clinical and Translational Science Institute (CTSI) Clinical Research Center where research nurses will measure your height and weight, and draw blood for glucose tests. Additionally, you will complete a questionnaire about your health and relationship.

Blood samples collected during the Pre Lab Assessments will not be used for whole genome or whole exome sequencing. This means that the researchers have no plans to look at or try to "read" the protein information that makes up your genes (DNA) from your blood sample. The samples will not be used to develop a commercial product or for any commercial profit. Lastly, samples will not be used for future research studies. Although we will share a summary of findings with all participants after the study is complete, we will not share your individual results with you.

Post Assessments. You will complete a 1 hour visit with study staff at the University of Utah DPP Classroom or in your home. Study

staff will measure your height and weight and administer a point-of-care HbA1c test. Additionally, you will complete a questionnaire about your health and relationship.

Baseline & Follow-Up 7-Day Assessments. You will be asked to wear an activity monitor for 7 days to collect data on your physical activity and sleep. You will also complete a 5-minute Daily Questionnaire each evening covering additional information on your health and relationship over the course of the day. This 7 day assessment period may occur before or after your lab assessment.

Lifestyle Intervention Program. You and your partner will be randomly assigned to either an individual lifestyle intervention (CDC *PreventT2* program for only partner(s) at high risk for type 2 diabetes) or a couple-based lifestyle intervention (i.e., *PreventT2 Together* program for both partners in the couple). If you are not at high risk for type 2 diabetes and are randomized to the individual intervention, you will not participate in a lifestyle intervention (only your partner will). However, we will still ask you to complete a brief monthly questionnaire during the time your partner attends *PreventT2* classes. If you participate in the intervention, you will be weighed (in private) at each class, and your attendance and engagement will be recorded, consistent with CDC standards for the intervention. If you participate in the intervention, you will also be asked to complete a monthly questionnaire. Additionally, you will have the option to complete an anonymous DPP evaluation at both the mid-point and end of the *PreventT2* or *PreventT2 Together* intervention, this survey is optional and is not compensated.

Interview. You and your partner will be asked to participate in a 2-hour joint audio-recorded interview for an in-depth assessment of your experiences at the end of the study.

The alternative to taking part in this study is to not participate.

PERSON TO CONTACT

If you have any questions, complaints, or concerns about the research, you or your legal representative are welcome to contact Dr. Katherine J.W. Baucom at (801) 587-7222 where you can leave a message 24 hours a day.

Institutional Review Board:
Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints, or concerns which you do not feel you can discuss with the investigator of the study. The University of Utah IRB may be reached by phone at (801) 581-3655 or by email at irb@hsc.utah.edu.

Research Participant Advocate:
You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION

Signing this document indicates that you allow the respective research team in this study to use some information about your health for this research study.

Below is the information we will use and disclose in our research records:

- Demographics and identifying information like name, telephone number, and email address.
- All tests and procedures that will be done in this study.

In order to conduct this study as described in this form, research records may be used and reviewed by others who are working with the research team on this research study:

- Members of the research team at the University of Utah.
- The University of Utah Institutional Review Board (IRB), which reviews research involving people to make sure the study protects your rights.
- The United States Food and Drug Administration (FDA) and/or the Office for Human Research Protections (OHRP).
- The National Institutes of Health, which sponsors this study, including persons or organizations working with the sponsors.

How we will protect and share your information:
We will keep all research records that identify you private to the extent allowed by law. All study data will be stored on a secure, password-protected server at the University of Utah. Any identifying information will be removed from our records and replaced with a code. All data collected will be identified only by that code. Your participation in this study will also be confidential. Documentation including your name and your partner's name will be kept in a locked file cabinet within a locked office, accessible only by the research team. The information collected about you and your partner will not be used for future research studies.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

If you disclose information that gives research staff a reason to believe that a child or disabled or elderly adult has been subjected to abuse or neglect, research staff will report that information to Child Protective Services, Adult Protective Services or the nearest law enforcement agency to the extent required by law. There are some cases in which a researcher is obligated to report issues, such as serious threats to public health or safety. If we share your identifying information with groups outside of the respective research team, they may not be required to follow the same federal privacy laws that we follow. They may also share your information with others not described in this form.

If you do not want the research team to use information about your health, you should not participate in the present research study. Your refusal to participate will involve no penalty or loss of benefits or care at the University of Utah to which you are otherwise entitled.

What if I decide to Not Participate after I sign the Consent and Authorization Form?

You can inform the research team at any point in the study that you no longer want to participate and do not want the research team to use your health information. If you decide to no longer participate, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already collected to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

VOLUNTARY PARTICIPATION

Your participation is voluntary. If you decide to participate, you will be asked to electronically sign this form and will be emailed a copy of it. Your refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may withdraw your consent at any time and discontinue participation without penalty. Such a decision will in no way cause any prejudicial action or negative consequences. You are not waiving any legal claims, rights, or remedies because of your participation in this research study.

COSTS AND COMPENSATION TO PARTICIPANTS

There are no costs for participating in this study. You will receive compensation for many aspects of your participation (see Study Assessments Table), for a maximum of $620 (up to $345 paid by check and up to $275 in electronic gift cards). You will only be paid for assessments that you complete.

Since you will be paid for participating in this study, it is necessary for us to collect your Social Security Number. You will provide this information for a Federal W-9 Form that is filed with our Accounts Payable department. The amount you receive for taking part in this study will be turned into the Internal Revenue Service (IRS) as taxable income. You can choose not to provide us with your Social Security Number for this form and still participate in this study; however, we will not be able to pay you as outlined in this consent form.

CONSENT

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep. I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.

_____
Participant's Name

_____ _____
Participant's Signature Date

_____
Name of Person Obtaining Authorization and Consent

_____ _____
Signature of Person Obtaining Authorization and Consent Date