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## Informed Consent Form

Fred Hutchinson Cancer Research Center

### Consent to take part in a research study:

## Telephone Delivered Weight Loss, Nutrition, Exercise Study (WeLNES)

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### Important things to know about this study.

You are invited to participate in a research study. We are doing a research study to see which of two telephone coaching programs for weight loss works better.

To help you decide if you want to take part in the WeLNES Study, this form tells you about the study and its activities. After that, you can also email us to ask any questions you like about the study and decide whether or not you want to take part.

### We would like you to join this research study.

Since you are a potentially eligible adult who wants to lose weight, we would like to invite you to join this study. A total of 398 people (199 in each program) are expected to take part. If you decide to take part, your involvement in the study would be completed within 2 years. As compensation for your time, you will receive \$20 if you complete each follow-up survey and save your weight on the study scale within 15 days at 6 months, 12 months, and 24 months respectively. An additional \$20 bonus will be offered if you complete the online version of the survey and scale weighing within 72 hours.

You do not have to join this study. You are free to say yes or no, or to drop out after joining. There is no penalty or loss of benefits if you say no. Whatever you decide, your regular medical care will not change. The study may benefit participants by helping them lose weight and learn healthy eating and exercise habits. Our primary hope is that the information we learn will help find more effective ways to help obese adults lose weight using telephone coaching programs. Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, you can print a copy of this form to keep for future reference.

### What are the procedures?

The WeLNES Study includes a telephone coaching program and a few surveys. If you agree to be in this study, these will be the procedures:

- First you will fill out a survey, called the *Baseline Survey*. It is a 30 minute web-based survey that asks questions about:
  - Your interest in losing weight
  - Details about your current eating and exercise behaviors and history
  - Demographics (for example, marital status and education)
  - Information to help us contact you for future study activities

You will have up to 1 week to complete this first study survey.

- Next you will be asked to set up a Fitbit account and authorize WeLNES to share your weight, food, and activity data. You will have up to 1 week to authorize Fitbit access.
- Then, you will receive a telephone call from us to answer a few questions to confirm your participation.
- Next you will be randomly assigned (like a coin toss) to one of two telephone coaching programs. Both programs provide:
  - 25 telephone coaching calls (the first call is 30-40 minutes and the remaining 24 calls are 15-25 minutes each) in the first year, and 9 telephone check-in calls in the second year (10-15 minutes each),
  - Fitbit Aria Air body weight scale,
  - Fitbit Inspire activity tracker,
  - Food measuring scale, and
  - Measuring cups and spoons.

In the first year, the coaching calls will be once every week for the first 16 weeks (4 months, for calls #1-16), then once every other week for the next 14 weeks (calls #17-23), then once a month for the last 2 months (calls #24-25). The check-in calls in the second year will be once a month for the first 6 months (calls #1-6), then once every other month for the last 6 months (calls #7-9).

We will record your coaching and check-in calls. We will also ask you questions about how you are managing your urges to eat, your commitment to losing weight, your eating and exercise behavior, and satisfaction with the telephone coaching program. We will advise you about nutrition and exercise, including encouraging you to drink recommended daily amounts of water associated with exercise, which we will give you information about.

To learn your weight loss status and your overall experiences with your telephone coaching program, we will conduct three 20-30 minute surveys (6 Month Follow-Up, 12 Month Follow-Up, and 24 Month Follow-Up). These surveys will be conducted via the web or telephone. We will ask you to weigh yourself on the body weight scale we send you, for the telephone calls and for your three Follow-Up surveys.

*You do not have to be in this study. You are free to say yes or no, or to drop out after joining. There is no penalty if you say no.*

## **How long will I be in this study?**

Your study participation will last for 24 months. This includes your time in the telephone program and the 6-, 12-, and 24-month surveys.

If you leave the study, your survey results and information cannot be removed from the study records.

## **Risks of being in this study**

- Because this study uses online surveys, there is a very small risk that your study information will be viewed online by an unauthorized party. However we have protected against this risk in the following ways: (1) your contact information data (e.g, name & phone number) will be collected and stored separately from all survey information; (2) your connection to the WeLNES website, where you fill out the surveys and your Fitbit data is saved will be password restricted and protected by transport-layer-security (TLS) encryption; and (3) the website's server will sit behind a hardware firewall.
- The survey questions we ask you about your health history are sensitive and may make you feel uncomfortable.
- The program includes recommendations about engaging in physical activity. You will also be asked to walk or exercise on your own, working up to levels of increased physical activity at a safe and gradual pace. However, there are risks associated with exercise, including fatigue, muscle soreness, and possible joint or bone injury. Additionally, any exercise program for persons with an underlying heart condition has a slight (less than 1 chance in 1,000) risk of having a sudden heart attack and an even slighter (less than 2 chances in 10,000) risk of sudden death. These risks will be reduced by proper warm-up/cool-down periods, guidance from your coach, and a slow-paced progression which will be determined by your current fitness level. We are not asking you to change your exercise and diet habits in a way that should cause these complications.
- If you experience shortness of breath, pain, or heart palpitations, report them to your physician and the WeLNES study team right away.
- If you have existing joint, bone, or muscle problems, we recommend you consult your doctor before engaging in the program.
- If you have a serious heart condition, diabetes, uncontrolled hypertension, or are currently being treated for cancer, we require that you consult your doctor before engaging in the program.

## **What are the benefits?**

We do not know if this study will benefit participants.

Your participation in this study may help you lose weight. You will also help the Fred Hutchinson Cancer Research Center see which of the two telephone coaching programs is most useful for people who are obese and trying to lose weight.

You also may personally benefit by the feeling that you have helped in this research.

## **You have other choices besides this study.**

You do not have to be in this study. You are free to say yes or no, or to drop out after joining. There is no penalty or loss of benefits for saying no or dropping out. Whatever you decide, your regular medical care will not change.

If you do not join this study, you have other choices. Each of these choices has risks and benefits. You should talk to your doctor or healthcare provider about them.

## **Protecting your Privacy as an Individual and the Confidentiality of Your Personal Information**

Some organizations may need to look at your research records for quality assurance or data analysis. They include:

- Researchers involved with this study.
- The study sponsors and their agents.
- Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Research Center IRB. An IRB is a group that reviews the study to protect your rights as a research participant.
- Fred Hutchinson Cancer Research Center.
- US National Institutes of Health, National Institute on Drug Abuse, Office for Human Research Protections, and other agencies as required.

If you have an adverse event or serious adverse event (an unexpected medical problem that happens during the WeLNES program and is related or possibly related to your telephone intervention) during your participation, particularly if you have a serious heart condition, diabetes, uncontrolled hypertension, or are being treated for cancer, we will request your authorization to access a copy of your medical records. Your medical records would be reviewed to determine safety of participation by organizations including:

- Researchers involved with this study, particularly the study physician.
- The study sponsors and their agents.
- The Fred Hutchinson Center IRB.
- The Fred Hutchinson Center Legal Department.

All your medical record information will be kept confidential and will be used for study purposes only.

We will do our best to keep your personal information confidential. But we cannot guarantee total confidentiality. Your personal information may be given out if required by law. For example, a court may order study information to be disclosed. Such cases are rare.

We will not use your personal information in any reports about this study, such as journal articles or presentations at scientific meetings.

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.

This research is covered by a Certificate of Confidentiality from the U.S. government. This Certificate helps protect the confidentiality of information about people who join this study. If you join the study, the Certificate means that generally we would not have to give out identifying information about you even if we were asked to by a court of law. We would use the Certificate to resist any demands for identifying information.

We could not use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person.

This protection has some limits. We would voluntarily provide the information:

- To a member of the federal government who needs it in order to audit or evaluate the research.
- To the funding agency and groups involved in the research, if they need the information to make sure the research is being done correctly.
- To the federal Food and Drug Administration (FDA), if required by the FDA.
- To someone who is accused of a crime, if he or she believes that our research records could be used for defense.
- To authorities, if we learn of child abuse, elder abuse, or if participants might harm themselves or others.

We will respect your privacy. We will only contact you at email addresses and phone numbers that you provide to us. Also, (1) we will only leave voice messages if you have told us it is okay to do so, (2) we will only email study-related letters to the email address(es) you provide all to us for such emailings. Please review the Privacy Policy and Terms of Service.

## **What will my information be used for?**

Your information will be used for the purposes of this study.

In addition, be aware that by agreeing to participate in this study, your information could be used for future research studies or sent to other investigators for future research studies without additional consent from you. These future research studies will be reviewed by an oversight group known as an institutional review board if required by law. The information that identifies you will first be removed from your information. If you do not want your information to be used for future research studies without your consent, you should not participate in this study.

## **Will you pay me to be in this study?**

\$20 will be offered as compensation upon completion of each survey and saving your scale weight on the Fitbit app within 15 days of receiving the survey invites (6 Month Follow-Up, 12 Month Follow-Up, and 24 Month Follow-Up) . If any of the surveys and scale weighings are completed within 72 hours of receiving the emailed survey, an additional \$20 bonus will be offered. You will receive up to \$120 if all three surveys are completed online and scale weighings provided within 72 hours.

You will also receive a Fitbit Aria Air body weight scale, Fitbit activity tracker, food measurement scale, and measuring cups and spoons for free.

If this research shows that our study program works to help people lose weight, it might become a product that is patented and sold. If that happens, you will not be paid for use of the patent.

## **How much will this study cost me?**

Normal cell phone minute charges apply, if your cell phone is a primary phone. There are no other costs for being in this study.

## **What if I get sick or hurt in this study?**

For a life-threatening problem, call 911 right away or seek help immediately. Contact us when the medical emergency is over or as soon as you can.

For all other problems related to the study, please contact the study PI at 877-250-6641. There are no funds to pay you for a research-related injury, added medical costs, loss of a job, or other costs to you or your family. State or national law may give you rights to seek payment for some of these expenses. You do not waive any right to seek payment by signing this consent form.

You or your insurer will be billed for treatment of problems or complications that result from your condition or from standard clinical care.

## **Your rights**

- You do not have to join this study. You are free to say yes or no. Your regular medical care will not change.
- If you join this study, you do not have to stay in it. You may stop at any time (even before you start). There is no penalty for stopping. Your regular medical care will not change.
- If you get sick or hurt in this study, you do not lose any of your legal rights to seek payment by signing this form.

## **For more information**

If you have any questions or concerns about this study you would like answered before deciding to participate, please email us at [welnes@fredhutch.org](mailto:welnes@fredhutch.org) or call 1-855-263-1279. We are committed to answering your questions within 2 business days.

Other people you can talk to are listed below.

<b>If you have questions about:</b>	<b>Call:</b>
This study (including complaints and requests for information)	855-263-1279 (Dr. Jonathan Bricker, Principal Investigator)
If you get sick or hurt in this study	877-250-6641 (Project Manager)
Your rights as a research participant	206-667-5900 or email <a href="mailto:irodirector@fredhutch.org">irodirector@fredhutch.org</a> (Director of Institutional Review Office, Fred Hutchinson Cancer Research Center)

☐

**I consent to participate in this study (check box and click)**

[Website proceeds to the Baseline Survey & Contact Form]

[If you have 30 minutes now, you can go ahead and do the first study survey. If not, please use the link emailed to you. You must complete this survey within 1 week of receiving it to be eligible to continue in the study.]

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**I do not consent to participate in this study (check box and click)**

[Website proceeds to the Decline Screen that asks "To help us improve this study, please tell us why you decided not to participate." Open-ended written answers provided.]

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